

**CES 234**

# **Compulsory Ethiopian Standard**

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## **Maternal and child health (MCH) Specialty Center**



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## Contents

1. Scope .....	1
2. Normative References.....	1
3. Terminologies and Definitions .....	1
4. General Requirement .....	2
5. Specific Requirement .....	3
5.1 Maternal and child HealthCenter .....	3
5.2 outpatient Medical service .....	8
5.3 Emergency service .....	10
5.4 Inpatient Medical service.....	12
5.5 Anesthesia service.....	14
5.6 Intensive care service.....	16
5.7 Radiology service.....	19
5.8 Medical Laboratory service.....	20
5.9 Pharmacy service.....	23
5.10 Medical Recording.....	28
5.11 Ambulance service Standards .....	30
5.12 Morgue service.....	32

## **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 3619:2012.

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.

# Maternal and child health (MCH) Specialty Center

## 1. Scope

This Ethiopian standard Specifies minimum requirements for Maternal and child health (MCH) Specialty Center with respect to practices, premises, professionals and products or materials put into use.

This standard shall be applicable for all specialty centers new and existing, governmental and non-governmental.

## 2. Normative References

The following referenced documents are indispensable for the application of this document. 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 definition in ES 6627 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.

#### **appropriate Law**

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

### 3.4.

#### **person**

shall mean any physical or juridical person

### 3.5.

#### **authorized Person**

shall mean any specialty center staff who is responsible for a given service

### 3.6.

#### **Maternal and child Health (MCH) Specialty Center:**

Shall mean a health facility which lies in secondary or tertiary level of health care system and provides a minimum of curative, preventive and promotion services in ambulatory & inpatient basis as stipulated in this standard. In addition to the emergency and isolation beds, the MCH specialty center shall have a minimum of 10 beds for inpatient services. The center shall have 24 hour emergency service in its respective specialty.

## 4. General requirements

**4.1** The MCH specialty center shall be directed/licensed by Gynecologist or pediatrician.

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

**4.3** The center shall control the nursing visits, care, and execution of orders.

## **CES 234**

- 4.4 The gynecologist shall be responsible for the follow-up clinics.
  - 4.5 Diseases under national surveillance shall be notified to the FMOH through the proper reporting channel.
  - 4.6 With regard to patient engagement and transparency:
    - a) The specialty center shall arrange system at outpatient center to collect feedback from clients,
    - b) The specialty center shall have formal administrative channel through which clients lodge their complaints and grievances,
    - c) The center shall conduct Patient satisfaction survey.
  - 4.7 The staff shall have regular supportive supervision by senior staff or peer review or case conferences at least every three months and it shall be documented.
  - 4.8 The specialty center shall display the following at visible place:
    - a) List of Services available in the specialty center during working hours & after working hours,
    - b) List of Professionals and specialties working in the center during & after working hours,
    - c) Updated list of Various fees and prices,
  - 4.9 The specialty center facilities shall be well marked and easily accessible for persons with disability.
  - 4.10 The center shall have fire extinguisher placed in visible area.
  - 4.11 All employees, including part-time and contract shall be trained in fire-fighting equipment and patient evacuation of center's buildings as part of their initial orientation and at least annually thereafter.
  - 4.12 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.
  - 4.13 Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.
  - 4.14 All patient care rooms shall be provided with running water supply & functional hand washing basin.
  - 4.15 The Internal surfaces of the center (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.
  - 4.16 Safety glass, tempered glass or plastic glass materials shall be used for paediatrics service units to avoid possible injuries.
  - 4.17 Glass doors shall be marked to avoid accidental collision.
  - 4.18 The specialty center 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.
  - 4.19 The specialty center shall carryout workload analysis.
- Nursing/midwife practice**
- 4.20 Nursing care service at different service delivery areas shall be directed by a licensed BSC nurse/midwife.
  - 4.21 There shall be written protocol describing the responsibilities of nurses for the nursing process in the specialty center. Such protocol shall be reviewed at least once every five years.
  - 4.22 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.
- 4.23** The Specialty center 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).
- 4.24** There shall be a procedure for standardized, safe and proper administration of medications by nurses or designated clinical staff.
- 4.25** The nursing care plan shall be initiated upon admission of the patient and shall include discharge plans as part of the long-term care provision goals.
- 4.26** The nurses shall assess and document the holistic needs of admitted patients:
- a) formulate, implement goal-directed nursing interventions,
  - b) evaluate the plan of nursing care and
  - c) Involve patients, their relatives or next of kin in decisions about their nursing care.
- 4.27** Nurses' documentation shall include:
- a) Medication/ treatment/ other items ordered by authorized attending physician,
  - b) Nursing care needed,
  - c) Long-term goals and short-term goals,
  - d) Patient/ family teaching and instructional programs,
  - e) The psycho- social needs of the patient,
  - f) Preventative nursing care.
- 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** Informed consent shall be sought before carrying out any procedure.
- 4.30** Patient discharge instructions shall be documented in the patient's medical record and verbal instruction shall be given.
- 4.31** Allergies shall be listed on the front cover of the patient's chart or highlighted on the screen in a computerized system.
- 4.32** There shall be a mechanism in place to ensure that assistance is provided for patients who require assistance.
- 4.33** There shall be a policy 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.
- 4.34** There shall be a policy for reporting and documenting medication errors and adverse drug reactions by attending nursing personnel immediately to the prescriber and/or Pharmacist.
- 4.35** There shall be a policy or a protocol that state the procedure to be followed for dying patients & dead body care.

**Professional Summary**

4.36 The MCH specialty center shall have the following summary of professionals:

**Table 1: Requirements for MCH specialty center professionals**

R.No	Professionals required	Number required
1.	Gynecologist	1
2.	Gynecologist/IESO/Msc midwife	1
3.	Pediatrician	1
4.	Radiologist/Radiology technologist (optional)	1
5.	Midwives	4
6.	GP/HO	1
7.	Nurses	8
8.	Anesthesiologist/Msc anesthetist-(optional)	1
9.	Bsc Anesthetist/ nurse anesthetist	2
10.	CSR nurse/ personnel	1
11.	Lab technologist	2
12.	Pharmacist /clinical pharmacist	2
13.	Pharmacy technician	1
14.	Radiographer (optional)	2
15.	Support staff <ul style="list-style-type: none"> <li>• Receptionist</li> <li>• Cleaner</li> <li>• Porter/ runner</li> <li>• Guard</li> <li>• Laundry personnel</li> </ul>	

4.37 Additional staff shall be considered based on the volume and type of work carried out (Workload Analysis).

**5. Specific Requirements**

**5.1. Maternal & Child Health (MCH) Center**

**5.1.1. Practices**

5.1.1.1. Comprehensive emergency obstetric care shall be available 24 hours a day, 365 days a year. This includes;

- a) Administration of antibiotics, oxytocin and anticonvulsants
- b) Manual removal of the placenta
- c) Removal of retained products following miscarriage or abortion
- d) Assisted vaginal delivery
- e) Blood transfusion
- f) Caesarean section
- g) Laparotomy
- h) Cervical cancer
- i) Major gynecological surgery

5.1.1.2. There shall be delivery service available for 24 hours a day, 365 days a year.

5.1.1.3. The center shall have full-fledged pediatrics services as per standards stipulated for pediatric specialty center except that this center has optional neonatology ICU.

**5.1.1.4.** Pediatrics & Essential newborn care shall be available including with the following:

- a) Newborn resuscitation,
- b) Routine examination for detection of congenital anomalies,
- c) Routine Immunization,
- d) Growth monitoring & Consultation on Nutrition and infant feeding,
- e) Assessment and treatment of sick babies,
- f) PMTCT services,
- g) Neonatology services with optional ICU care,
- h) Transfer or referral of neonates to next level neonatal unit,
- i) Follow up of babies and children with common chronic conditions like diabetes, asthma, congenital problems and neurological problems.

**5.1.1.5.** Gynecological services shall be available 24 hours a day, 365 days a year.

**5.1.1.6.** The MCH center shall provide the following functions for women:

- a) Care of women in ambulatory basis,
- b) Ante Natal Care (ANC) service,
- c) Post Natal Care (PNC) service,
- d) Immunization
- e) Family planning service,
- f) Infertility work up and treatment,

**5.1.1.7.** The center shall have blood transfusion services with proper storage facilities and delivery/ transfusion protocol.

**5.1.1.8.** The MCH center shall have written policies and procedures that shall include:

- a) Admission and discharge criteria for patients,
- b) Visitors policy that specifies the number of visitors permitted for each patient at any time,
- c) Infection prevention
- d) Monitoring and follow-up of patients,
- e) Transfer and referral of patients,

**5.1.1.9.** The MCH center shall avail updated reference materials, treatment guidelines and manuals,

**5.1.1.10.** Diseases under national surveillance shall be notified to the FMOH through the proper reporting channel.

## **5.1.2. Premises**

**5.1.2.1.** Labor room and delivery room shall be contiguous and shall have a means (swinging or self-closing doors) for communication.

**5.1.2.2.** The corridor to delivery room shall be not less than 1.2m to allow easy transport of laboring women with support.

**5.1.2.3.** In addition to emergency and isolation, the specialty center shall have at least ten inpatient beds.

**5.1.2.4.** The nursery room shall have single entrance.

**5.1.2.5.** Curtain tracks shall be installed around each bed, or in their absence bed screens shall be provided.

**5.1.2.6.** The Placental pit shall be well secured, protected from water and animals; the outer part made of concrete; the opening shall be raised and not more than 20cmX20cm wide and provided with properly fitting cover.



- 5.1.2.7. The vaccination room shall organize the cold chain properly; refrigerator with monitors, cold boxes, vaccine syringes and diluents shall be kept in orderly.
- 5.1.2.8. The premises for MCH center shall be child friendly.
- 5.1.2.9. The premise for MCH center shall have the following summarized rooms :

**Table 2: Requirements for MCH Center layout**

<b>R.No</b>	<b>Rooms required</b>	<b>Number required</b>	<b>Area required</b>
1	Delivery room with 1 delivery couch,	1	20 sq. m
2	Laboring/ prenatal room, with two beds	1	20 sq. m
3	Nursery	1	8sq. m
4	Operation Room		
5	Operation theatre	1	30sq. m
6	Scrub area	1	6sq. m
7		2	6sq. m each
8	Nurse station/doctor’s room	1	12sq. m
9	Duty room male/female	1	6 sq.m each
10	Janitor’s closet or area	1	6sq. m
11	Toilet with shower	1	4sq. m
12	Recovery room with 2 beds	1	16sq. m
13	Sterilization room	1	16sq. m
14	Neonatology unit with optional ICU	1	12sq.m
15	Growth monitoring & Immunization room	1	12sq.m
16	Ultrasound room	1	12sq.m
17	Duty rooms with lockers (male/ female) [Staff room for changing clothes]	2	12sq. m each
18	General purpose store room	1	12sq.m
19	Morgue	1	16sq. m

**5.1.3. Professionals**

- 5.1.3.1. MCH center shall be directed by a licensed obstetrician and gynecologist (Ob/Gyn specialist) or a pediatrician with two years of relevant clinical experience.
- 5.1.3.2. At least one specialist shall be assigned to run the outpatient service for each maternal and child health services during working time.
- 5.1.3.3. There shall be one specialist assigned to run the inpatient services for each maternal and child health services during working time.
- 5.1.3.4. One nurse for a maximum of 6 patients shall be available to provide nursing care services for inpatients.
- 5.1.3.5. The nursing service in the specialty center shall be directed by licensed nurse. The nurse may be BSc with 3 years of experience or Diploma with 5 years of experience or Post Basic BSC with 1 year experience if they have 2-5 years of work experience before BSc program or Post Basic with 3 years of experience if they have less than 2 years of work experience before BSc program.
- 5.1.3.6. All nursing staff shall receive orientation, training and/or update at least annually on the following topics:
  - (a) Emergency procedures,
  - (b) Infection prevention and control,
  - (c) Non-emergency nursing clinical procedures,
  - (d) Specialty center’s policies and procedures,
  - (e) Refresher training on programmatic (HIV/AIDS, TB and other relevant initiatives) issues.

5.1.3.7. MCH center shall have the following minimum professionals:

**Table 3: Requirements for MCH Center Professionals**

R.No	Professionals required	Number required
1	Obstetrician/ Gynecologist	1
2	Obstetrician/ Gynecologist/IESO	1
4	Pediatrician	1
5	Radiologist (optional)	1
6	Midwives	4
7	GP/HO (optional)	1
8	Nurses	8
9	Anesthesiologist-optional but preferable	1
10	Bsc Anesthetist/anesthesia nurse	2
11	CSR nurse/ personnel	1
12	Lab technologist	2
13	Pharmacist /clinical pharmacist	2
14	Pharmacy technician	1
15	Radiographer (optional)	2
16	Support staff <ul style="list-style-type: none"> <li>• Receptionist</li> <li>• Cleaner</li> <li>• Porter/ runner</li> <li>• Guard</li> <li>• Laundry personnel</li> </ul>	

#### 5.1.4. Product

5.1.4.1. Equipment for nursery:

- |  |                                   |
|--|-----------------------------------|
| a) Vacuum aspirator, 0 - 250 mm/Hg, with bottle and tubing | e) IV stand                       |
| b) Flow meter, 0 - 15 l/min                                | f) Baby warmer or overhead heater |
| c) Oxygen source   | g) Neonatal resuscitation kit     |
| d) Baby cot  | h) Infant scale                   |
|  | i) Pedal bin                      |

5.1.4.2. The Delivery service shall have the following equipments:

- |                                |   |
|--------------------------------|---|
| a) Delivery couches            | q) Infusion stand   |
| b) Stethoscope                 | r) Baby crib/ Baby cot  |
| c) Sphygmomanometer            | s) Pickup forceps with jar  |
| d) Measuring tape              | t) Vacuum extractors  |
| e) Fetoscope                   | u) Vacuum aspirator, 0 - 250 mm/Hg, w bottle and tubing               |
| f) Fetal Doppler               | v) Ball suction (Neonatal),   |
| g) Thermometer                 | w) Manual/ Suction apparatus  |
| h) Weighing scale, Adult       | x) Resuscitation set (Ambu bag, endo-tracheal tube, laryngoscope set) |
| i) Weighing scale, Baby        | y) Neonatal resuscitation set,  |
| j) Vaginal speculum (assorted) | z) Refrigerator   |
| k) Episiotomy set              | aa) Oxygen source   |
| l) Delivery instrument set     | bb) Wall clock  |
| m) Outlet delivery forceps     | cc) Dressing trolley, two trays                                       |
| n) Stand lamp                  |   |
| o) Evacuation & curettage set  |   |
| p) Tourniquet                  |   |

## **CES 234**

- dd) Soiled linen trolley, 2 rings
- ee) Bowl and stand
- ff) Instrument tray
- gg) Instrument trolley

- hh) Heater
- ii) Kick bucket, stainless steel
- jj) Newborn care table

### **5.1.4.3. Equipments for Operating theatre:**

- a) Anaesthesia trolley and Oxygen cylinders
- b) Instrument table,
- c) Stool
- d) IV fluid pressure bag
- e) IV stand
- k) Coagulation unit, electro, mobile, 200 W x 1 (optional)
- l) Light, operating, 1 large copula, ceiling mounted
- m) Examination/ mobile operation light
- n) Operating table, 3 sections,
- o) Anesthesia machine with ventilator, 2 vaporizers, and gas cylinders
- p) Laryngoscope set (Mackintosh)
- q) Magill forceps (adult)
- f) Swab rack with drip tray
- g) Swab count record board
- h) Bowl and stand x 3
- i) Tourniquet Elapsed time clock
- j) Pulsoximeter
- r) Suction machine
- s) Laryngeal mask set and Mask holder
- t) Mouth gag
- u) Patient monitor
- v) Worktable with laminated top
- w) Neonatal resuscitation table/ couch
- x) Radiant/ heater
- y) Kick bucket

### **5.1.4.4. Equipment for operating theatre sterile supply:**

- a) General purpose trolley with 2 trays,
- b) Gyn/Obs- Obstetric forceps Gyn/Obs- Caesarean section set
- c) Gyn/Obs- Abdominal hysterectomy set
- d) Gyn/Obs- Vaginal hysterectomy set, extras
- e) Gyn/Obs- Gynaecology examination set (EUA)

**5.1.4.5.** Emergency medicines for obstetrics service shall be available at all time.

## **5.2. Outpatient Medical Services**

### **5.2.1. Practice:**

**5.2.1.1.** The Specialty center outpatient service shall provide the following core functions:

- a) Care of ambulatory patients with outpatient service,
- b) Examination and management of preadmission patients,
- c) Follow up of discharged and ambulatory patients,
- d) Pharmacy service,
- e) Diagnostic services

**5.2.1.2.** The outpatient services shall comply with the standards prescribed under patient rights and responsibilities section of this standard.

**5.2.1.3.** The outpatient service shall have policies and procedures regarding access and availability of quality service. It shall include the following:

- a) The outpatient service shall be available for regular working hours,
- b) The specialty center may have a system for providing medical services after regular working hours. In case of this, the type of service and time schedule shall be posted at a visible place to the public,
- c) The outpatient service shall have consultation with functional intra and inter facility referral system which at least include:
  - Procedure for identifying cases for referral,
  - Procedure for referring patients directly to respective services,
  - List of potential referral sites with contact address (referral directory),
  - Referral forms and Documentation for referred clients,
  - Referral tracing mechanism (linkage) and Feedback providing mechanism,
  - Procedure to minimize delay for referral and managing referred patients

**5.2.1.4.** There shall be medical assessment at outpatient services which includes at least:

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

**5.2.1.5.** The outpatient service shall have clinical protocols for management of at least common disease and locally significant diseases in line with the national and/or international guidelines in absence of the national one.

**5.2.2. Premises**

**5.2.2.1.** The outpatient layout shall include the following:

**Table 4: Requirements for outpatient layout**

S.No	Rooms required	Number required	Area required
1	Reception, registration/ recording & waiting area	1	40 Sq.m
2	Emergency room with 2 resuscitation couches	1	16 Sq.m
3	Examination rooms with Gynecologic couch	1	12 Sq.m
4	Pediatric Examination room	1	12 Sq.m
5	Treatment/ injection room	1	9 Sq.m
6	Toilet rooms with hand washing basin(male Female)	2	
7	Minor OR with patient changing area	1	20 Sq.m

**5.2.2.2.** All outpatient rooms shall have adequate light, water and ventilation

**5.2.2.3.** The room arrangements of outpatient services shall consider proximity between related services

**5.2.2.4.** The outpatient clinical setup shall have easy access to pharmacy, laboratory and other diagnostic services.

**5.2.2.5.** The outpatient clinic shall be well marked and easily accessible for disabled clients, elderly patients, under five children and pregnant mother.

**5.2.2.6.** 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 (in- patient , laboratory etc )

**5.2.2.7.** The outpatient clinics shall have fire extinguishers placed in visible area.

**5.2.3. Professionals**

**5.2.3.1.** The outpatient service shall have the following professionals:

- a) Ob/Gyn specialist
- b) Pediatrician
- c) Nurses,
- d) Cleaners,
- e) Runner,

**5.2.3.2.** The actual number of personnel shall be determined by workload analysis.

**5.2.3.3.** The staff shall have regular supportive supervision by senior staff or peer review or case conferences at least every three months and it shall be documented.

**5.2.4. Products**

**5.2.4.1.** The following products shall be available for outpatient service.

- a) Examination Coach
- b) Gynecologic examination couches
- c) Fetoscope
- d) Fetal Doppler
- e) Measuring tape
- f) Cold chain boxes
- g) FP equipments
- h) X-ray viewer (optional)
- i) Refrigerator with thermometer
- j) Weighing scale (adult & child)
- k) Vital Sign and Diagnostic Set

**5.2.4.2.** Equipment for Minor Operation/ procedure room:

- a) Minor OR table/ gynecologic couch
- b) Examination/ mobile operation light
- c) Evacuation & curettage set
- d) Manual Vacuum Aspiration set with cannula,
- e) Cervical biopsy set
- f) Gen.surg- Minor surgical set
- g) Gen.surg- Circumcision set, newborns,
- h) Vaginal specula,
- i) Gyn/Obs-IUD set,
- j) Gyn/Obs- Dilation & evacuation (D&E) set
- k) Gyn/Obs- Manual vacuum aspiration set

**5.3. Emergency Services**

**5.3.1. Practice**

**5.3.1.1.** The specialty center shall provide basic life support to its level of emergency care for 24hrs a day and 365 days a year which shall include but not limited to:

- a) Airway management and/or oxygen supply,
- b) Cardiopulmonary resuscitation (CPR),
- c) Bleeding control,
- d) Fluid resuscitation (shock management),
- e) Prevention of further damages.

**5.3.1.2.** On top of the above article (5.2.1.1), the specialty center shall avail advanced emergency services specific to the specialty.

- 5.3.1.3. The Specialty center shall have MOH written protocols for the initial management of emergency cases.
- 5.3.1.4. Infection prevention standards shall be implemented in the emergency room as per the IP standards.
- 5.3.1.5. If referral is needed, it shall be done after providing initial stabilization and after confirmation of the availability of the required service in the facility where the patient is to be referred to.
- 5.3.1.6. 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.
- 5.3.1.7. There shall be a mechanism of quality improvement for the service at least by collecting feedback from clients.

### 5.3.2. Premises

- 5.3.2.1. The emergency room shall be located in a place where it is easily recognizable to the public and shall be labeled in bold.
- 5.3.2.2. The emergency premise shall be low traffic area and there shall be reserve parking place for ambulances.
- 5.3.2.3. The corridor to emergency rooms shall be stretcher friendly and not less than 1.2meter.
- 5.3.2.4. The size of the door for the emergency room shall not be less than 1.5 meter.
- 5.3.2.5. The emergency premise shall allow patient dignity and privacy.
- 5.3.2.6. The emergency room shall have the following facilities:
  - a) Adequate water, light and ventilation.
  - b) Fire extinguishers placed in visible area.
  - c) Telephone
  - d) Hand washing basin

### 5.3.3. Professionals

- 5.3.3.1. After working hours, a specialist/ MSC clinical midwife shall be available for emergency consultation on call basis.
- 5.3.3.2. At least a general practitioner shall be available for emergency services at all times.
- 5.3.3.3. The actual number of personnel required shall be adjusted based on Workload analysis.

### 5.3.4. Products

- 5.3.4.1. The emergency service shall have readily arranged emergency medicines and supplies on cupboard or trolley.
- 5.3.4.2. There shall be at least two coaches at emergency room.
- 5.3.4.3. The emergency service shall have at least the following products:
 

a) Examination coach	i) NG tube
b) Stretcher with wheel	j) Minor surgical set
c) Wheelchair	k) Different types of splints
d) IV Stand	l) Mobile examination light
e) EKG (shared)	m) Hot air oven (shared)
f) Suction machine	n) Oxygen supply
g) Defibrillator (shared with OR)	o) Resuscitation set on trolley
h) Tracheotomy set	p) Intubation set

**5.4. Inpatient services**

**5.4.1. Practice**

- 5.4.1.1. The specialty center shall make inpatient service available 24 hrs a day and 365 days a year,
- 5.4.1.2. The specialty center shall have clinical protocols for management of at least common causes of admission,
- 5.4.1.3. The specialty center shall have written protocol of MOH for admission and discharge.
- 5.4.1.4. A specialty center shall have at least ten inpatient admission beds. When two or more specialty centers combined together the number of inpatient beds shall be a minimum of twenty.
- 5.4.1.5. The specialty center shall provide a clean gowns/ patient pyjamas, clean bed, bed sheet, blanket, bed spread and pillow to admitted patients.
- 5.4.1.6. The specialty center shall secure the properties of admitted patients in a cabinet or room with shelves.
- 5.4.1.7. The inpatient service shall arrange the post discharge instructions and follow up.
- 5.4.1.8. The Specialty center shall contact the municipality or responsible body for burial service if there is no family/guardian for the deceased.
- 5.4.1.9. There shall be written protocols describing the responsibilities of nurses for the nursing process in the specialty center. Such policies shall be reviewed at least once every five years.
- 5.4.1.10. The Specialty center shall have established procedures for verbal and written communication about patient care.
- 5.4.1.11. Informed consent shall be sought before carrying out any procedure.
- 5.4.1.12. Patient discharge instructions shall be documented in the patient's medical record and verbal instruction shall be given.
- 5.4.1.13. Allergies shall be listed on the front cover of the patient's chart or highlighted on the screen in a computerized system.
- 5.4.1.14. There shall be a mechanism in place to ensure that assistance is provided for patients who require assistance.
- 5.4.1.15. There shall be a protocol or procedures to report any suggestive signs of child abuse, substance abuse and/ or abnormal psychiatric manifestations by the patients under their care.
- 5.4.1.16. There shall be a procedure for reporting and documenting medication errors and adverse drug reactions by attending nursing personnel immediately to the prescriber and/or Pharmacist.
- 5.4.1.17. There shall be a procedure or a protocol that state the procedure to be followed for dying patients & dead body care.
- 5.4.1.18. There shall be one specialist /Msc clinical midwifery assigned to run the inpatient services for each maternal and child health services during working time.

**5.4.2. Premises**

5.4.2.1. Inpatient service of the specialty center shall have the following rooms:

**Table 5: Requirements for inpatient service layout**

R.No	Room required	Number Required	Area Required
1	Inpatient room:		
2	Admission rooms (with a maximum of 6 beds capacity)	2	96sq. m
3	Isolation room	1	12 sq. m

4	Nurse station/doctor's office	1	12sq. m
5	Clean utility room or shelves	1	If room 6sq. m
6	Soiled utility room/shooting system/closed garbage bin	1	If room 6sq. m
7	Toilet room with hand washing basin [the inpatient toilet can be self-contained in the admission rooms or can be separate]	3	
8	Male and female duty rooms shared with all department	2	8sqm each

**5.4.2.2.** The number of beds per room shall not exceed six (6) with the following specification:

- a) Distance between beds shall be 1.2 m
- b) The rooms shall have safe and continuous water supply, light and ventilation
- c) There shall be washing basins for each room.

**5.4.2.3.** The nurse station shall have the following pacification:

- a) Nurse's station located in the middle of the inpatient room(s) with free access to all rooms.
- b) Hand washing basin and
- c) Procedure room for nursing procedures
- d) Nurse changing room with cabinet, chairs, cupboard (shared)

**5.4.2.4.** Isolation Rooms shall have adjoining bath and toilet room,

**5.4.2.5.** In case of common bathing and toilet room, one toilet and bath shall be dedicated for a maximum of six patients at all times.

#### **5.4.3. Professionals**

**5.4.3.1.** Gynecologist shall be physically available during working hours at inpatient service unit.

**5.4.3.2.** One nurse/ one midwife for a maximum of six (6) patients per shift shall be available to provide nursing care/ one midwife services.

**5.4.3.3.** Support staff such as runner and cleaner shall be available all the time.

**5.4.3.4.** general facility maintenance shall be available during working hours and shall be also available either on duty or on call basis during non-working hours.

#### **5.4.4. Products**

**5.4.4.1.** The following products shall be available for inpatient services. Products specific to specialty services are indicated in respective specialty standards.

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>a) Beds with wheels</li> <li>b) Beds and mattress</li> <li>c) Baby cot</li> <li>d) Bed side cabinet</li> <li>e) Feeding table,</li> <li>f) Bed pans</li> <li>g) Urinal (Male and Female)</li> <li>h) IV Stand</li> <li>i) Stretcher</li> <li>j) Oxygen source</li> <li>k) Wheel chair</li> </ol> | <ol style="list-style-type: none"> <li>l) Safety Box or needle Melter</li> <li>m) Suction machine</li> <li>n) Resuscitation set</li> <li>o) Patient Chart Folders</li> <li>p) Patient chart holder,</li> <li>q) Trolley for vital sign monitoring</li> <li>r) Thermometer</li> <li>s) Stethoscope</li> <li>t) Sphygmomanometer</li> <li>u) Refrigerators</li> <li>v) Folding screens</li> </ol> |
|---|---|



w) Soiled linen trolley

x) Waste basket,

**5.4.4.2. Nursing procedure equipment:**

a) Dressing trolley

i) Kidney basin, 475ml x 5

b) Dressing set,

j) Mobile Examination light,

c) Minor set,

k) Plastic apron,

d) Enema set,

l) Drapes,

e) Oxygen trolley,

m) Rubber sheets,

f) Oxygen cylinder,

n) Connectors,

g) Oxygen regulator/gauge,

o) Cushion bags,

h) Oxygen mask/ nasal catheters,

**5.5. Anesthesia Services**

**5.5.1. Practices**

**5.5.1.1.** There shall be a written protocol about administration of regional and general anesthesia in the center.

**5.5.1.2.** Information on any medicines or treatments such as blood transfusion shall be discussed with the patient.

**5.5.1.3.** The anesthetist shall ensure that all the necessary equipment and medicines are present and checked before starting anesthesia.

**5.5.1.4.** The anesthetist shall confirm the identity of the patient before inducing anesthesia.

**5.5.1.5.** The conduct of the anesthesia and operation is monitored and recorded in line with the monitoring standards and formats.

**5.5.1.6.** Patients shall be managed in a recovery room, except patients requiring transfer for intensive care in ICU, until overcome effect of anesthetic.

**5.5.1.7.** The protocols and guidelines used for anesthesia service shall be available.

**5.5.1.8.** Anesthetic agents administered with the purpose of creating conscious sedation, deep sedation, major regional anesthesia, or general anesthesia shall be in accordance with anesthesia policies and procedures.

**5.5.1.9.** The general anesthesia service shall be provided in the Operation theatre (OR), together with the surgical services.

**5.5.1.10.** At all time at least two Anesthetists per table shall be assigned for the betterment of patient out come and prevention of intra operative Morbidity and mortality.

**5.5.2. Premises**

**5.5.2.1.** There shall be a mechanism for taking exhaust air from anesthesia machine to outside of OR; important when performing open system for pediatric anesthesia,

**5.5.2.2.** There shall be central oxygen system or a system where there is a continuous supply of charged Oxygen cylinders

**5.5.2.3.** Regarding the anesthesia store:

(a) It shall be well ventilated and illuminated room with shelves and cabinets,

(b) The anesthetic shall be kept on shelves and/ or cabinets, separate from medicines, properly labeled,

(c) There shall be at least 4 electric plugs in the room,

(d) Anesthetic equipments shall be stored clean and being ready for use,

(e) Ambu bags and resuscitation kits shall be kept labeled in easily reachable place,

(f) There shall be separate place for keeping new and rechargeable Batteries and dry cells. Used batteries

and cells shall be stored and discarded properly, refer to IP and waste disposal protocol,

**5.5.2.4.** Recovery Room shall be sited within the operating suit and has a minimum of:

- a) two beds with side protection,
- b) resuscitation equipment including a defibrillator on trolley,
- c) oxygen source with face mask and or nasal catheter,
- d) ensures ease of communication and access for anesthesia department staff for close follow up,

### **5.5.3. Professionals**

**5.5.3.1.** This standard allows to licensed Bsc anesthetist/ MSC Anesthetists, Bsc, Anesthetists or Anesthesiologists.

**5.5.3.2.** All anesthesia providers who administer and/or supervise the administration of general anesthesia, major regional anesthesia, or conscious sedation anesthesia shall maintain current training in Advanced Cardiac Life Support.

**5.5.3.3.** At all times, at least one anesthetist/ least two Anesthetists per table shall be assigned for the betterment of patient out come and prevention of intra operative Morbidity and mortality shall be on-site.

**5.5.3.4.** General or major regional anesthesia shall be administered and monitored only by the following:

- a) An anesthesiologist/ Bsc Anesthetist or/ An anesthesiologist Bsc Anesthetist or and should be replaced Anesthesiologists, Msc Anesthetists and sse Anesthetists (By trained Anesthetists)
- b) A registered nurse anesthetist or registered anesthetist or physician resident (anesthesiology), a student nurse anesthetist, a student anesthetist under the supervision of an anesthesiologist /A registered nurse anesthetist or registered anesthetist or physician resident(anesthesiology), a student nurse anesthetist, a student anesthetist under the supervision of Msc Anesthetists or senior Anesthetists or anesthesiologist

**5.5.3.5.** Minor regional blocks shall be administered by the following registered professionals:

- a)An Anesthesiologist/Bsc Anesthetist,
- b)Msc Anesthetists
- c)A nurse anesthetist, or
- d)A physician
- e)A medical intern, a physician resident, or a student nurse anesthetist, or student anesthetist, or a health officer, or a registered nurse, midwife, under the supervision of at least nurse anesthetist.

### **5.5.4. Products**

**5.5.4.1.** Anesthesia equipment shall include the following:

- a) Time clock
- b) Anesthesia machine with ventilator, 2 vaporizers, and gas cylinders
- c) Adult and pediatric anesthesia circuits with filters
- d) Mechanical ventilators
- e) Oxygen cylinders, oxygen trolley and oxygen regulator
- f) Worktable with laminated top
- g) Resuscitation equipments; Ambu bags (adult/ pediatric/ neonates), with inflatable bag,
- h) Refrigerator with thermometer,
- i) Stools
- j) Clips
- k) Resuscitation trolley

## CES 234

- l) Syringe pump/infusion pump
- m) Defibrillator
- n) Blood gas analyzer (optional)
- o) Dust bin
- p) Blankets
- q) Air conditioner and heater
- r) Framed boards with pencil trays
- s) IV stands, infusion pumps, IV fluid pressure bags, blood warmer and IV fluid warmer
- t) Tourniquets, tongue depressors, disposable
- u) Operation table with minimum of smoothly adjustable 3 sections and accessories;
  - Pillows, abduction
  - Support, head, operating table
  - Positioner bag, small, medium and large
  - Adjustable Head screen
  - Patient transferring Stretchers
  - Suction machines
- v) Goggles and boots
- w) Patient monitor
- x) laryngoscope with different type of blade, fibro scope for difficult air way management, nerve stimulators.  
ultrasound for peripheral blocks
  - ECG monitor
  - 3 leads Electrode, Monitor
  - Pulse oximeter
  - Temperature monitor
  - BP apparatus with different size cuffs
- y) Shelves
- z) Lockable cabinets for anesthesia drug

**5.5.4.2.** All medicines and supplies shall be available as per the national medicines list for this level of health facility.

## 5.6. Intensive care (IC) service (Optional)

### 5.6.1. Practices

- 5.6.1.1.** The ICU service shall be open 24 hours and 7 days a week with available medical personnel with Advanced Life Support (ALS) training available round the clock with shift.
- 5.6.1.2.** The ICU shall have written policies and procedures that are reviewed at least once every 3 years and implemented. They shall include at least:
  - a. Criteria for admission to ICU,
  - b. Criteria for discharge and transfer;
  - c. A list of procedures that registered physicians, who are certified/ accredited in intensive care, may or may not perform;

- d. Protocols for transfer and transport of patients within the specialty center or from the center to another facility including who shall accompany the patient being transferred or transported;
  - e. Infection control procedures and/or protocols as indicated under infection prevention standards;
  - f. A visitors policy that specifies visiting hours and number which subject to the discretion of the patient's physician or primary care nurse;
  - g. A policy defining the physician, specialist and consulting physician to be called for patient emergencies, including a response time for physicians to respond to patient emergencies;
- 5.6.1.3.** Roles and responsibilities of specialists in management of ICU patients shall be available in written policy or protocol.
- 5.6.1.4.** Nursing functions shall be the responsibility of a licensed nurse and shall be accountable to the attending ICU physician,
- 5.6.1.5.** The patient's medical service record shall be integrated with the patient's over-all specialty center's record,
- 5.6.1.6.** There shall be portable life-support equipment for use in patient transport, both within the center and for transfer. All ventilators in use shall be equipped with an integral minimum ventilation pressure (disconnect) alarm. There shall be a system for obtaining immediate emergency replacement or repair of equipment in the critical care service.
- 5.6.1.7.** There shall be a mechanism in place for the critical care service to have access to nutritional support services for advice on both enteral and parenteral nutritional techniques.

#### **5.6.2. Premises**

- 5.6.2.1.** The ICU shall be located in access restricted area of the center and well identified. and shall have the following rooms;

**Table 6: Requirements for ICU layout**

<b>R.No</b>	<b>Rooms Required</b>	<b>Number Required</b>	<b>Area</b>
<b>1</b>	Intensive Care Unit		
<b>2</b>	IC room	1	40sq. m
<b>3</b>	Nurse station (inside IC room)	1	Included
<b>4</b>	Change room/ Nurse locker	1	12sq. m
<b>5</b>	Clean utility room	1	6sq. m
<b>6</b>	Soiled Utility/ Sluice room	1	6sq. m
<b>7</b>	Staff room	1	12sq. m
<b>8</b>	ICU mini- store room	1	12sq. m
<b>9</b>	Toilets with shower and hand washing basin	2	
<b>10</b>	Cleaner's closet	1	6sq. m

- 5.6.2.2.** The ICU room shall be at least 40 sqm in size that accommodate a maximum of 2 electrically or manually operated ICU patient beds fitted with full range of monitors and a screen.
- a) The header of beds shall be 1 m away from the wall
  - b) There shall be a 2m wide free traffic area by side of beds and between any of two beds.
  - c) There shall be a nurse station within the ICU having a computer and a computer point, telephone and telephone point, cabinets and shelves, and lockers for controlled drugs.

- d) There should be a separate physical area devoted to nursing management for the care of the intermediate patient (12 sq m area including nurse station).

**5.6.2.3. Nurse station in the ICU:**

- a) Full visual access to monitor admitted patients on monitors,
- b) Equipped with chairs, working laminated top tables, drawers and computers,
- c) Linen boards, shelves, lockers
- d) Telemetry monitoring (optional) for critical or post operative patients with transmitters,
- e) Telephone end,

**5.6.2.4. The ICU shall have hand wash basin or sanitizer around the entrance-exit door.**

**5.6.3. Professionals**

**5.6.3.1.** The specialty center ICU shall be directed by a licensed anesthesiologist or intensivist or ICU trained internist or MSc Anesthetist.

**5.6.3.2.** The physicians working in the ICU shall be completed a formal training program in critical care approved by the licensing body in the country.

**5.6.3.3.** A ratio of 2 patients to 1 nurse shall be available at a general ICU.

**5.6.3.4.** The nursing staff of each unit within the ICU service shall have special training in critical care nursing or took on job training.

**5.6.3.5.** All practicing nurses and nurse assistance in the ICU shall be trained and certified in basic cardiac life support.

**5.6.4. Products**

**5.6.4.1.** Medicines selected for ICU services shall be available at all times

**5.6.4.2.** The ICU shall have the following equipment, instruments and system:

- a) The ICU beds shall have removable side protections; functional wheels; shall be easily adjustable to multipurpose positions
- b) 2 functional mechanical ventilator
- c) Different size endotracheal tubes and tracheotomy sets, at least 4 sets,
- d) monitoring equipment,
- e) cardiac monitors including telemetry,
- f) Standard 12 lead EKG machines,
- g) external pacemakers (optional),
- h) defibrillators
- i) Reliable Oxygen delivery systems
- j) Oxygen regulator, at least 2
- k) pulse oximeter,
- l) end-tidal carbon dioxide monitoring, (optional)
- m) Infusion pumps,
- n) A web of intravenous lines for medicines infusions, fluids or total parenteral nutrition,
- o) Laryngoscopes with different size blades,
- p) Ophthalmoscope, fundoscope
- q) Mouth gags, different size
- r) Air ways, different size

- s) Resuscitation trolleys,
- t) Endotracheal tubes ,(different sets)
- u) Wheel chair,
- v) Patient transport stretcher,
- w) Sphygmomanometer, with adult and pediatric cuffs,
- x) Sthethoscopes: pediatric and adult,
- y) I suction machine
- z) Nasal CPAP,
- aa) Bed pan
- bb) Pacing boxes (at least 2)(optional) cc) Wall clock
- cc) Soiled cloth hampers
- dd) Patient screen per bed and
- ee) IV stands, at least one per bed

## **5.7. Radiological Services (Optional)**

### **5.7.1. Practices**

- 5.7.1.1.** Basic Radiology service shall be available for specialty center, which at least includes X-Ray.
- 5.7.1.2.** The radiology service shall have written policies and procedures that are reviewed regularly and implemented. These policies and procedures shall include at least:
  - a) Safety practices;
  - b) Management of the critically ill patient;
  - c) Infection control, including patients in isolation;
  - d) Timeliness of the availability of diagnostic imaging procedures and the results;
  - e) Quality control program covering the inspection, maintenance, and calibration of all equipment.
- 5.7.1.3.** The Specialty center shall post/ put in easily accessible place the approval certificate from the Ethiopian Radiation Protection Authority through periodic inspection.
- 5.7.1.4.** There shall be documentation of the report for periodic radiation exposure dose readings for Radiation workers by the use of exposure meters or badge tests.
- 5.7.1.5.** Requests for x-ray examination shall contain a concise statement of reason for the examination.
- 5.7.1.6.** X-ray films shall be labeled with minimum information such as date, name, age, sex, right/left marks, name of institute.
- 5.7.1.7.** Reporting form shall have minimum information such as date, patient's name, age, sex, findings and name and signature of radiologist.

### **5.7.2. Premises**

- 5.7.2.1.** The radiology unit for specialty center shall fulfill the design requirements of Ethiopian Radiation Protection Authority (ERPA) guidelines.

### **5.7.3. Professional**

- 5.7.3.1.** The radiology service of the center shall be directed by a licensed radiologist or a licensed radiology technologist.
- 5.7.3.2.** A radiologist shall be available in the center during working hours all the time or if on call shall arrive within 30 minutes of being summoned
- 5.7.3.3.** A licensed radiology technologist or radiographer shall be present in the center at all times.

**5.7.3.4.** A licensed professional nurse may be available in the radiology service to administer medications and perform other nursing care.

**5.7.3.5.** A receptionist, cleaners shall be available in radiology service as full time..

**5.7.4. Products**

**5.7.4.1.** All medical equipments which shall be available for radiology services at Specialty center are indicated below:

- a) X-ray machine ,
- b) Ultrasound,
- c) X-Ray viewing boxes,
- d) Dark room film processing baths (if necessary),
- e) Drier (if necessary),
- f) Radiation protection equipments:
  - lead gloves,
  - lead apron,
  - lead goggle,
  - gonad shield,

**5.7.4.2.** The X-Ray machine shall be regularly inspected, maintained, and calibrated; appropriate records of maintenance shall be maintained.

**5.7.4.3.** Installation and un-installation of X-Ray machine shall follow the safety procedures set by the Ethiopian Radiation Protection Authority during all procedures.

**5.8. Medical Laboratory Services**

**5.8.1. Practices**

**5.8.1.1.** The specialty center shall have a minimum of basic laboratory service working for 24 hours a day & 365 days a year.

**5.8.1.2.** The specialty center laboratory service shall provide Basic Hematology, Bacteriology, Clinical Chemistry, parasitology, urinalysis & Serology test profiles.

**5.8.1.3.** The specialty center laboratory shall have written procedures and policy QMS (Quality management system and safety).

**5.8.1.4.** The Specialty center laboratory shall maintain a record of all samples received.

**5.8.1.5.** Once a sample is used, remnant shall be discarded in the laboratory following standard IP in the lab.

**5.8.1.6.** The laboratory for specialty center should establish an external quality control system with accredited agencies and shall participate nationally or internationally in EQA at least once yearly.

**5.8.1.7.** The specialty center Laboratory shall produce report which shall contain the following:

- a) All laboratory test result/reports shall have reference (normal) ranges.
- b) Files of reported results shall be retained by the laboratory.
- c) In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be contained in the medical record.
- d) Test results shall be reported on standard forms 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.

e) Specialty center address.

f) Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them.

g) The laboratory shall have policies and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic. Policies shall be established which define who may access patient data and who is authorized to enter and change patient results.

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

**5.8.1.9.** Safe disposal of samples shall be in line with according to infection prevention guideline.

**5.8.1.10.** No eating, drinking, smoking or other application of cosmetics in laboratory work areas or in any area where workplace materials shall be handled.

**5.8.1.11.** No food or drink shall be stored in the laboratory.

**5.8.1.12.** 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.

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

## 5.8.2. Premises

**5.8.2.1.** The laboratory service shall have the following premises

**Table 7: Requirements for laboratory service layout**

S.No	Room required	Number required	Area required
1	Laboratory room (can be 1 room with open platform)	1	39 sq. m
2	Specimen collection	1	6sq. m
3	Hematology & clinical chemistry	1	9sq. m
4	Parasitology, urinalysis & serology	1	9sq. m
5	Bacteriology	1	6sq. m
6	Blood bank/storage room	1	9sqm

**5.8.2.2.** The laboratory working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste materials.

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

**5.8.2.4.** The laboratory shall have monitored room temperature.

**5.8.2.5.** Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.

**5.8.2.6.** 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,

- c) Continuous power supply,
- d) Fitted with laboratory benches, Working surface covered with appropriate water proof, corrosive resistance materials,
- e) Ergonomically chair.
- f) Laboratory furniture shall be capable of supporting anticipated loading and uses.
- g) Spaces between benches, cabinets, and equipment shall be accessible for cleaning.
- h) Lockable doors and cupboards.
- i) Closed drainage from laboratory sinks (to a septic tank or deep pit)
- j) Separate toilet for patients.

**5.8.2.7.** Emergency of safety services such as deluge showers and eye-wash stations, fire alarm systems and emergency power supplies shall be included in the laboratory services design specifications.

### **5.8.3. Professionals**

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

**5.8.3.2.** The specialty center shall have & maintain Job descriptions including qualification for each lab staff.

**5.8.3.3.** The specialty center shall facilitate access to relevant trainings, continuing education and assess staff competency at regular intervals.

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

### **5.8.4. Products**

**5.8.4.1.** Specialty center medical laboratory shall have the following equipments:

- a) Safety cabinet (optional)
- b) Microscope, binocular 2
- c) Centrifuge,
- d) Autoclave (shared)
- e) Refrigerator with thermometer,
- f) Bunsen Burner (optional)
- g) ESR with stand and tubes,,
- h) Water distillation apparatus (optional)
- i) WBC chamber,(optional)
- j) Shaker/ Roller
- k) Timer
- l) Lab bench,
- m) Differential counter (optional)
- n) Hematology analyzer,
- o) Clinical Chemistry analyzer (semi-automated\*/ automated),
- p) Water bath,
- q) Assorted lab glass wares,
- r) Biohazard bag,
- s) Safety box,
- t) Glucometer

**5.8.4.2.** The consumables, Lab Chemicals and solutions shall be required

## 5.9. Pharmacy Services

### 5.9.1. Practices

#### Dispensing and Medication Use Counseling

- 5.9.1.1.** Standard operating procedure (SOP) for dispensing and medication use counseling shall be established to ensure patients' safety and correct use of medications.
- 5.9.1.2.** Dispensers shall make sure that prescriptions are legible, written by authorized prescriber and complete. Prescription papers shall be standardized and must contain at least the following information and the prescriber shall complete all these information:
- a) Name of patient, sex, age and medical record number,
  - b) Diagnosis and allergy, if any,
  - c) Name of the medicines, strength, dosage form, dose, frequency, and route of administration,
  - d) Duration of treatment,
  - e) Prescriber's name, qualification and signature,
  - f) Prescriber's address (name and address of Specialty center).
- 5.9.1.3.** The pharmacist shall check the correctness of prescriptions in terms of appropriateness for patients and of dosage, strength and drug interactions based on approved standard treatment guidelines”
- 5.9.1.4.** All medicines shall be dispensed with adequate and appropriate information and counseling to patients for correct use of their medications.
- 5.9.1.5.** The pharmacist shall make an in-depth professional judgment to make sure that each medicines and its dosage form has all of its attributes of quality and an acceptable ratio of safety.
- 5.9.1.6.** The containers used for dispensing shall be appropriate for the product dispensed and all containers intended for pharmaceuticals shall be protected and kept free from contamination, moisture and light.
- 5.9.1.7.** All pharmaceuticals to be dispensed shall be labeled and the labels shall be unambiguous, clear, legible and indelible. The following minimum information shall be indicated on the label/ sticker:
- a)the generic name of the product or each active ingredient, where applicable;
  - b)the strength, dose, frequency of administration and total quantity;
  - c)the name of the person for whom the medicines are dispensed;
  - d)the name of the prescriber and patient card number;
  - e)the directions for use and route of administration tailored to patient or caregiver literacy and language;
  - f) the name and business address of the dispenser;
  - g)date of dispensing; and
  - h)Special precautions as applicable
- 5.9.1.8.** Filled prescriptions shall be signed and accountability must be accepted by the dispensing Pharmacist.
- 5.9.1.9.** Each Specialty center shall establish and implement policies, guidelines and procedures for reporting any errors or any suspicion in administration or provision of prescribed medications. Errors shall be reported to the prescriber in a timely manner upon discovery and a written report of the error prepared and documented. Any suspicion or error shall be communicated to the prescriber and clarified/corrected before dispensing without affecting patient's confidence on medical practices.

**5.9.1.10.** The counseling of patients or their caregivers shall be undertaken to promote the correct and safe use of pharmaceuticals. The responsible Pharmacist must ensure that patients are counseled before they receive pharmaceuticals that they are to self-administer.

**Control of Drug Abuse, Toxic or Dangerous Drugs**

**5.9.1.11.** The specialty center shall establish Policies and procedures to control the administration of narcotic drugs and psychotropic substances with specific reference to the duration of the order and the dosage in accordance with relevant laws.

**5.9.1.12.** A record of the stock on hand and of the dispensing of all these drugs shall be maintained in such a manner that the disposition of any particular item may be readily traced.

**5.9.1.13.** A licensed pharmacist shall dispense all controlled substances (narcotic and psychotropic drugs) to the authorized health professional designated to handle controlled substances in the specialty center. When the controlled substance is dispensed, the following information shall be recorded into the controlled substances (proof-of-use) record.

- a) Name and signature of Pharmacist dispensing the controlled substance
- b) Name and signature of designated licensed person receiving the controlled substance.
- c) The date and time controlled substance is dispensed.
- d) The name, the strength, and quantity of controlled substance dispensed.
- e) The serial number assigned to that particular record, which corresponds to same number recorded in the pharmacy's dispensing record.

**5.9.1.14.** When the controlled substances are not in use, they shall be maintained in a securely locked, substantially constructed cabinet or area. All controlled substance storage cabinets shall be permanently affixed. Controlled substances removed from the controlled substance cabinet shall not be left unattended.

**5.9.1.15.** The administration of all controlled substances to patients shall be carefully recorded into the standard record for controlled substances and returned back to the Pharmacist upon refill of controlled substances. The following information shall be recorded during administration to patients.

- a) The patient's name, card number
- b) The name of the controlled substance and the dosage administered.
- c) The date and time the controlled substance is administered.
- d) The signature of the practitioner administering the controlled substance
- e) The wastage of any controlled substance.
- f) The balance of controlled substances remaining after the administration of any quantity of the controlled substance
- g) Day-ending or shift-evening verification of count of balances of controlled substances remaining and controlling substances administered shall be accomplished by two (2) designated licensed persons whose signatures shall be affixed to a permanent record.

**5.9.1.16.** All partially used quantities of controlled substances shall be licensed in to the control substance record and returned back to the responsible Pharmacist for control substances for disposal.

**5.9.1.17.** All unused and unopened quantities of controlled substances which have been removed from the controlled substance cabinet shall be returned to the cabinet by the practitioner at the end of each shift.

- 5.9.1.18. Any return of controlled substances to the pharmacy in the Specialty center shall be documented by a licensed Pharmacist responsible for controlled substance handling in the Specialty center.
- 5.9.1.19. The Specialty center shall implement procedures whereby, on a periodic basis, a licensed Pharmacist shall reconcile quantities of controlled substances dispensed in the Specialty center against the controlled substance record. Any discrepancies shall be reported to the head of the center. Upon completion, all controlled substance records shall be returned to the pharmacy by the designated responsible person.
- 5.9.1.20. The center shall submit regular report to the appropriate organ regarding the consumption and stock of controlled drugs.

### **Clinical Pharmacy Services**

- 5.9.1.21. The specialty center should establish policies and procedures for the provision of clinical pharmacy services through drug and therapeutic committee.
- 5.9.1.22. The pharmacist for clinical pharmacy services shall have access to patient specific medication therapy information.
- 5.9.1.23. Patient-specific medication therapy information must be evaluated and a drug therapy plan shall be developed by the pharmacist mutually with the patient, the prescriber and nurse as appropriate.
- 5.9.1.24. The pharmacist shall review, monitor and propose for modification of the therapeutic plan in case of adverse effects, patient noncompliance and evidence- based efficacy problem and as appropriate, in consultation with the patient, prescriber and nurse.
- 5.9.1.25. Through prescription and medication history monitoring, the pharmacist shall identify problems or opportunities for optimizing treatment and hence safeguard the patient and ensure the optimal use of medicine
- 5.9.1.26. Medication education shall be delivered to patients or their caregivers upon discharge by the pharmacist.
- 5.9.1.27. The pharmacist shall make sure that the patient has all supplies, information and knowledge necessary to carry out the drug therapy plan.
- 5.9.1.28. As a member of the specialty center team, the pharmacist shall attend and participate at patient visits and contribute to patient care through the provision of medicine information, dose calculations and adjustment, assisting in the rational prescribing decision, alternative regimens & combinations and reducing the frequency and duration of medication errors.
- 5.9.1.29. The specialty center (drug and therapeutic committee) shall develop/adopt and implement policy on antimicrobial prescribing, dispensing and usage.

### **Adverse Drug event, DIS/ Pharmacovigilance**

- 5.9.1.30. The pharmacy of the specialty center shall appoint an ADE (adverse drug event) focal person responsible for the collection, compilation, analysis and communication of adverse drug reaction, medication error and product quality defects related information to the DTC and then to FDA.
- 5.9.1.31. Health professionals of the center shall be responsible to report suspected ADE cases to the ADE focal person.
- 5.9.1.32. DTC shall discuss and make necessary recommendations to the center's management for decision on adverse drug event reported within the health facility.

**5.9.1.33.** The pharmacy of the center shall consistently update the safety profile of medicines included in the formulary list for immediate medicines use decisions and consideration during the revision of the list.

**5.9.1.34.** Adverse medication effects shall be noted in the patient's medication record.

**5.9.1.35.** All the ADE reports, patient identity, reporters and medicine trade names shall be kept confidential.

**5.9.1.36.** The reporting of ADE shall be done by the national ADE prepaid yellow form prepared by FDA.

### **Pharmaceutical Supply and Management**

**5.9.1.37.** The pharmacist shall ensure that both the supplier and the source of any medicine purchased are reputable and registered by the FMACA.

**5.9.1.38.** The center shall introduce and maintain stock control system (manual and/or computerized system) in the pharmacy store and dispensaries.

**5.9.1.39.** The center shall be responsible to make sure that pharmaceuticals promotion made by suppliers or manufacturers in the center's premises is made by a registered pharmacist in accordance with the country's laws.

**5.9.1.40.** Special storage conditions shall be maintained for pharmaceuticals requiring cold chain system, controlled substances, radiopharmaceuticals and medical gases.

**5.9.1.41.** Firefighting equipment or system shall be installed to pharmaceutical storage places

**5.9.1.42.** Distribution of pharmaceuticals within a center shall be under the direction and control of a pharmacist and must be in accordance with the policy developed by DTC. All issuing activities shall be made using official and serially numbered vouchers.

**5.9.1.43.** Written SOPs shall be provided on how supplies of stock are to be obtained from the pharmaceuticals store. Procedures must define normal action to be taken by pharmaceutical staff for routine stock replacement and action to be taken in the case of incomplete documentation or other queries.

**5.9.1.44.** Written procedures shall be available for the return of expired, damaged, leftover and empty packs from outlets to pharmaceuticals store to prevent potential misuse.

**5.9.1.45.** The center shall maintain stock control system (manual and/or computerized system) in the central medical store and dispensary.

**5.9.1.46.** The center pharmacist who is responsible for the management of pharmaceuticals should conduct regular medicines use studies to ensure maximum patient benefit from the formulary list

**5.9.1.47.** The DTC should be responsible for developing policies and guidelines on how to organize and conduct medicines use studies.

### **Medicines Waste Management and Disposal**

**5.9.1.48.** The disposal of medicine wastes shall be in compliance with the medicines waste management and disposal directives issued by FDA.

**5.9.1.49.** Specialty center pharmacy shall take responsibility, through supportive policies and procedures for the environmental and societal safety by efficiently managing the pharmaceutical wastes.

**5.9.1.50.** All personnel involved in medicines waste handling shall be trained and/or well informed about the potential risks of hazardous medicines waste and their management.

**5.9.1.51.** Cleaners or anybody to handle hazardous pharmaceutical wastes shall wear protective devices like apron, plastic shoes, gloves, head gears and eye glasses when the need arises.

- 5.9.1.52. General wastes shall be collected daily from the pharmacy and placed in a convenient place outside the pharmacy to facilitate coordinated disposal by the center.
- 5.9.1.53. Solid wastes from the pharmacy shall be categorized as “hazardous” and “non-hazardous” and shall be collected separately for proper treatment.
- 5.9.1.54. All hazardous chemicals spills shall be immediately reported to head of the pharmacy or responsible person for safety (if available) to minimize the risk and take immediate action.
- 5.9.1.55. Spillages of low toxicity shall be swept into a dust pan and placed into a suitable container for that particular chemical and dispose accordingly.
- 5.9.1.56. Medicines in single dose or single use containers which are open or which have broken seals, medicines in containers missing medicines source and exact identification (such as lot number), and outdated medications shall be collected to the pharmacy for disposal.
- 5.9.1.57. The Specialty center shall form a pharmaceutical waste disposal committee to ensure safety, accountability and transparency.
- 5.9.1.58. Disposal of pharmaceutical wastes shall be supported by proper documentation including the price, batch number & expiry date of the products for audit, regulatory or other legal requirements.

## **5.9.2. Premises**

- 5.9.2.1. The design and layout of the pharmacy shall permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimize the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of medicines and service delivery.
- 5.9.2.2. The area(s) of counseling shall be arranged or constructed in such a manner that it provides adequate space, have professional look and ensure reasonable privacy to the patient at all times and eliminate background noise as much as possible.
- 5.9.2.3. Dispensing counter &/ or counseling area shall be designed to secure patient privacy and confidentiality.
- 5.9.2.4. All parts of the pharmacy premises shall be maintained in an orderly and tidy condition.
- 5.9.2.5. Entrances, dispensing counters and doorways shall be accessible to persons with disability.
- 5.9.2.6. The dispensing environment (dispensing counter and counseling area) shall ensure confidentiality and allow simultaneous service delivery for multiple customers by multiple providers.
- 5.9.2.7. The pharmacy premises shall be clearly demarcated and identified from the premises of any other business or practice. The pharmacy shall be secure from theft & any other disaster like fire & flood.
- 5.9.2.8. A procedure shall be in place to ensure access to pharmacy premises in an emergency situation.
- 5.9.2.9. The ceiling height of the pharmacy store shall not be less than 2.6m. This height requirement shall increase depending on the climatic condition of the area
- 5.9.2.10. The wall and floor shall be constructed to protect the safety of pharmaceuticals from burglary, rodents, direct sunlight, moisture and others.
- 5.9.2.11. Medicines shall be shelved a minimum of 20cm above the floor, 1m wide between shelves and 50cm away from the wall and ceiling. If pallets are used, there shall be 20cm above the floor, one meter between pallets and 50cm away from the wall.
- 5.9.2.12. The pharmacy premises shall have the following minimum space.

**Table 8: Requirements for laboratory layout**

R.No	Room required	Number required	Area required
1	Pharmacy		
2	Medicines shelf, working space, dispensing counter and patient waiting area with counseling area	1	25sq. m
3	Pharmacy store	1	25sq. m

**5.9.3. Professional**

- 5.9.3.1.** The pharmacy service shall be directed by a licensed pharmacist with a minimum of two years work experience.
- 5.9.3.2.** The dispensing of all prescriptions and medication use counseling shall be carried out by licensed pharmacists.
- 5.9.3.3.** The center shall have one additional pharmacist
- 5.9.3.4.** In addition, the center may have additional licensed pharmacists based on workload analysis.
- 5.9.3.5.** The center shall have a pharmacy technician for the central medical store and inventory management
- 5.9.3.6.** The pharmacy service shall have support staff such as clerks, porters and cleaners.

**5.9.4. Products**

- 5.9.4.1.** The pharmacy in Specialty center shall have medicine lists within the framework of the national medicine list prepared by the regulatory authority.
- 5.9.4.2.** The Specialty center shall have central medical store equipped with fire extinguisher, refrigerators, deep freezers (optional) and racks/shelves.
- 5.9.4.3.** In general, minimum standard for pharmacy equipment and facilities shall be as follows.

**Equipment and facilities**

- a) Refrigerators
- b) Deep freezer (optional)
- c) Refrigerator Thermometer
- d) Tablet counter
- e) Calculator
- f) Table and chair
- g) Scissors
- h) weighing scale
- i) Room thermometer
- j) Telephone line

**5.10. Medical Recording****5.10.1. Practices**

- 5.10.1.1.** Medical record shall be maintained in written form for every patient seen at all points of care.
- 5.10.1.2.** The Specialty center shall maintain individual medical records in a manner to ensure accuracy and easy retrieval. A patient shall have only one medical record in the Specialty center.
- 5.10.1.3.** If the patient received medical intervention while on ambulance, the medical information of a patient during ambulance service including medication administered shall be documented properly and attached into the medical record,

- 5.10.1.4.** Each piece of paper or format that contains a patient medical information/ record shall carry the appropriate identification,
- 5.10.1.5.** The Specialty center shall have a written policy and procedure which include at least:
- (a) Procedures for record completion,
  - (b) Conditions, procedures, and fees for releasing medical information,
  - (c) Procedures for the protection of medical record information against the loss, tampering, alteration, destruction or unauthorized use.
- 5.10.1.6.** When a medical record is taken out until returned to the record room it shall be documented to create a good tracking mechanism.
- 5.10.1.7.** Any medical record shall be kept confidential, available only for use by authorized persons or as otherwise permitted by law.
- 5.10.1.8.** 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.
- 5.10.1.9.** The medical record forms shall be prepared in line with the national HMIS guidelines.
- 5.10.1.10.** Each medical record shall at least contain the following information:
- a) Identification (name, age, sex, address),
  - b) History, physical examination, investigation results and diagnosis,
  - c) Medication, procedure and consultation notes,
  - d) Name and signature of treating physician, date,
  - e) Consent form
- 5.10.1.11.** Any consent form for medical treatment that the patient signs shall be printed in an understandable format and the text written in clear, legible and non-technical language.
- 5.10.1.12.** There shall be a mechanism for medical record controlling and tracing, whenever patients medical records are taken from and returned to the central medical record room.
- 5.10.1.13.** There shall be a mechanism to make medical records with appointment ready for use and return seen cards back to the central medical record room within 24hrs.
- 5.10.1.14.** If death happens in the center, the necessary information of the patient's death shall be documented in the patient's medical record upon death; date, time, any intervention, etc.,
- 5.10.1.15.** Original medical records shall not leave Specialty center premises unless they are under court order or in order to safeguard the record in case of a physical plant emergency or natural disaster.
- 5.10.1.16.** If a patient or the patient's legally authorized representative requests in writing, a copy of the medical record shall be given.
- 5.10.1.17.** If the patient is provided with medical certificates, copies of certificates shall be documented and/or recorded on the original medical record.
- 5.10.1.18.** If the Specialty center ceases to operate, the appropriate organ shall be notified in writing about how and where medical record will be stored at least 15 days prior to cessation of operation. The patient choice on where to transfer his/her medical record shall be respected.
- 5.10.1.19.** Medical records shall be destroyed as per the law by using techniques that assures confidentiality of the medical records. However, records which are active for more than ten years shall not be destroyed.



**5.10.2. Premises**

**5.10.2.1.** The premises for medical record room shall have enough space between and around shelves. The medical records shall be shelved a minimum 10cm above the floor.

**5.10.2.2.** The medical record room shall have adequate space to accommodate the following:

- a) Central filing space,
- b) Work space,
- c) Supply/ Storage area,
- d) Archive space with shelves,

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

**5.10.2.4.** There shall be a room/ place for archiving dead files until they are permanently destroyed.

**5.10.3. Professionals**

**5.10.3.1.** There shall be full-time assigned custodian/ medical record personnel with basic computer skill and ability to organize medical records for medical records management.

**5.10.3.2.** The Specialty center shall provide basic training on medical record keeping to all medical record unit staff.

**5.10.4. Products**

**5.10.4.1.** The Medical record room shall have:

- a) Shelves,
- b) Table,
- c) Master patient index boxes,
- d) Log books,
- e) Patient folders,
- f) Computer,
- g) printer
- h) Cart
- i) Ladder & Fire extinguisher

**5.11. Ambulance Service standards**

**5.11.1. Practice**

**5.11.1.1.** The ambulance service shall be provided to every emergency patient

**5.11.1.2.** The ambulance service shall be available 24 hrs a day and 365 days a year,

**5.11.1.3.** The ambulance service shall provide the following services to patients with urgent need of medical attention or in a medical emergency.

- a) Transportation service from the Specialty center to other health facilities
- b) Clinical examinations including brief history, vital signs, very pertinent physical examination and glucose test when needed
- c) Clinical life saving support that includes:
  - Fluid resuscitation
  - Bleeding control
  - Air way cleaning , oxygen administration, severe asthma management
  - Attending labor

- Immobilizing a fracture
- Managing seizure
- Providing emergency medicines

**5.11.1.4.** The ambulance service shall comply with the patient rights standards stated under this standard.

**5.11.1.5.** Upon arrival the handover of patients shall be accompanied by a written document which at least includes identification, date, time and services provided until arrival to the Specialty center.

**5.11.1.6.** If death happens on the way to a Specialty center, the dead body shall be taken to this specialty center and death shall be confirmed.

**5.11.1.7.** Ambulances of the Specialty center shall serve only for designated emergency medical services

**5.11.1.8.** After providing a service the vehicle shall be cleaned and disinfected

**5.11.1.9.** The ambulance kit shall be checked every time after providing the service

### **5.11.2. Professionals**

**5.11.2.1.** The nurses shall be trained on emergency medical services,

**5.11.2.2.** The driver shall be oriented on emergency situation management,

### **5.11.3. Products**

**5.11.3.1.** The Specialty center shall avail ambulance car which shall have adequate space for accommodating the following whenever required:

a) A foldable stretcher

b) Ambulance Bed (couches) with security belts, fixed chair that is designed for ambulances

c) Medical box for items needed for providing immediate life saving support.

d) Log book (stating time of call, time of arrival, time of return)

**5.11.3.2.** The vehicle shall be labeled and have siren and emergency light.

**5.11.3.3.** The vehicle shall have adequate internal light and ventilation.

**5.11.3.4.** The vehicle shall fulfill requirements of road transport authority.

**5.11.3.5.** Ambulance kit:

a) Medicines:

- Anti pains,
- Adrenaline inj.,
- Hydralazine inj.,
- IV fluids (all types),
- Dextrose 40%,
- Diazepam inj.,
- Phenytoin inj.,
- Atropine inj.

b) Supplies

- IV cannula,
- IV stand,
- syringe with needle,
- tourniquet,

- plaster,
- gauze,
- bandage,
- spatula,
- antiseptic solution,
- catheters
- Personal protective devices (gown, mask, gloves, goggles)
- Waste disposing containers
- Support material for immobilization purpose for immobilization purpose

**c) Equipment:**

- Minor surgical set,
- Oxygen supply,
- Ambu bag,
- suction machine,
- Stethoscope,
- sphygmomanometer,
- thermometer,
- Portable radio or telephone,
- c-collar, log roller
- Emergency tracheostomy (wide bore needle insertion),
- air way,
- laryngeal mask,
- intubation set,
- Glucometer

**5.12. Morgue Services**

**5.12.1. Practices**

**5.12.1.1.** The Specialty center shall have written policies and procedures for dead body care services. These policies shall delineate the responsibilities of the medical staff and nursing staff and shall include procedures for at least the following:

- a) Identification of the body, recording and labeling,
- b) Safe and proper handling of the body to prevent damage and this shall be according to the patient religion and culture,
- c) Treatment of the dead body with formalin,
- d) Safeguarding personal effects of the deceased and release of personal effects to the appropriate person,
- e) Proper handling of toxic chemicals by morgue and housekeeping staff,
- f) Infection control, including disinfection of equipment as per IP standard,
- g) Identifying & handling high-risk and/or infectious bodies,
- h) Release of the body to the family shall be as immediately as possible,

**5.12.1.2.** There shall be a death certificate issued by authorized medical practitioner for each death and this shall be documented.

**5.12.1.3.** The specialty center shall provide the necessary care for dead body until delivered to the relatives/ care givers.

**5.12.1.4.** The service shall be available for 24 hours a day and 365 days of a year.

**5.12.1.5.** Any dead body shall be sent to/ pass through morgue after death confirmation.

**5.12.1.6.** Dead body discharge shall be through the morgue exit.

## **5.12.2. Premises**

**5.12.2.1.** The morgue premises at specialty center shall fulfill at least the followings:

- a) Adequate Water supply,
- b) Well ventilated,
- c) Adequate supply of light,
- d) Hand wash sink,
- e) Secured with locks,

## **5.12.3. Professionals**

**5.12.3.1.** The morgue service shall have the following designated personnel:

- (a) Morgue attendant,
- (b) Cleaner.

## **5.12.4. Products**

**5.12.4.1.** The center shall have at least two couches (double deck if possible).

**5.12.4.2.** In addition, the following products shall be available for morgue services:

- a) Plastic sheets
- b) Stretcher
- c) Formalin
- d) Syringe with needle
- e) Detergents
- f) Cotton
- g) Gloves
- h) Aprons
- i) Boots
- j) Gowns
- k) Head cover
- l) Goggles
- m) Disinfectants
- n) Plastic bags
- o) White loose fabric/ clothes
- p) Body table with hot and cold water sink
- q) Cupboard

## 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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### International Involvement

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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