CES xxx **Compulsory**

Ethiopian Standard

Second Edition
2018

Gastroenterology and hepatology Specialty Center Requirement

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Foreword

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

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

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

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

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

Internal medicine specialty center _Requirement

1. Scope

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

2. Normative References

3. Terminologies and Definitions

3.1 Appropriate Organ: Shall mean a state government organ authorized to implement food, medicine and healthcare administration and control activities at a state level;

3.2 Authority: Shall mean the Ethiopian Food, Medicine and Healthcare Administration and Control Authority.

3.3 Proclamation: Shall mean the Ethiopian Food, Medicine and Healthcare Administration and Control proclamation No 661/2009.

3.4 Appropriate Law: Shall mean a law issued by a state to implement regulatory activities regarding food, medicine and healthcare.

3.5 Person: Shall mean any physical or juridical person

3.6 Authorized Person: Shall mean any specialty center staff who is responsible for a given service

3.7 Gastroenterology and hepatology 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 internal medicine 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 requirement

4.1 The gastroenterology and hepatology speciality center shall be directed by Gastroenterology and hepatology subspecialist

4.2 The center shall have at least one Gastroenterology and hepatology subspecialist shall be physically available 24 hours a day 365 days a year.

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

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

4.5 A Gastroenterology and hepatology subspecialist shall be responsible for the follow-up clinics.

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

4.7 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.

4.8 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.

4.9 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,

4.10 The speciality center facilities shall be well marked and easily accessible for persons with disability.

4.11 The center shall have fire extinguisher placed in visible area.

4.12 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.

4.13 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.

4.14 Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.

4.15 All patient care rooms shall be provided with running water supply & functional hand washing basin.

4.16 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.

4.17 The circulation ways and sub corridors shall be a minimum 2m wide.

4.18 Patient serving corridors shall not be less than 240cm wide,

4.19 Safety glass, tempered glass or plastic glass materials shall be used for paediatrics service units to avoid possible injuries.

4.20 Glass doors shall be marked to avoid accidental collision.

4.21 Gastroenterology and hepatology speciality 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.

4.22 The speciality center shall carryout workload analysis.

Nursing practice

4.23 Nursing care service at different service delivery areas shall be directed by a licensed BSC nurse.

4.24 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.

4.25 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.

4.26 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).

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

4.28 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.

4.29 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.

4.30 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.

4.31 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.

4.32 Informed consent shall be sought before carrying out any procedure.

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

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

4.35 There shall be a mechanism in place to ensure that assistance is provided for patients who require assistance.

4.36 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.

4.37 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.

4.38 There shall be a policy or a protocol that state the procedure to be followed for dying patients & dead body care.

4.39 The gastroenterology and hepatology speciality center shall have the following summary of professionals:

Professionals required	Minimum # required
• Gastroenterology and hepatology subspecialist	1
• Gastroenterology and hepatology subspecialist /internist /general practitioner	1
• Radiologist	1
• Pathologist (can be on call)	1
• GP	1
• Anaesthetist	1
• Nurses:	
○ Emergency	2
○ OPD	2
○ Ward/ inpatient	3
○ Endoscopy	3
Instrument processing 01	
Procedure and Recovery 02	
• Lab technologist	1
• Lab Technician/lab technologist	3
• Lab technician for pathology service	1
• Pharmacist	2
• Radiologist technologist /Radiographer	2
Support staff	
• Receptionist	
• Cleaner	
• Porter/ runner	
• Biomedical engineer /Technician	1

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

5. Specific Requirement

5.1 Outpatient Medical Services

5.1.1 Practice:

5.1.1.1 The gastroenterology and hepatology Specialty center outpatient service shall provide the following core functions:

a) Care of ambulatory patients with outpatient service,
b) Emergency diagnosis and gastroenterology and hepatopancriatobiliary interventions
c) Inpatient care for different gastroenterology diseases,
d) Investigation & interventions with both upper and lower GI endoscopies.

e) Ultrasound guided liver biopsy, aspiration, injection
f) Pathology service.
g) Advanced diagnostic and interventional GI endoscope services(ERCP,EUS,

5.1.1.2 The speciality center should provide Rehabilitation service.

5.1.1.3 There shall be written protocols/ procedures for the consultation and management of cases that shall include:

(a) Identifying critical cases,
(b) Handling of Emergency & critically ill patients,
(c) Infection control specified under this standard and National IP guideline,
(d) Procedures, interventions and special investigations like Endoscopy, colonoscopy ,etc. ,
(e) Referral of patients,
(f) Monitoring and follow-up of patients.
(g) Inpatient Gastroenterology Service.
(h) Standardized documentation and reporting for procedures

5.1.1.4 The outpatient service shall have protocol 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,

5.1.1.5 The center shall have protocol for patient preparation, sedation for endoscopy procedure, occupational safety.

5.1.1.6 The outpatient service shall have consultation with functional intra and inter facility referral system as per the national patient referral guideline 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

5.1.1.7 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^o & pain assessment), weight and height
    - Clinical examination pertinent to the illness,
(c) Laboratory and radiographic (roentigenographic) workups when indicated.
(d) Diagnostics impression

5.1.1.8 The Gastroenterology center shall avail updated reference materials, treatment guidelines and manuals within the scope of practice (e.g. pain management, cirrhosis & complication management ART, viral hepatitis management guideline, diabetic management guideline, management of GI bleeding guideline, etc)

5.1.1.9 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.

5.1.1.10 The center shall have a follow-up service for patients with chronic ailments.

5.1.1.11 There shall be a protocol for instrument processing, high level disinfection & sterilization.

5.1.2 Premises

5.1.2.1 The outpatient service shall be well marked and easily accessible for disabled clients, elderly, children's and pregnant mother.

5.1.2.2 The outpatient service shall be located where access for ambulatory patients is the easiest and where in coming client would not have to pass through other care service outlets (in- patient , laboratory etc).

5.1.2.3 The room arrangements of outpatient services shall consider proximity between related services with easy access to pharmacy, laboratory and other diagnostic services.

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

5.1.2.5 Communication system shall be connected with major functional areas.

5.1.2.6 The outpatient department shall have fire extinguishers placed in visible area.

5.1.2.7 The outpatient layout shall include the following:

Room required	**No of room**	**Area required**
Waiting area/ reception /recording		30sqm
Triage and Nursing station		**12sq.m**
Examination room	2	12sqm each
Procedure room	1	12sq.m
Room for providing injections and dressing	**1**	**9sq.m**
Staff room (for changing cloth)	**1**	**12sq.m**
Endoscopy room	1	20 sq. m
○ Instrument processing and disinfection room with inlet and outlet for endoscopy	1	16sq.m
○ Store room	1	9sq.m
○ Patient preparation room with 1 coach and toilet	1	12sq.m
○ Recovery room with 2 beds	1	16sq.m

○ Reception/counselling and recording area for endoscopy		
Central Sterilization room	**1**	**16sqm**
Toilet (male and female)	**2**	**4sq.m each**
Staff toilet	**1**	**4sq.m**
Store room	**1**	
Cleaners room/ closet		

Room required	**No of room**	**Area required**
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• Gastroenterology ward/ inpatient room		
○ Patient rooms for a minimum of 10 beds {with maximum room capacity not more than 6 beds}	2	96sq. m
○ Isolation rooms	~~2~~	~~30~~16sq. m
○ Nurse station	1	12sq. m
○ Duty rooms with lockers (male/ female)	2	24sq. m
○ Clean utility & linen room	1	6sq. m
○ Soiled utility room	1	6sq. m
○ Mini-Store	1	12sq. m
○ Toilet rooms (can be in each patient room)	4	16sq. m
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• Pharmacy		
○ Medicines shelves, working space, dispensing counter and patient waiting area	1	25sq. m
○ Counselling room/ area	1	9sq. m
○ Pharmacy store	1	25sq. m
○ Office/ duty room	1	9sq. m
• General purpose store room (Optional)	1	16sq. m
• Morgue	1	24sq. m

5.1.3 Professionals

5.1.3.1 At least one gastroenterology and hepatology subspecialist shall be available to run the respective specialized outpatient service.

5.1.3.2 A pathologist shall be available at least on call bases.

5.1.3.3 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.

5.1.3.4 The outpatient service shall have the following professionals:

Professionals required	**Minimum Number required**
Gastroenterology and hepatology sub specialist	2
Pathologist (can be on call)	1
Anaesthetist (on call)	1
Nurses	5
o OPD 02	
Endoscopy	
o Instrument processing 01	

o Procedure and Recovery 02	
Cleaners	
Runner	
Receptionist	

5.1.4 Products

5.1.4.1 The following products shall be available for outpatient service.

a) Vital Sign and Diagnostic Set
   - Thermometer
   - Stethoscope
   - Sphygmomanometer
   - Fundoscope
   - Otoscope
   - Pulseoxymeter
   - Reflex hammer
   - Snellen's chart

b) Examination couch,
c) Weighing Scale
d) Refrigerator
e) Endoscope,with acceries
f) colonoscope,
g) Laryngoscope
h) Endotrachial tube
i) Monitor
j) Trolley
k) X-Ray Film viewer
l) Safety Box
m) Folding screen 3 section
n) Torch,
o) Height measurement,
p) Spatula, surgical and disposable gloves, antiseptics, cotton, gauze

5.1.4.2 The following products shall be available for procedure room

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

dd) Connectors,
ee) Cushion bags,

5.1.4.3 The following Products shall be available for endoscopy room

a) Endoscope
b) Endoscopy accessories including disinfectant and enzymatic solutions
c) Suction machine
d) Resuscitation set (laryngoscope,ambubag, endotrachial tube, face mask
e) Oral airway
f) Oxygen cylinder
g) Medication trolley
h) Vital sign equipments
i) Cardiac monitor
j) Gastroscope,colonoscope, dodenoscope
k) wheelchair
l) cabinet
m) Nasal prong
n) IV cannula
o) Kidney dish
p) Garbage bins
q) Safety box
r) Syringe
s) Plastic bed sheet
t) Adrenaline
u) Rubber bands
v) Diazepham/Midazolam
w) Fentanyl /propofol
x) Xylocain jel/spray/lidocain gurgle
y) Simethicone
z) Sclerosing agents
aa) Stretchers

5.2 Emergency Services

5.2.1 Practice

5.2.1.1 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.

5.2.1.2 On top of the above article (5.2.1.1), the specialty center shall avail advanced emergency services specific to the specialty which shall include but limited to

a) Intubation and urgent referral
b) Central line/Venus cut down
c) Blood transfusion, vaso pressure
d) Cardio version /defibrillation(management of arrhythmia)

e) Emergency management of poisoning

5.2.1.3 There shall be emergency handling plan.

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

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

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

5.2.1.6 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.

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

5.2.1.8 In conditions of emergency management, all interventions, medications administered and the clinical condition shall be communicated to the patient or available family member following the emergency responses/ resuscitation measures.

5.2.1.9 The emergency service shall promote the dignity and privacy of patients.

5.2.1.10 There shall be protocol that facilitates support from other services for emergency service.

5.2.1.11 The specialty center shall assign health professional to look after the emergency service.

5.2.2 Premises

5.2.2.1 The emergency room shall be located in a place where it is easily recognizable to the public and near to the gate and shall be labelled in bold.

5.2.2.2 The emergency premise shall be low traffic area and there shall be reserve parking place for ambulances.

5.2.2.3 The corridor to emergency rooms shall be stretcher friendly and 2.4m wide.

5.2.2.4 The emergency area shall be spacious enough to provide a space for the following tasks:

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

(b) Admitting for a maximum of 24 hrs to provide emergency care with 2 beds.

(c) Emergency medicines, supplies and equipments.

(d) Staff/duty room (can be shared).

5.2.2.5 Observation coach shall be arranged as the description of inpatient beds' arrangement.

5.2.2.6 The size of the door for the emergency room shall not be less than 1.5 meter.

5.2.2.7 The emergency premise shall allow patient dignity and privacy.

5.2.2.8 The rooms shall be arranged in such a way that the first encounter to an emergency patient coming from outside will be the emergency triage and resuscitation.

5.2.2.9 The emergency room shall have the following facilities:

(a) Adequate water, light and ventilation.

(b) Fire extinguishers placed in visible area.

(c) Telephone

(d) Functional Hand washing basin in each room

(e) Sub waiting area for attendants and caregivers

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

5.2.3 Professionals

5.2.3.1 There shall be at least one Gastroenterology and hepatology subspecialist /emergency and critical care professionals/internist/General Medical Practitioner for emergency services for 24 hours a day and 365 days a year.

5.2.3.2 The staff assigned at emergency service shall have training on EKG,

5.2.3.3 The center shall arrange Drill-exercise of emergency case management at least quarterly among the teams assigned in the emergency service.

5.2.3.4 The center shall have a protocol for organizing a team for emergency service. The emergency team for all the shifts shall contain a minimum of:

Professionals required	**Minimum Number required**

Gastroenterology and hepatology subspecialist/internist/General practitioner /emergency and critical care professional	1
Nurse	2
Cleaners	
Runner	

5.2.4 Products

5.2.4.1 The emergency service shall have readily arranged emergency medicines and supplies on cupboard or trolley.

5.2.4.2 There shall be at least two coaches at emergency room.

5.2.4.3 The emergency service shall have at least the following products:

(a) Vital Sign and Diagnostic Set
- Thermometer
- Stethoscope
- Sphygmomanometer
- Fundoscope
- Otoscope
- Pulseoxymeter
- Reflex hammer

(b) Glucometer and glucosticks,
(c) Refrigerator
(d) Cardiac Monitor
(e) Examination coach
(f) Stretcher with wheel
(g) Enema can
(h) Rectal tube
(i) Wheelchair
(j) IV Stand
(k) EKG (shared)
(l) Suction machine
(m) Defibrillator
(n) Tracheostomy set
(o) NG tube
(p) Minor surgical set
(q) Different types of splints
(r) Mobile examination light
(s) Cut down set,
(t) Pericadiocentesis set,
(u) Hot air oven (shared)
(v) Infusion pump
(w) Nebulizer (optional)
(x) Safety Box
(y) Oxygen concentrator (optional)
(z) Oxygen supply: oxygen, cylinder with flow meter, trolley and nasal prongs
(aa) Resuscitation set on trolley
(bb) Intubation set
(cc) Ambu bag

5.2.4.4 The center shall have the following emergency medicines and supplies at all times.

a) Emergency medicines peculiar for GE center
   a. Vasoactive drugs (terliprsine/octreotid,)

b. Esomprazole inj./ omeprazole iv
c. CPZ
d. Noradrenalin/Adrenaline, dopamine
e. Diazepam/Midazolam, Flumazenil
f. Pethidine,
g. Hydrocortisone,
h. Antiemetics
i. Lidocaine,
j. KCl ampule
k. Calcium Gluconate,
l. Thiamin
m. Dextrose 40%
n. Vitamin K injection
o. IV fluids, of all types,

b) Spatula, K-Y jelly, surgical and disposable gloves, antiseptics, cotton, gauze

5.3 Inpatient services

5.3.1 Practice

5.3.1.1 The specialty center shall make inpatient service available 24 hrs a day and 365 days a year,

5.3.1.2 The specialty center shall include at least the following service for admitted patients:

a) Taking comprehensive medical and social history, comprehensive physical examination and performing relevant laboratory & other medical workups upon admission and when indicated,
b) Providing 24 hours nursing care service that complies with the nursing service standard,
c) Detailed daily round/ patient evaluation by the attending physician,
d) Referral service to health facilities where the service is available.

5.3.1.3 The specialty center shall have clinical protocols for management of at least common causes of admission,

5.3.1.4 The service shall have written protocol 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 control specified under this standard,
d) Monitoring and follow-up of patients,
e) Transfer and referral of patients,

5.3.1.5 The specialty center shall have a system to make follow up of patients by the same or equivalent physician,

5.3.1.6 All admitted patients shall be under the supervised care of a licensed nurse at all times.

5.3.1.7 The clinical impression, range of treatment options and treatment plans shall be communicated to patients/ clients and/or their families and/or next of kin and documented accordingly.

5.3.1.8 The specialty center shall provide a clean gowns/ patient pyjamas,clean bed, bed sheet, blanket, bed spread and pillow to admitted patients.

5.3.1.9 The specialty center shall secure the properties of admitted patients in a cabinet or room with shelves.

5.3.1.10 The inpatient service shall have access to pharmacy, laboratory and imaging/diagnostic services as per their respective standards,

5.3.1.11 The inpatient service shall arrange the appropriate post discharge instructions and follow up.

5.3.1.12 The Specialty center shall have a mechanism to contact the municipality or responsible body for burial service if there is no family/guardian for the deceased.

5.3.2 Premises

5.3.2.1 The arrangement of rooms shall consider proximity between related services.

5.3.2.2 The gastroenterology and hepatology specialty center shall have at least ten inpatient admission beds in addition to the one isolation beds.

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

a) Distance of bed from fixed walls shall be 0.9 m
b) Distance between beds shall be 1.2 m
c) Adult beds shall have 1m width and 2m length
d) Each bed room shall have alarm
e) The rooms shall have safe and continuous water supply, light and ventilation
f) Washing basins for each room.

5.3.2.4 Nurse's station shall be located in the middle of the inpatient room(s) with free access to all room and with Hand washing basin and toilet room at nurse station.

5.3.2.5 Isolation Rooms:

a) The isolation room shall have adjoining bath and toilet room,
b) Shall be equipped with hand-washing and gown changing facilities at the entrance of the room.
c) Air circulation and traffic shall be arranged to be not into the corridor,

5.3.2.6 The arrangement of the rooms for the neonatal care shall avoid wind draft and shall be access limited.

5.3.2.7 Inpatient service of the specialty center shall have the following rooms:

Rooms required	No. of Rooms Required	Area Required
○ Admission rooms (with a maximum of 6 beds capacity)	2	96sq. M
○ Procedure room(shared)	1	16Sq.m
○ Isolation room	1	16 sq.m
○ Nurse station	1	12sq.m
○ Doctor's office	1	12sq. m
○ Soiled utility room/area	1	6sq. m
○ Toilet for staff	1	4sq.m
○ Toilet room with shower and hand washing basin [the inpatient toilet can be self contained in the admission rooms or can be separate]	2	4sq. m each
• Duty rooms with lockers (male/ female) [Staff room for changing clothes]	2	16sq. m
• General purpose store room	1	12sq.m

5.3.3 Professionals

5.3.3.1 Gastroenterology and hepatology subspecialist shall be physically available during working hours at inpatient service unit.

5.3.3.2 One nurse for a maximum of five (5) patients per shift shall be available to provide nursing care services.

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

5.3.3.4 Biomedical Engineer or technician for equipment maintenance and 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.

5.3.3.5 The inpatient service shall have the following professionals:

Professionals required	Minimum Number required
Gastroenterology and hepatology subspecialist (shared from OPD)	1
General practitioner (optional)	1
Nurse	3

Cleaners	
Runner	

5.3.4 Products

5.3.4.1 The following products shall be available for inpatient services.

a) Beds with wheels
b) Bed side cabinet
c) Bed pans
d) Urinal (Male and Female)
e) Bed Pan carriage
f) Bed pan Racks
g) IV Stand
h) Stretcher
i) Wheel chair
j) Safety Box
k) Suction machine
l) Cardiac monitor at least 1
m) Resuscitation set
n) Thermometer
o) Stethoscope
p) Sphygmomanometer
q) Fundoscope
r) Otoscope(shared)
s) Reflex hammer
t) Refrigerators
u) Dressing Set
v) Enema Set
w) Lumbar puncture(LP) set
x) Catheterization set
y) Folding screens
z) X-ray Film Viewer
aa) Weighing scales,
bb) Examination couch,
cc) Medicine trolley,
dd) Bone marrow aspiration set,
ee) pleural biopsy set,
ff) tracheotomy set,
gg) chest tube,
hh) EKG machine(shared),
ii) Drip counters/Infusion pump,
jj) Tourniquet,
kk) Oxygen concentrator(optional)
ll) Oxygen trolley,
mm) Oxygen cylinder,
nn) Oxygen regulator/gauge,
oo) Oxygen mask/ nasal catheters
pp) , Rubber Sheets
qq) Patient Chart Folders
rr) wall clock,
ss) Mobile Examination light
tt) Nasal prongs catheters,
uu) Face mask
vv) Laryngoscope,
ww) Cannulas,
xx) Nasogastric tubes,
yy) Equipment for skin scrapings and biopsy of dermatological lesions, bone marrow trephine needles and slides and others
zz) Glucometer and glucostick,
aaa) Pulseoximeter,
bbb) Over bed table(for feeding),
ccc) Curtain fixed with the ceiling,
ddd) Kick buckets,
eee) Cup board

fff) Emergency medicines
ggg)General purpose trolley, two trays

5.4 Radiological Services

5.4.1 Practices

5.4.1.1 Basic Radiology service shall be available for specialty center, which at least includes X-Ray & ultrasound.

5.4.1.2 The radiology service shall have written policies and procedures that are reviewed at least once every five years 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.

5.4.1.3 The specialty center shall make policies and procedures for radiology services available to all staff in the radiology unit.

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

5.4.1.5 The radiology service of the Specialty center shall have X-Ray & Ultrasound services.

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

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

5.4.1.8 The Specialty center shall post/ put in easily accessible place the approval certificate from the Ethiopian Radiation Protection Authority through periodic inspection.

5.4.1.9 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.

5.4.1.10 Signed reports shall be filed with the patient's medical record and duplicate copies kept in the service unit.

5.4.1.11 Requests for x-ray examination shall contain a concise statement of reason for the examination.

5.4.1.12 X-ray films shall be labelled with minimum information such as date, name, age, sex, right/left marks, name of institute and name of radiographer.

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

5.4.2 Premises

5.4.2.1 The radiology unit for specialty center shall fulfil the design requirements of Ethiopian Radiation Protection Authority (ERPA) guidelines.

Rooms required	No. of Rooms Required	Area Required
• X-Ray room(s),		
○ X-ray and Fluoroscopy room	1	2432sq. m
○ CT room (Optional)	1	28sq. m
○ Barium kitchen with sink	1	6sq. m
○ Dark room (If necessary)	1	6sq. m
○ Toilets	2	8sq. m
○ Patient dressing cubicles (inside X-ray rooms)	1	(4sq. m)
○ Sub waiting area	1	12sq. m
• Ultrasound room with two coach (liver biopsy)	1	16 sq. m
• Fibro scan room (optional) shared with US room		

5.4.3 Professional

5.4.3.1 The radiology service of the center shall be directed by a licensed radiologist.

5.4.3.2 A radiologist shall be available in the center during working hours all the time

5.4.3.3 A licensed radiology technologist or radiographer shall be present in the center at all times.

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

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

5.4.4 Products

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

a) X-ray machine , fluoroscopy machine
b) Color Duplex Ultrasound,
c) Fibro scan machine

d) X-Ray viewing boxes
e) Dark room film processing baths (if necessary),
f) Drier (if necessary),
g) MRI or CT scan machine depending on the type of the specialty center,
h) Radiation protection equipments:
    - lead gloves,
    - lead apron**,**
    - lead goggle,
    - gonad shield,
    - Abdominal shield

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

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

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

5.5 Medical Laboratory Services

5.5.1 Practices

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

5.5.1.2 The specialty center laboratory service shall provide Basic Haematology, Bacteriology, Clinical Chemistry, parasitology, urinalysis, pathology, cytology electrolyte immunoassay (Viral load, gene expert, optional) coagulation test & Serology test profiles.

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

a. **Hematology tests:**

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

b. Clinical chemistry:

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

c. **Urinalysis and body fluid analysis**

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

d. **Parasitology**

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

e. Bacteriological examination

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

f. Serological tests and other tests

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

5.5.1.4 The specialty center laboratory shall have written procedures for the following:

a) Procedure manuals (Standard Operating Procedure, SOP) or guidelines for all tests and equipments,
b) Report times for results(established turnaround time)
c) Quality assurance and control processes,
d) Inspection, preventive maintenance & calibration of all equipment,
e) Management of reagents including availability, storage, and testing for efficacy,
f) Procedures for collecting, identifying, processing and disposing of specimens,
g) All normal ranges for all tests shall be stated
h) Laboratory safety program, including infection control
i) Documentation of quality Assessment, calibration report and refrigerator readings.

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

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

5.5.1.7 The Specialty center Laboratory staff shall prepare criteria for acceptance and rejection of clinical specimens.

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

5.5.1.9 The laboratory for specialty center shall establish an external quality control system.

5.5.1.10 The specialty center Laboratory shall produce report which shall contain the following:

a) All laboratory test result/reports shall have reference (normal) ranges.

b) Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained shall be 5 years for legal reason minimal errors or loss of patient test results.

c) Reports shall be filed with the patient's medical record and duplicate copies shall be filed in the laboratory in a manner which permits ready identification and accessibility and with appropriate backup.

d) In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be contained in the medical record.

e) Quality assured test results shall be reported on standard forms to the general medical practitioner with the following minimum information:

- Patient identification (patient name, age, gender).
- Date and time of specimen collection.
- The test performed and date of report.
- The reference or normal range.
- The name and initial of the person who performed the test, and the authorized signature of the person reviewing the report and releasing the results.
- Specialty 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 protocol and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic. Protocols shall be established which define who may access patient data and who is authorized to enter and change patient results.

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

5.5.1.12 Safety signage shall be posted in the laboratory.

5.5.1.13 Wearing of protective clothing of an approved design (splash proof), always fastened, within the laboratory work area and removed before leaving the laboratory work area.

5.5.1.14 There shall be a policy and procedure for regular calibration and running of control tests for laboratory equipments: semi-automated/ automated machines. Documentation shall be maintained.

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

5.5.1.16 Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices. Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled.

5.5.1.17 There shall be a written safety procedure for handling hazardous chemical reagents used in the laboratory. The procedure shall define at least the following:

a) The storage requirements,
b) Handling procedures,
c) Requirements for personal protective equipment,
d) Procedures following accidental contact or overexposure,

5.5.2 Premises

5.5.2.1 There shall be separate sputum collection area.

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

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

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

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

5.5.2.6 The laboratory facilities shall meet at least the following general requirements:

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

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

Rooms required	No. of Rooms Required	Area Required
• Laboratory room (can be 1 room with open platform)	1	73 sq. m
○ Specimen collection room	1	6sq. m
○ Hematology & electrolyte immunoassay with clinical chemistry	1	16sq. m
○ Parasitology, urinalysis & serology	1	9sq. m
○ Molecular & flow cytometry (CD4 optional)	1	6sq. m
○ Bacteriology,(culture optional)	1	6sq. m
○ Disinfection & sterilization room (shared)	1	9sq. m
○ Blood bank	1	12sq.m
• Pathology and cytology room	1	16Sq.m
• Viral load, gene expert room		
○ for extraction	1	16sq.m
○ for amplification	1	12sq.m
• Duty room	1	9sq.m

5.5.3 Professionals

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

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

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

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

5.5.3.5 The laboratory service shall have the following professionals;

Professional required	**Number required**
Laboratory technologist	1
Laboratory technician	3

5.5.4 Products

5.5.4.1 Specialty center medical laboratory shall have the following equipments:

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

5.5.4.2 The minimum equipments for Clinical chemistry services:

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

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

a) Binocular Microscope,
b) Slides

5.5.4.4 **The minimum equipment for Hematology:**

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

5.5.4.5 Internal medicine specialty center should have viral load and CD4 machines.

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

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

5.5.4.7 The following Products shall be available for blood bank room

a) Water bath
b) Agitator

c) Refrigerator
d) Centrifuge(shared)
e) Microscope
f) Blood warmer (optional)

5.5.4.8 The following products shall be available for pathology service

5.6 Pharmacy Services

5.6.1 Practices

Dispensing and Medication Use Counselling

5.6.1.1 Standard operating procedure (SOP) for dispensing and medication use counselling shall be established to ensure patients' safety and correct use of medications.

5.6.1.2 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).

5.6.1.3 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.

5.6.1.4 All pharmaceuticals to be dispensed shall be labelled 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;
h) Expire date
i) Special precautions as applicable

5.6.1.5 Filled prescriptions shall be signed and accountability must be accepted by the dispensing Pharmacist.

5.6.1.6 Each paediatrics Specialty center shall establish and implement policies, guidelines and procedures for reporting any errors or any suspicion in administration or provision of prescribed medications.

Extemporaneous Pharmaceuticals Preparations (optional)

5.6.1.7 Written procedures/SOPs for center based pharmaceutical preparations shall be established for preventing errors, drug-drug interactions and drug contamination. This SOP shall contain an approved Master Formula for each type of preparation that shows the list of ingredients and their quantities required for the formulation of a specified amount of the preparation.

5.6.1.8 Licensed pharmacists shall be responsible for the preparations of various pharmaceutical formulations such as eye drop preparations, dosage form changes, extemporaneous preparations, IV infusions and IV admixture when deemed necessary by the center.

5.6.1.9 The center shall have a pharmacy-based intravenous infusion admixture program, which may include services related to preparation of total parenteral nutrition, antineoplastic agents, and large and small, continuous or intermittent volume products for infusion. A pharmacist licensed to practice pharmacy shall prepare, sterilize if necessary, and label parenteral medications and solutions.

5.6.1.10 The pharmacist responsible for pharmaceutical preparations shall ensure that quality is built into the preparations of products.

5.6.1.11 Ingredients used in preparations shall have their expected identity, quality, and purity and shall be from legally licensed sources.

5.6.1.12 Pharmaceutical preparations shall be of acceptable strength, quality and purity, with appropriate packaging and labeling, and prepared in accordance with good compounding practices, international standards, and relevant scientific data and information. Labels on compounded products for individual patient shall have a minimum of the following information:

a) Patient's name
b) Name of the compounding pharmacist
c) Name and address of the compounding institution
d) A complete list of ingredients and preparation name
e) Strength
f) Quantity of each ingredients and total quantity
g) Directions for use
h) Date of preparation
i) Beyond-use date
j) Storage condition
k) Batch number

5.6.1.13 Critical processes shall be validated to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.

5.6.1.14 Appropriate stability evaluation shall be performed or determined using international standards for establishing reliable beyond-use date to ensure that the finished preparations have their expected potency, purity, quality, and characteristics, at least until the labeled beyond-use date.

5.6.1.15 Written procedures and records shall exist for investigating and correcting failures or problems in compounding, testing, or in the preparation itself.

5.6.1.16 Pharmaceutical preparations compounded in the center shall be packaged in containers meeting standard requirements mentioned under the official national or international standards for such preparations.

Control of Drug Abuse, Toxic or Dangerous Drugs

5.6.1.17 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.

5.6.1.18 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.

5.6.1.19 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.

5.6.1.20 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.

5.6.1.21 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.

5.6.1.22 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.

5.6.1.23 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.

5.6.1.24 Any return of controlled substances to the pharmacy in the Specialty center shall be documented by a licensed Pharmacist responsible for controlled substance handing in the Specialty center.

5.6.1.25 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.

5.6.1.26 The center shall submit regular report to the appropriate organ regarding the consumption and stock of controlled drugs.

Clinical Pharmacy Services (optional):

5.6.1.27 The specialty center shall establish policies and procedures for the provision of clinical pharmacy services through drug and therapeutic committee.

5.6.1.28 The pharmacist for clinical pharmacy services shall have access to patient specific medication therapy information.

5.6.1.29 The pharmacy shall keep individualized information for patients with chronic illnesses medication program using standardized information tracking formats and update patient medication profile during each refill visit.

5.6.1.30 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.

5.6.1.31 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.

5.6.1.32 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

5.6.1.33 Medication education shall be delivered to patients or their caregivers upon discharge by the pharmacist.

5.6.1.34 The pharmacist shall make sure that the patient has all supplies, information and knowledge necessary to carry out the drug therapy plan.

5.6.1.35 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.

5.6.1.36 The specialty center (drug and therapeutic committee) shall develop/adopt and implement policy on antimicrobial prescribing, dispensing and usage.

Adverse Drug event, DIS, ADE/ Pharmacovigilance

5.6.1.37 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 EFDA

5.6.1.38 Health professionals of the speciality center shall be responsible to report suspected ADE cases to the ADE focal person.

5.6.1.39 DTC shall discuss and make necessary recommendations to the center's management for decision on adverse drug event reported within the health facility.

5.6.1.40 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.

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

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

5.6.1.43 The reporting of ADE shall be done by the national ADE prepaid yellow form prepared by EFDA

Pharmaceutical Supply and Management

5.6.1.44 A drug and therapeutics committee (DTC) representing different service units of the center shall be in place for selection of medicines and ensure proper use

5.6.1.45 The purchase of pharmaceuticals shall be the responsibility of a pharmacist who is assigned to manage and control the supply of medicines.

5.6.1.46 The center shall have procurement protocol to ensure the continuous supply of safe, quality and effective medicines.

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

5.6.1.48 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.

5.6.1.49 The center shall be responsible to make sure that donation of pharmaceuticals has been made in accordance with the country's laws.

5.6.1.50 The responsible pharmacist shall ensure that all medicine storage areas are inspected regularly to ensure that:

a) pharmaceuticals are stored and handled in accordance with the pharmaceutical manufacturer's requirements and regulatory standards

b) expired or obsolete pharmaceuticals are stocked separately until disposition
c) pharmaceuticals requiring special environmental conditions shall be stored accordingly
d) Temperature and humidity are maintained according to manufacturer's requirement
e) stock levels are adequate to ensure the continuous supply and acceptability of pharmaceuticals at all times, including the availability of essential medicines as per the latest edition of the medicines formulary list
f) inflammable substance are stored separately and in an appropriate manner
g) disinfectants and preparations for external use are stored separately from pharmaceuticals for internal use

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

5.6.1.52 Fire fighting equipment or system shall be installed to pharmaceutical storage places

5.6.1.53 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.

5.6.1.54 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.

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

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

5.6.1.57 Daily medicines consumption at different outlets of the center shall be recorded, compiled, analyzed and reported.

5.6.1.58 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

Medicines Waste Management and Disposal

5.6.1.59 The disposal of medicine wastes shall be in compliance with the medicines waste management and disposal directives issued by EFDA.

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

5.6.1.61 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.

5.6.1.62 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.

5.6.1.63 Solid wastes from the pharmacy shall be categorized as “hazardous” and ‘non-hazardous” and shall be collected separately for proper treatment.

5.6.1.64 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.

5.6.1.65 Spillages of low toxicity shall be swept into a dust pan and placed into a suitable container for that particular chemical and dispose accordingly.

5.6.1.66 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.

5.6.1.67 The Specialty center shall form a pharmaceutical waste disposal committee to ensure safety, accountability and transparency.

5.6.1.68 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.

Recording

5.6.1.69 There shall be a standardized Prescription Registration Book for recording prescriptions and dispensed medicine. A computerized dispensing and registration system with backup can be used instead if available.

5.6.1.70 Each patient with a chronic disease shall have a separate Patients Medication Profile Card (PMP) that should be filled appropriately with all the relevant information for each patient. A computerized system with backup can be used instead if available.

5.6.1.71 Controlled and non-controlled prescriptions shall be documented and kept in a secure place that is accessible only to the authorized personnel for at least five and three years respectively.

5.6.1.72 Patient and medication related records and information shall be documented and kept in a secure place that is easily accessible only to the authorized personnel

Billing

5.6.1.73 Pharmaceuticals shall be received and issued using standard receiving and issuing vouchers with serial number. Issuing and receiving of pharmaceuticals has to be signed by both the receiver and issuer and approved by an authorized Pharmacist. Receiving and issuing vouchers shall have the following minimum information.

a) Name of medicines received and issued,
b) Unit of measurement, quantity and source (supplier's or manufacturer's name) of medicines,
c) Expiry date and batch number,
d) Unit and total price,
e) Date received and issued,
f) Name and signature of receiver and issuer,
g) Address of the Specialty center,

5.6.1.74 All medicines issued from the pharmacy dispensary shall be dispensed/ sold using standard sales ticket with serial number. Sales tickets shall be signed and stamped.

5.6.1.75 Dispensing pharmacies shall use a standard stamp and seal for approving legal transactions.

5.6.1.76 The consumer has the right to know the exact price of a prescription before it is filled on sales ticket.

Organization Management and Quality Improvement

5.6.1.77 A multidisciplinary drug and therapeutic committee chaired by the medical director and supported by a licensed pharmacist representing the center pharmaceutical services as a secretary must be functional for the overall improvement of pharmaceutical services in the center.

5.6.1.78 The pharmaceutical services shall be represented by a licensed senior pharmacist in every management meetings of the center.

5.6.1.79 Customer satisfaction survey on pharmaceutical services shall be conducted at least once in a year and measures shall be taken in accordance with survey findings.

5.6.1.80 There shall be a program of continuous quality improvement for the pharmaceutical service that is integrated into the center continuous quality improvement program and includes regularly collecting and analyzing data to help identify pharmaceutical service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

5.6.1.81 The pharmaceutical service shall have in effect a patient profile system for monitoring medicine therapy. This system shall be used by the center to identify inappropriate prescribing practices and develop interventions.

5.6.1.82 The medicines supply and management officer shall inspect all patient care areas in the center, where medicines intended for administration to patients are stored, dispensed, or administered at least once every two months. The pharmaceutical service shall maintain a record of the inspections and action taken for identified problems.

5.6.1.83 A quality improvement program of the pharmaceutical service shall monitor, at a minimum, the use of medicines, including medication errors and use of antibiotics. Serious or consistent patterns of medication error shall be reported to the drug and therapeutics committee or its equivalent for correction and this must be documented

5.6.2 Premises

5.6.2.1 Entrances, dispensing counters and doorways shall be accessible to persons with disability.

5.6.2.2 The dispensing environment (dispensing counter and counselling area) shall ensure confidentiality and allow simultaneous service delivery for multiple customers by multiple providers.

5.6.2.3 Dispensing counter &/ or counselling area shall be designed to secure patient privacy and confidentiality.

5.6.2.4 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

5.6.2.5 The wall and floor shall be constructed to protect the safety of pharmaceuticals from burglary, rodents, direct sunlight, moisture and others.

5.6.2.6 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.

5.6.2.7 The pharmacy premises shall have the following minimum space at different service delivery points.

Rooms required	**No. of Rooms Required**	**Area Required**
• Pharmacy		
○ Medicines shelves, working space, dispensing counter and patient waiting area	1	25sq. m
○ Counseling room/ area	1	9sq. m
○ Pharmacy store	1	25sq. m
○ Duty room	1	9sq.m

5.6.2.8 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.

5.6.2.9 The area(s) of counselling 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.

5.6.2.10 Dispensing counter &/ or counselling area shall be designed to secure patient privacy and confidentiality.

5.6.2.11 All parts of the pharmacy premises shall be maintained in an orderly and tidy condition.

5.6.2.12 Entrances, dispensing counters and doorways shall be accessible to persons with disability.

5.6.2.13 The dispensing environment (dispensing counter and counselling area) shall ensure confidentiality and allow simultaneous service delivery for multiple customers by multiple providers.

5.6.2.14 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.

5.6.2.15 A procedure shall be in place to ensure access to pharmacy premises in an emergency situation.

5.6.2.16 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

5.6.2.17 The wall and floor shall be constructed to protect the safety of pharmaceuticals from burglary, rodents, direct sunlight, moisture and others.

5.6.2.18 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.

5.6.2.19 The pharmacy premises shall have the following minimum space at different service delivery points.

a) Waiting area
b) Inpatient dispensing room, as appropriate
c) Outpatient dispensing with counseling room
d) Emergency dispensing room/lockable cabinet with shelve
e) Compounding room, as appropriate
f) Cold room, optional
g) Medicine information center room(s), as appropriate
h) Cashier room
i) Medical store intended for medicines, vaccines, lab reagents and medical equipment storage
j) Office and duty room
k) Staff toilet (female and male)

5.6.2.20 In general, minimum standard for pharmacy premises for different specialty center shall be as indicated in their respective standards

5.6.3 Professional

5.6.3.1 The pharmacy service shall be directed by a licensed pharmacist with a minimum of two years work experience.

5.6.3.2 The dispensing of all prescriptions and medication use counseling shall be carried out by licensed pharmacists.

5.6.3.3 The center shall have one additional pharmacist

5.6.3.4 In addition, the center may have additional licensed pharmacists based on workload analysis.

5.6.3.5 The center shall have a pharmacy technician for the central medical store and inventory management

5.6.3.6 The pharmacy service shall have support staff such as clerks, porters and cleaners.

Profession required	**Number required**
Pharmacist /clinical pharmacist	1
Pharmacy technician	1
Cleaner (shared)	
Cashier	1

5.6.4 Products

5.6.4.1 The pharmacy in Specialty center shall have medicine lists within the framework of the national medicine list prepared by the regulatory authority.

5.6.4.2 There shall be adequate, suitable dispensing equipment in the dispensary.

5.6.4.3 The Specialty center shall have central medical store equipped with fire extinguisher, refrigerators, deep freezers and racks/shelves.

5.6.4.4 The Specialty center pharmacy shall be provided with continuous supply of electricity, telephone access.

5.6.4.5 In general, minimum standard for pharmacy equipment and facilities shall be as follows.

5.6.4.6 Equipment and facilities

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

5.6.4.7 In cases when the center has center based pharmaceutical preparation services, the following additional products shall be available

a) Working bench: Level, smooth, impervious, free of cracks and crevices and non-shedding; covered with protector sheets of plastic, rubber or absorbable paper when appropriate
b) Mortar and pestle: 250 ml capacity or more; glass type and porcelain type
c) Water distiller: Stainless steel of 20 liter capacity or more
d) Water bath: Stainless steel of 4 openings or more
e) Electrical hotplate: Various Sizes and Features

f) Evaporating dish: Stainless steel (glazed inside) and porcelain type; with/without handling
g) Spatula: Stainless steel and plastic type, flexible and non-flexible, different blade lengths
h) Gloves: disposable, non-sterile
i) Glass rod: Different length and thicknesses
j) Wash bottle: 250ml capacity, polyethylene
k) Funnel: Glass type and plastic type (polyethylene)
l) Beakers: Glass type; different capacity
m) Volumetric flask: Glass type; different capacity
n) Balances: Prescription, torsion, manual triple beam, electronic; capacities of not less than 300 gm; sensitivity of not less than 0.1 mg
o) Ointment tile: Glass type
p) Micropipettes: Glass type; different capacities (less than 1ml); with pipette bulb
q) Glass type; different capacities (1ml-100ml); with pipette bulb
r) Cylindrical graduate: Glass and plastic type; different capacity
s) Conical graduate: Glass and plastic type; different capacity
t) Weighing dishes: Plastic, aluminum, stainless steel type
u) Weighing paper: Normal paper; grease-proof for semisolids

5.7 Medical Recording

5.7.1 Practices

5.7.1.1 Medical record shall be maintained in written form for every patient seen at all points of care.

5.7.1.2 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.

5.7.1.3 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,

5.7.1.4 The Specialty center shall establish a master patient index with a unique medical number for each patient,

5.7.1.5 Each piece of paper or format that contains a patient medical information/ record shall carry the appropriate identification,

5.7.1.6 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.

5.7.1.7 When a medical record is taken out until returned to the record room it shall be documented to create a good tracking mechanism.

5.7.1.8 Any medical record shall be kept confidential, available only for use by authorized persons or as otherwise permitted by law.

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 The medical record forms shall be prepared in line with the national HMIS guidelines.

5.7.1.11 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 where applicable which shall be signed by the patient. In case where someone other than the patient signs the forms, the reason for the patient's not signing it shall be indicated on the face of the form, along with the relationship of the signer to the patient.

5.7.1.12 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.

5.7.1.13 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.

5.7.1.14 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.

5.7.1.15 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.,

5.7.1.16 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.

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

5.7.1.18 If the patient is provided with medical certificates, copies of certificates and other records shall be documented and/or recorded on the original medical record.

5.7.1.19 If the patient is transferred to another facility on a non emergency basis, the Specialty center shall maintain a transfer record reflecting the patient's immediate needs and send a copy of this record to the receiving facility.

5.7.1.20 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.

5.7.1.21 The Specialty center shall establish a procedure for removal of inactive medical records from the central medical record room.

5.7.1.22 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.

5.7.1.23 There shall be procedure for data collection, compilation, processing and reporting system.

5.7.2 Premises

5.7.2.1 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.

5.7.2.2 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,

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

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

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

5.7.3 Professionals

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

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

5.7.4 Products

5.7.4.1 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

5.8 Ambulance Service standards

5.8.1 Practice

5.8.1.1 The ambulance service shall be provided to every emergency patient who needs the service without any prerequisite and discrimination.

5.8.1.2 The ambulance service shall be available 24 hrs a day and 365 days a year,

5.8.1.3 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
   - Providing anti-pain
   - Managing seizure

- Providing emergency medicines like adrenaline, hydralazine, glucose etc

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

5.8.1.5 Up on arrival to the Specialty center the ambulance staff shall transfer the patient to the emergency service. 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.

5.8.1.6 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. Dead body care shall be provided as per the standards stated under the morgue service standard.

5.8.1.7 Ambulances of the Specialty center shall serve only for designated emergency medical services

5.8.1.8 After providing a service the vehicle shall be cleaned and disinfected

5.8.1.9 The ambulance kit shall be checked every time after providing the service

5.8.2 Professionals

5.8.2.1 There shall be emergency medical technician for ambulance service.

5.8.2.2 The nurses pulled from emergency service shall be trained on emergency medical services

5.8.2.3 The driver shall be trained on emergency situation management,

5.8.3 Products

5.8.3.1 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)

5.8.3.2 The vehicle shall be labeled and have siren and emergency light.

5.8.3.3 The vehicle shall have adequate internal light and ventilation.

5.8.3.4 The vehicle shall fulfill requirements of road transport authority.

5.8.3.5 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
- tourniquet

(c) Equipment:

- Minor surgical set,
- Oxygen supply,
- Ambu bag,
- suction machine,
- Stethoscope,
- sphygmomanometer,
- thermometer,
- Portable radio or
- Telephone
- C-collar
- Log roller

- Personal protective devices (gown, mask, gloves, goggles)
- Waste disposing containers
- Support material for immobilization purpose

- Emergency tracheostomy (wide bore needle insertion),
- air way,
- laryngeal mask,
- intubation set,
- Glucometer,

5.9 Health Promotion Services

5.9.1 Practices

5.9.1.1 The Specialty center shall plan, schedule, coordinate, lead and monitor a minimum of specialty center specific health promotion activities.

5.9.1.2 The Specialty center shall make sure that health promotion practice provides unbiased and evidence based information.

5.9.1.3 Patient education shall be customer focused.

5.9.1.4 The health promotion activity of the center shall respect the national health policy, legislations, protocols and directives.

5.9.2 Premises

5.9.2.1 The center shall have the following minimum premises requirements

a) Waiting areas suitable for health education

b) Meeting hall

5.9.3 Professionals

5.9.3.1 A health professional shall be designated to coordinate health promotion activities.

5.9.3.2 The roles and responsibilities of the designee in relation to health promotion shall be specified in his/her job descriptions.

5.9.3.3 Health professionals shall provide health education in their specific discipline.

5.9.4 Products

5.9.4.1 The Specialty center shall have the following health promotional materials:

a. Information desk with Printed materials (Posters, Brochures, Leaflets, News paper, Health bulletin)
b. IEC materials,
c. Audio visual materials: TV, VCD/ DVD, Radio, Tape-recorder,
d. Public health journals (Optional)
e. Internet (Optional)

5.10 Morgue Services

5.10.1 Practices

5.10.1.1 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,

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

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

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

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

5.10.1.6 Dead body discharge shall be through the morgue exit.

5.10.2 Premises

5.10.2.1 The morgue premises at specialty center shall fulfill at least the followings:

(a) Dead body care & stay room,
(b) Adequate Water supply,
(c) Well ventilated,
(d) Adequate supply of light,
(e) Hand wash sink,
(f) Secured with locks,
(g) Attendant office

5.10.2.2 The morgue premises shall be secured and provided with lock.

5.10.3 Professionals

5.10.3.1 The morgue service shall have the following designated personnel:

(a) Morgue attendant,
(b) Cleaner.

5.10.4 Products

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

5.10.4.2 The center shall have body refrigerator which shall be maintained at temperatures between 0° and 6.6°C (32° and 45° Fahrenheit) and shall have an automatic alarm system that monitors the temperature.

5.10.4.3 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

5.11 Infection Prevention

5.11.1 Practices

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

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

5.11.1.3 The Specialty center shall identify the procedures and processes associated with the risk of infection and shall implement strategies to reduce infection risk.

5.11.1.4 The Specialty center shall perform the following infection risk-reduction activities:

a) equipment cleaning and sterilization in particular invasive equipment
b) laundry and linen management
c) disposal of infectious waste and body fluids
d) handling and disposal of blood and blood components
e) kitchen sanitation and food preparation and handling
f) Operation of the mortuary and postmortem area;
g) disposal of sharps and needles
h) separation of patients with communicable diseases from patients and staff who are at greater risk due to immune-suppression or other reasons
i) management of hemorrhagic (bleeding) patients
j) Engineering controls, such as positive ventilation systems, biological hoods in laboratories and thermostats on water heaters.

5.11.1.5 The following written policies and procedures shall be maintained:

a) Hand hygiene
   - Standard precautions for hand hygiene
   - Personal protective measures
   - Monitoring and surveillance of hand hygiene practices
b) Transmission-based precautions
   - Contact precautions
   - Droplet precautions
   - Airborne precautions
c) Post-Exposure Prophylaxis programming (PEP) for some communicable diseases like rabies, HIV, meningitis
   - Standard precautions to follow
   - PEP policy
   - Procedures for PEP
d) Environmental infection prevention
   - General Specialty center hygiene
   - Structural infection prevention
   - Physical Specialty center organization

e) Waste management
- Cleaning medical instruments
- Implementation of a disposal system
- Handling medical waste
- Waste removal

5.11.1.6 The following specific standard precautions shall be practiced and the Specialty center shall have its own guidelines:

a) Hand hygiene shall be performed after touching blood, body fluids, secretions, excretions, and contaminated items, both immediately after removing gloves and between patient contacts.
- Thorough hand washing
- Use disinfectants
- Standard procedure for using anti-septic cleaner

b) The Specialty center staff shall consider that every patient is infectious

c) The Specialty center shall have personal protective equipment such as gloves, mask, eye protection (goggles) and face shield
- Gloves shall be worn in the following situations but not limited to:
    - When there is direct contact with exposed wounds, blood, body fluids, body organs or any type of lesion.
    - When drawing blood or handling medical instruments involved with invasive procedures (catheters, IV insertion, probes, etc.).
    - When there is contact with a patient who might be infectious.
    - When handling contaminated items.
    - When cleaning patient areas.
- Gowns shall be worn when but not limited to:
    - Performing surgical procedures,
    - Splattering of blood or body fluids is possible,
    - Handling bulk soiled linen (housekeeping),
    - Performing waste collection for infectious waste,
    - Handling any type of medical waste,
    - Conducting Specialty center laundry washing.
- Masks, goggles, or other types of face shields shall be worn when but not limited to:
    - Splattering of blood or body fluids to the face is possible,
    - Handling biohazardous and soiled linens
    - Performing waste collection for hazardous or non-hazardous waste.

d) Soiled patient-care equipment, textiles and laundry shall be handled appropriately

e) Any type of face shield that is apparently soiled or splattered with body fluids shall be washed and sterilized with a disinfectant.

f) Procedures shall be developed and implemented for routine care, cleaning, and disinfecting environmental surfaces, especially frequently touched surfaces in patient care areas.

g) Used needles shall not be recapped, bent, broken, or manipulated by hand. Single handed scoop technique shall only be used when recapping is required.

h) Safety features shall be used when available and used "sharps" shall be placed in a puncture-resistant container specially designated bin for hazardous waste.

5.11.1.7 There shall be transmission-based precautions and the Specialty center shall have its own guideline for the followings:

a) Contact precautions

- Shall be intended to reduce the risk of transmission through direct and indirect contact with an infectious patient.
- Shall be used when a patient is known to have a specific disease that is easily transmitted by direct contact.
- Shall be used for known multi-drug resistant disease, such as some forms of TB.
- Shall exercise strict barrier precautions for any type of contact with the patient and their surrounding environment.
- Do not share medical equipment between patients
- Clean surfaces near patients daily
- Wash linens and surfaces after patient discharge
- Clean medical equipment

b) Droplet precautions

c) Airborne precautions (for diseases like SARS ,TB, Swine flu, etc)

- Isolation room
- Negative pressure in relation to surrounding areas
- A minimum of 6-9 air exchanges per hour
- Air discharged outside the building and away from intake ducts, or through a high-efficiency filter if re-circulated
- Door kept closed whether or not patient is in the room
- After discharge door kept closed until sufficient time has elapsed to allow removal of airborne organisms
- Patient confined to room
- Room shall have toilet, hand washing and bathing facilities

5.11.1.8 Each Specialty center site shall train all staff on how to minimize exposure to blood-borne diseases. These include:

a) Immediate first aid

b) Reporting exposures

c) Assign area for starter packs 24-hours access per day

d) Counseling and testing for exposed staff

e) Reporting and monitoring protocols
f) Evaluate PEP program

5.11.1.9 The infection prevention committee or designate shall have written protocols, procedures and shall oversee the following activities and this shall be documented:

a) Developing the health facility annual infection prevention and control plan with costing, budgeting and financing
b) Monitoring and evaluating the performance of the infection prevention program by assessing implementation progress as well as adherence to IPC practice
c) Conducting surveillance to monitor nosocomial infections, antimicrobial use and outbreaks of infectious diseases.
d) Formulating a system for surveillance, prevention and control of nosocomial infections.
e) Reviewing surveillance data, reporting findings to management and other staff and identifying areas for intervention
f) Assessing and promoting improved IPC practice within the Specialty center
g) Developing an IEC strategy on IP for health-care workers
h) Ensuring the continuous availability of supplies and equipment for patient care management
i) Monitoring, providing data and measuring the overall impact of interventions on reducing infection risk

5.11.1.10 The Specialty center shall provide regular training on infection prevention and control practice to staff, patients and as appropriate, to family and caregivers

5.11.1.11 The following training guidelines shall be available

a) Prevention of the spread of infections
b) Improving the quality of patient care
c) Promoting safe environment for both patients and staff

5.11.1.12 The Specialty center shall have procedures in place to minimize crowding and manage the flow of visitors. This shall include

a) Patient crowd control
b) Assess urgent and non-urgent cases
c) Patient sign-in
d) Caregiver and visitor control.

5.11.2 Premises

5.11.2.1 The center shall have a dedicated office for IP officer,

5.11.2.2 The center shall have a room or area for temporary storage of waste containers,

5.11.2.3 The Specialty center shall have a centralized sterilization room as per the surgical service standards.

5.11.2.4 The center shall have incinerator with ash and burial pits.

5.11.2.5 The center may have placenta pit (Mandatory for MCH center).

5.11.3 Professionals

5.11.3.1 The Specialty center shall have a designated staff to serve as IP infection prevention and control officer.

5.11.3.2 The officer shall be a licensed infectious diseases specialist or IP trained health professional (physician or health officer or nurse), or a public health specialist knowledgeable of infection prevention principles and health care epidemiology.

5.11.4 Products

5.11.4.1 The Specialty center shall have the following adequate supplies and equipment needed for infection prevention and control practice.

a) Waste management equipment and supplies:
- Safety boxes
- Garbage bins
- Wheelbarrows
- Large garbage bin
- Plastic garbage bags

b) Cleaning
- Mop
- Bucket
- Broom
- Dust mop
- Cleaning cloth
- Detergent
- Bleach

c) Laundry
- Washing machine
- Sink
- Washing basin
- Drying rack/line
- Dryers
- Irons
- Trolley
- Detergent
- Bleach

d) Instrument processing:
- Autoclaves and steam sterilizers
- Test strips
- Boiler
- Oven
- Storage shelves for the medical equipment
- Chemicals & disinfectants: 0.5% chlorine solution (diluted bleach)
- Brushes (tooth brush for small items)

e) Hand hygiene
- Sinks (ward & other areas)
- Water container with faucet
- Soap dispenser

- Alcohol based hand rub
- Personal Towels
- Paper Towels

f) Personal Protective Equipment

- Heavy duty glove
- Examination/ Surgical glove
- Disposable glove
- Eye shield
- Goggle
- Visors
- Dust mask
- Respiratory mask
- Other types of face mask
- Plastic apron
- Other types
- Boots
- Nurse shoes
- Other protective shoes
- Caps
- Face shield

5.12 Sanitation and Waste Management

5.12.1 Practices

5.12.1.1 Specialty center environment shall ensure the following conditions:

a) Clean sanitation and safe environment,

b) Access to continuous, safe and ample water supply

5.12.1.2 There shall be written procedures to govern the use of sanitation techniques in all areas of the Specialty center.

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

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

5.12.1.5 Infectious and non infectious medical waste contained in disposable containers shall be placed temporarily for disposal or transport in leak proof drums, pails or portable bins. The containment system shall be leak proof, have tight-fitting covers and be kept clean and in good repair.

5.12.1.6 Reusable containers for infectious medical waste and general medical waste shall be thoroughly washed and decontaminated each time emptied according to the recent Health Care Waste Management National Guidelines/Directives

5.12.1.7 Reusable pails, drums, or bins used for containment of infectious waste shall not be used for containment of waste to be disposed of as noninfectious waste or for other purposes except after being decontaminated by procedures described in the latest Health Care Waste Management National Guidelines/Directives.

5.12.1.8 Placenta disposal pit shall be available in the Specialty center where the service is applicable. The pit shall be secured and shall be protected, secured and with properly fitting cover.

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

a) Separate different types of waste as per the guideline,

b) The Specialty center shall provide colored waste receptacles specifically suited for each category of waste,

c) Segregation shall take place at the source, like ward bedside, OR, laboratory etc.

d) There shall be 3 bin systems used to segregate different types of waste in the Specialty center:

Segregation category	Color	Container
Non risk waste	Black	bag or bin
Infectious waste	Yellow	bag or bin
Sharp waste	Yellow	safety box
Heavy Metal	Red	secure container
Medicine vials, ampoules	White	bag or bin

Hazardous medicines and cytotoxic wastes	yellow	bag or bin

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

a) By incineration,
b) By sanitary landfill,
c) By burial at an approved landfill,
d) Chemical sterilization,
e) Gas sterilization (shall be handled safely).

5.12.1.11 The Specialty center shall have an organized waste disposal and/ or removal system and shall ensure the safe handling of all wastes.

5.12.1.12 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).

5.12.1.13 The center shall have a medical waste management plan which includes at least the following:

a) Segregation of medical waste,
b) Temporary storage of medical waste,
c) Transport of medical waste,
d) Disposal of medical waste,

5.12.1.14 The Specialty center shall routinely clean and sanitize patient areas and waiting rooms at least twice daily and more when ever needed. Areas where there is blood splash shall be cleaned immediately.

5.12.1.15 The Specialty center shall ensure appropriate ventilation system.

5.12.1.16 In order to maintain a clean and safe environment, the Specialty center shall have an organized method for the transport and washing of linens.

5.12.1.17 Housekeeping items shall be cleaned and sanitized regularly.

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

a) A functional sewerage system,
b) Dispose of sanitary waste through connection to a suitable municipal sewerage system,
c) Flush toilet system,
d) A designated waste storage room for solid waste &/ or a septic tank for liquid waste,
e) Written procedures defining instrument processing procedures (disinfection and sterilization).
f) All fixtures located in the kitchen, including the dishwasher, shall be installed so as to empty into a drain which is not directly connected to the sanitary house drain.

g) Kitchen drain shall empty into a manhole or catch basin having a perforated cover with an elevation of at least 24 inches below the kitchen floor elevation, and then to the sewer.

5.12.1.19 The center shall have Plumbing system that fulfill the following conditions:

a) An approved municipal water system,
b) An approved method of supplying hot water,
c) Supply piping within the building shall be according to the requirements in the standard mentioned under the physical facility,

5.12.1.20 The center shall have Catering hygiene that fulfill the following conditions:

a) There shall be a procedure for management of pest control, restriction of animal entry (eg. cats, dogs etc), posted in a visible area in the kitchen.
b) There shall be a system for regular screen and control of the health of kitchen personnel.
c) The health of kitchen personnel shall be controlled for:
    - Personal hygiene including uniform (protective clothes),
    - Periodical medical check-up for acute and chronic diarrhea and other infectious diseases,
    - Kitchen personnel with infected open skin lesions, communicable diseases shall not be allowed to work as kitchen personnel until confirmed safe.

5.12.1.21 The Specialty center shall have the following supportive sanitation measures:

a) Clean water where there is no plumbing,
b) Hand hygiene practice,
c) Sterilization of medical instruments,
d) Isolating infectious patient in special isolation room,
e) Alternatives to protective equipment.

5.12.2 Premises

5.12.2.1 Placenta disposal pit shall have a dimension of 1m X 1m and 2m deep. Lateral to the disposal pit, the two sides shall be filled with concrete. The top shall be made of concrete with raised opening & cover.

5.12.2.2 The Specialty center sanitary system shall have:

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

5.12.3 Professionals

5.12.3.1 Specialty center sanitation service shall be administered by environmental health professional together with infection prevention activities.

5.12.3.2 The Specialty center shall have the following personnel to conduct sanitation activities:

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

5.12.3.3 The Specialty center shall officially designate staff in charge of handling waste on a regular basis.

5.12.3.4 The assigned staff shall be responsible for the collection and disposal of waste products in the Specialty center.

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

5.12.3.6 Staff shall be oriented on personal protection methods.

5.12.4 Products

5.12.4.1 The Specialty center shall have equipment and supplies required for sanitation activities. Required equipment and supplies includes:

a) Incinerator
b) Safety boxes
c) Leak proof containers for waste
d) Trolley to transport waste
e) PPE (personal protective equipments)
f) Steam or dry Autoclave,
g) Pressure cooker/dry oven.
h) Cleaning supplies (detergents, disinfectants and other cleaning solutions etc).
i) Laundry washers,
j) Laundry dryers,
k) Mops and dust bins

5.13 Food and Dietary Services

5.13.1 Practices

5.13.1.1 The Specialty center shall provide nutritionally adequate meals, supplemental food supplies for inpatients and staffs on duty.

5.13.1.2 The dietary service shall be available for 24 hours a day and 365 days a year.

5.13.1.3 The dietary service activities shall be managed by a dietician or a catering chief.

5.13.1.4 The center shall ensure that there is good food hygiene practices along the preparation process

5.13.1.5 The dietary service shall have written policies and procedures for all dietary services which at least includes:

a) Purchasing, preparation and handling,
b) Meal distribution,
c) Handling special diet order,
d) A diet manual detailing nutritional and therapeutic standards for meals and snacks, and a nutrient analysis of menus.
e) Nutritional assessment guide for patients' nutritional needs for food and food supplements.

5.13.1.6 An updated diet menu shall be available at each nurse's station and in the dietary service unit.

5.13.1.7 There shall be a policy to promote the participation of the dietary service in meetings of multidisciplinary health care teams.

5.13.1.8 New admissions shall be listed for the dietary service according to the order.

5.13.1.9 The patient's diet shall be documented in the medical record. Documentation of diet instructions shall include a description of:

a) The diet instruction provided to the patient and/or responsible person.
b) Patient response, participation and understanding.
c) Written instructional material provided to the patient and/or responsible person.

5.13.1.10 Diets shall be prepared in conformity with the Specialty center's dietary manual/ menu.

5.13.1.11 The dietary service shall follow the policies and procedures developed by the drug and therapeutics committee regarding possible food/drug interactions.

5.13.1.12 At least three meals (breakfast, lunch and dinner) shall be served daily, and not more than 15 hours shall elapse between dinner and breakfast.

5.13.1.13 Nourishment may be provided between meals and at night.

5.13.1.14 Food production shall be sufficient in quantity and quality to meet nutritional needs of individual patients.

5.13.1.15 Changes in diet orders made by the treating physician shall be effected by the next mealtime.

5.13.1.16 There shall be a mechanism for evaluating admitted patients to ensure they are being adequately nourished.

5.13.1.17 There shall be a mechanism for the dietary service to be informed if the patient does not receive the diet that has been ordered, or is unable to consume the diet.

5.13.1.18 There shall be a mechanism for patients and their families to interact with the dietary service.

5.13.1.19 Dietary instruction for patients with special dietary needs from the treating physician shall be communicated to the dietary service.

5.13.1.20 The dietitian or the catering chief shall provide diet information to the Canteen staff for appropriate selections of food items during purchase.

5.13.1.21 The dietitian or the catering chief shall provide nutrition information as requested by the patient, family, or treatment team which includes:

a) diet instructions,
b) written instructional material,
c) community dietary referrals regarding special diets,
d) current diet order,
e) nutritional problems,
f) appetite,
g) nutritional counseling,
h) comprehension of diet instruction,

5.13.1.22 The dietitian or catering chief shall provide dietary information to the discharging patient as per the treating physician instructions or as planned by the treatment team.

5.13.1.23 Diet instructions for Inpatients or discharged patients shall include educations involving:

a) therapeutic or modified diets
b) food-drug interactions
c) nutritional care for certain diagnoses/conditions
d) recommendations for changes in diet order,
e) treatment plan,
f) significant food allergy (lactose, wheat gluten, Soya ,egg, dairy)

5.13.1.24 Nutrition consultations:

a) Nutrition consultations shall be completed immediately after general medical practitioner's order.
b) Nutrition consultations shall be individual or group, and may include family and/or responsible person.
c) The dietitian or Specialty center catering chief shall determine the type and frequency of follow-up care after the initial consultation. Follow-up consultation may include evaluation of nutritional care, diet education, or other nutritional concerns.

5.13.1.25 Treatment Planning: Therapeutic goals related to nutritional needs shall be based on the following standards

a) Standard Height/Weight Tables
b) Dietary Reference Intakes
c) Nutrition-related laboratory values
d) Body Mass Index for Adults

5.13.1.26 Diet Orders and Nutritional Supplements

a) General medical practitioner/health officer diet orders shall be legible, concise and written in an understandable manner. The following information shall be included in diet orders:
    - Patient Name
    - Unit
    - Date
    - Specific diet order; including food allergies/intolerances
    - General medical practitioner's / health officer signature
b) Dietary services shall receive written notification of:
    - New diet orders
    - Change in diet order
    - Discontinued or canceled diet orders
    - Unit transfers
    - Isolation or special trays
c) All written diet orders shall be sent to dietary services immediately.
d) Special requests for meals or supplemental foods shall be provided as ordered to accommodate alterations in diets or meal service schedules due to new admissions, personal dietary needs, or other circumstances.
e) Diabetic and Calorie-Controlled diet orders shall include the calorie level desired.
f) The dietitian or Specialty center catering chief shall recommend appropriate nutritional supplemental foods according to general medical practitioner/health officer orders.
g) An electronic or manual spreadsheet of all diet orders shall be maintained by the dietitian or Specialty center catering chief to provide a current resource of all regular and therapeutic diets.
h) Dietary and nursing services shall be responsible to ensure dietary compliance and quality nutritional care of patients receiving general medical practitioner/health officer-ordered diets.

5.13.1.27 There shall be appropriate food safety and sanitations to ensure safe food service for the patients.

5.13.1.28 Dry or staple food items shall be stored at least 12 inches off the floor in a ventilated room which is not subject to sewage or waste water back-flow, or contamination by condensation, leakage, rodents or vermin.

5.13.1.29 All perishable foods shall be refrigerated at the appropriate temperature and in an orderly food safety manner (cold and hot holding principle).

5.13.1.30 Each refrigerator shall contain a thermometer in good working order.

5.13.1.31 Foods being displayed or transported shall be protected from contamination.

5.13.1.32 Three compartments washing procedures and techniques shall be developed and carried out in compliance with the national hotel and catering sanitary control guideline.

5.13.1.33 All garbage and kitchen refuse which is not disposed of mechanically shall be kept in leak proof non-absorbent containers with close fitting covers and be disposed of routinely in a manner that will not permit transmission of disease, a nuisance, or a breeding place for flies.

5.13.1.34 All garbage containers shall be thoroughly cleaned inside and outside each time emptied.

5.13.1.35 Requests for alternative food supplies shall be considered on an individual basis.

5.13.1.36 Foods shall be transported and served as close to preparation/re-thermalization time as possible. Maximum cold food temperatures shall be 5°C and minimum hot food temperatures shall be 60° C at time of service.

5.13.1.37 Dietary services shall ensure prescribed diet compliance as well as minimize food-borne illness.

5.13.1.38 Cancellations of ordered diets shall be made as soon as possible to avoid possible spoilage and/or waste of food items.

5.13.1.39 The specialty center may provide dietary services by one of the followings:

a) In traditional configuration where the kitchen is located in the center premise;
b) Provide the service directly, but may prepare the bulk of the meals in a kitchen owned by the center, located off-site; and
c) Contract out for dietary services through an off-site vendor and the contract shall be documented. However, regardless of how the center provides the service, the center shall ultimately be responsible for meeting the dietary service standards.

5.13.1.40 When dietary services are provided from an off-site location, the center shall be responsible to ensure:

a) Compliance with the quality assurance system,
b) Compliance with the infection prevention standards
c) Compliance with the dietetic policies and procedures in regards to meal service for off hours' admissions, late trays, food substitutions, reasonable meal schedules, posting of current menus in the center as well as in the off-site kitchen, tray accuracy, food handling safety practices, emergency food supplies and deliveries, staffing and patient satisfaction,

d) The presence of a current therapeutic diet manual approved by the dietitian and medical staff,

e) The presence of nutritional assessment indicating nutritional needs are in accordance with recognized dietary practices as well as with orders of the practitioners responsible for the care of the patients.

5.13.1.41 In cases when this service is outsourced to a contractor, the center is responsible to ensure contractor compliance with all the standards for food and dietary services.

5.13.1.42 Catering hygiene shall fulfill the following conditions

a) There shall be guidelines for pest control and restricting the presence of animals (eg. cats, dogs etc) visibly posted in the kitchen.

b) There shall be a system to screen and control the health of kitchen personnel.

c) The responsible kitchen personnel health shall be controlled for:

- Personal hygiene including uniform (protective clothes)
- Periodical medical check-up for acute and chronic diarrhea and other infectious diseases
- Those with infected open skin lesions are not allowed to work as kitchen personnel.

5.13.2 Premises

5.13.2.1 The following minimum facilities shall be available for dietary services:

a) Food preparation room

- All cooking appliances shall have ventilating hood,
- Washing sink with three compartments:
  - Dish washing sink
  - Pot washing sink
  - Cart cleaning sink
  - Can washing sink

b) Storage room

c) Cart storage.

d) Dietitian's office.

e) Janitor’s closet

f) Personnel toilets with hand washing facilities and lockers convenient to but not in the kitchen.

g) Approved automatic fire extinguisher system in range hood.

h) Continuous electricity (power) supply

i) safe and adequate water supply

5.13.3 Professionals

5.13.3.1 The Specialty center shall have an organized dietary service unit directed by a dietitian or catering chief (who has a basic education on dietetic sciences).

5.13.3.2 In addition the Specialty center shall have the following food handlers:

(a) Meal distributors,
(b) Chief cook,
(c) Kitchen workers,
(d) Store keeper,
(e) Bakers,
(f) Dishwashers,

5.13.3.3 The number of personnel, such as cooks, bakers, dishwashers and clerks shall be adequate to perform effectively all defined functions (based on workload analysis).

5.13.3.4 There shall be procedures to control dietary employees with infectious and open lesions (controlling personal hygiene).

5.13.3.5 Food handlers shall meet routine health examinations according to the Ethiopian Food Handlers' Hygiene Guideline for food service personnel.

5.13.3.6 There shall be an in-service training program on proper handling of food and personal grooming to dietary employees.

5.13.3.7 All kitchen workers shall wear protective kitchen clothes according to the Ethiopian Food Handlers' Hygiene Guideline.

5.13.3.8 A dietitian or catering chief shall be a full-time employee.

5.13.3.9 Written job descriptions for all dietary employees shall be given and documented.

5.13.4 Products

5.13.4.1 The following products shall be available for dietary services:

a) Refrigerator
b) Kitchen utensils
c) Pots
d) Jars
e) Dishes
f) Knives
g) Pressure cooker/ dry oven
h) Oven
i) Detergents
j) Stoves
k) Carts
l) Working clothes
m) apron,
n) boots,
o) hair cover,
p) gown,
q) hand gloves,
r) Barrel (garbage)

5.14 Housekeeping, Laundry and Maintenance Services

5.14.1 Practices

5.14.1.1 The housekeeping service shall have the following sanitary activities.

a) Basic cleaning such as dusting, sweeping, polishing and washing
b) Special cleaning of
   - Different types of floors
   - Wall & ceiling
   - Doors & windows
   - Furniture & fixtures
   - Venetian blinds
c) Cleaning and maintenance of toilet.
d) Water treatment, filtering & purification.

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

5.14.1.3 Collection, transportation and disposal of Specialty center wastes shall be supervised and controlled

5.14.1.4 The safety of fire, electrical and natural hazards in the risk areas in the Specialty center shall be supervised and controlled and shall work closely with Specialty center fire brigade and safety committee.

5.14.1.5 The designee/ sanitarian shall identify, supervise and organize the control and eradication of pests, rodents and animal nuisance in the Specialty center.

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

5.14.1.7 The housekeeping staffs shall ensure proper lighting and ventilation in different Specialty center areas.

5.14.1.8 The following LINEN services shall be provided in the Specialty center

a) Maintain an adequate supply of clean linens at all times
b) Obtain linen from stores and laundry.
c) Ensure proper storage of linen.
d) Supervise washing, sterilization in the laundry.
e) Maintain linen properly
f) Issues linen in service units like wards.
g) Keep proper accounting of linen.
h) Ensure proper sorting of linen.
i) Understand different color scheme.

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

5.14.1.10 The infection control measures shall be carried out in accordance with the Specialty center infection prevention standard

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

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

5.14.1.13 There shall be a plant safety maintenance organization as described below:

a) A multidisciplinary safety committee that develops a comprehensive center-wide safety program and reviewed.

b) A mechanism to report all incidents, injuries and safety hazards to the safety committee.

c) The multidisciplinary safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.

5.14.1.14 Facility maintenance services

a) The building maintenance service shall have written policies and procedures that are reviewed for routine maintenance, preventive maintenance and renovation maintenance.

b) The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with accepted engineering practices.

c) Floors, ceilings, and walls shall be free of cracks and holes, discoloration, residue build-up, water stains, and other signs of disrepair.

d) Routine inspections of elevators shall be conducted.

5.14.1.15 Construction and renovation

a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.

b) The infection control program shall review areas of potential risk and populations at risk.

5.14.1.16 There shall be written protocols and procedures for medical equipment maintenance including:

a) Plan for equipment maintenance (both preventive and curative), replacements, upgrades, and new equipments

b) Safe disposal procedures

c) An effective tracking system to monitor equipment maintenance activity.

d) A monitoring method that ensures diagnostic equipment operates with predicted specificity and sensitivity.

5.14.1.17 The maintenance personnel including the management of the center shall take basic trainings on the following issues and this shall be documented.

a) Building fabrics and utilities

b) Building services and economics

c) Planning maintenance demand

d) Preventive and routine maintenance practice

e) Maintenance with regard to IP and hygiene

5.14.1.18 Fire and emergency preparedness

a) The center shall comply with the National Fire Protection standard

b) All employees, including part-time employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and patient evacuation of center buildings as part of their initial orientation and shall receive printed instructions on procedures and at least annually thereafter.

c) A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall in each patient care unit.

d) Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydro-tested as required by manufacturer's instructions; and labeled with the date of the last inspection.

e) Fire detectors, alarm systems, and fire suppression systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last two inspections shall be kept on file.

f) There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.

5.14.1.19 Housekeeping equipment or supplies used for cleaning in isolation or contaminated areas shall not be used in any other area of the center before it has been properly cleaned and sterilized.

5.14.1.20 All areas of the center, including the building and grounds, shall be kept clean and orderly.

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

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

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

5.14.1.24 No flammable cleaning agents or other flammable liquids or gases shall be stored in any janitor's closet or other area of the center except in a properly fire rated and properly ventilated storage area specifically designed for such storage.

5.14.1.25 If the center does not have its own housekeeping, laundry and maintenance services; it may have a contract agreement with external organizations. The center shall check and maintain the sanitary standards of the center regarding the processing of its linens and shall maintain a satisfactory schedule of pickup and delivery.

5.14.1.26 If the center contract out for housekeeping, laundry and maintenance services there shall be documentation for a contractual agreement.

5.14.1.27 In cases when the center outsources this service to a contractor, the standards mentioned for housekeeping, laundry and maintenance shall be adhered by the contractor.

5.14.2 Premises

5.14.2.1 If the center maintains its own laundry, it shall have separate areas for:

a) Collection of soiled linens.
b) Washing, drying and ironing.
c) Clean linen storage and mending area.

5.14.2.2 The laundry design and operation shall comply with the manufacturer's requirements and/or institutional sanitation guideline

5.14.2.3 Clean linen storage shall be readily accessible to nurses' stations

5.14.2.4 Dirty linen storage shall be well ventilated and shall be located convenient to the laundry or service entrance of the center. The storage of appreciable quantities of soiled linens is discouraged.

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

5.14.2.6 A separate office shall be available for the maintenance and the housekeeper.

5.14.2.7 Adequate space shall be available for service specific janitor's closets and cleaning equipment & supplies which shall be maintained separately for the following areas (shall not be used for cleaning in any other location):

a) Surgical suites
b) Delivery suites
c) Dietary service unit
d) Emergency service unit
e) Patient areas
f) Laboratories, pharmacy, radiology, offices, locker rooms and other areas

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

5.14.2.9 The center shall have an alternate emergency power supply. If such emergency power supply is a diesel emergency power generator, there shall be enough fuel to maintain power for at least 24 hours.

5.14.3 Professionals

5.14.3.1 The housekeeping, maintenance and laundry functions of the center shall be under the direction of a licensed environmental health professional or engineer.

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

5.14.3.3 The housekeeping, maintenance and laundry personnels shall take basic trainings on the following issues and this shall be documented in their personal profile.

a) Basic principles of sanitation and peculiarity to center environment.
b) Basic principles of personal hygiene

c) Basic knowledge about different detergent and disinfectants
d) Different cleaning procedures applicable to different treatment areas
e) Basic knowledge about cleaning equipments operation techniques and their maintenance.
f) Different processes of water treatment & purification, removing bacteria.
g) Basic principles of ventilation, composition of air, air flow, humidity and temperature.
h) Common types of odors and their sources of origin, identification and control.
i) Removal and control technique of different types of odors.
j) Various equipments and materials used for odor control operation.
k) Medical waste, source and generation of waste
l) Hazards of medical waste to population and community.
m) Principles of collection of different types of medical wastes
n) Operational procedures of equipments
o) Safety measures in operation
p) Center lay out, configuration work, flow of men, material and equipment in different areas. Air, water, noise, pollution, causes of pollution and their control and prevention in center.

5.14.3.4 In addition the center shall have electrician, plumber, painter, building maintenance technician, diagnostic equipment maintenance technician

5.14.4 Products

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

5.14.4.2 The center shall have the following tools, equipment & materials for housekeeping services.

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

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

Bibliography

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

2.1. Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No. 661/2009

2.2. Ethiopian Food, Medicine and Healthcare Administration and Control Regulation No. 189/2010

2.3. National Health Policy of the Transitional Government of Ethiopia,

1993

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

2.5. Commercial Code of Ethiopia

2.6. Criminal Code of Ethiopia

2.7. Medicines Waste Management and Disposal Directive No 2/2011

2.8. Ethiopian National Guideline for Health Waste Management, 2008

2.9. Ethiopian Building Proclamation, No. 624/2009