CES xxx **Compulsory**

Ethiopian Standard

Second Edition
2018

Orthopedic 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.

Orthopedic Specialty Center _Requirement

1. **Scope**

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

1.2. The standard covers the minimum requirements with respect to practices, premises, professionals and products or materials put into use for orthopaedic specialty centers.

2. **Normative Reference**

3. **Terms and Definitions**

For the purpose of this standards the definition in *Orthopaedic Specialty Center* and the following definitions shall apply

3.1. Appropriate Organ:

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

3.2. Appropriate Law:

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

3.3. Authorized Person

Shall mean any orthopaedic specialty center staff who is responsible for a given service.

3.4. 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. Depending on the type of service(s), the Specialty center shall have varying number of beds with a minimum of 10 beds for inpatient services per specialty. The center shall have 24 hour emergency service in its respective specialty.

4. **General requirement**

4.1. The orthopaedic specialty center shall be directed by a licensed orthopaedic surgeon.

4.2. Orthopaedic surgical service shall be available 24 hours a day, 365 days a year.

4.3. The center shall have at least one orthopaedic surgeon shall be physically available 24 hours a day 365 days a year.

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

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

4.6. The orthopaedic surgeon shall be responsible for the follow-up clinics.

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

4.8. The center shall avail updated reference materials, treatment guidelines and manuals like National TB and leprosy, pain management, Malaria treatment, ART.

4.1 The medical record for patients shall include, but not limited to,

a. Pertinent history and physical examination
b. Documentation of Growth assessment: record of weight & height or length,
c. Documentation of a basic developmental assessment: sensory screenings, cognitive, &
d. Record of immunization status.

4.2 The speciality clinic shall have a program of continuous quality improvement for the service which includes regularly collecting and analyzing data to help identify health-service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data

4.3 The speciality shall establish quality team to improve quality of service deliveries.

4.4 The specialty clinic shall asses its staffs current knowledge and practice and observes utilization of national guidelines for the services it renders every six month.

4.5 The specialty clinic shall provide or facilitate training to their staffs.

4.6 The specialty clinic shall display the following at visible place:

(a) List of Services available in the specialty clinic during working hours & after working hours,
(b) List of Professionals and specialties working in the clinic during & after working hours,
(c) Updated list of Various fees and prices,

4.7 The orthopaedics speciality clinic facilities shall be well marked and easily accessible for persons with disability.

4.8 The orthopaedics speciality clinic shall have fire extinguisher placed in visible area.

4.9 All employees, including part-time and contract shall be trained in fire-fighting equipment and patient evacuation of clinic's buildings as part of their initial orientation and at least annually thereafter.

4.10 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.

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

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

4.13 The Internal surfaces of the clinic (floors, walls, and ceilings) shall be:

a. Smooth, impervious, free from cracks, recesses, projecting ledges.
b. Easy to clean and decontaminate effectively,
c. Constructed of materials that are non-combustible or have high fire-resistance and low flame-spread characteristics.

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

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

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

4.17 Glass doors shall be marked to avoid accidental collision.

4.18 Orthopaedics specialty center where functional units are at different floor shall have a mechanism of accessing all the functioning rooms horizontally either by stairs and ramp or stair and elevator.

4.9. With regard to quality assurance 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,

4.10. The specialty center shall display the following at visible place:

(d) List of Services available in the specialty center during working hours & after working hours,

(e) List of Professionals and specialties working in the center during & after working hours,
(f) Updated list of Various fees and prices,

Nursing practices

4.11. Nursing care service at different service delivery areas specifically at emergency and operation service (OR) shall be directed by a licensed MSc nurse or BSC nurse with two years of work experience/specialist nurses.

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

4.13. 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.

4.14. 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).

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

4.16. 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.

4.17. The nursing care of patients undergoing orthopedic surgery shall be planned and documented in the medical record, directed by a trained nurse, and includes the following:

(a) Pre-operative care,
(b) Location of post-operative care,
(c) Type of post-operative care and monitoring needed,
(d) Pain management, and
(e) Patient's understanding of discharge instructions.

4.18. 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,

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

4.20. Implementation of infection prevention procedures and provision of information on IP practices to patients, clients, family members and other caregivers, as appropriate, shall be done by the nurses;

4.21. 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.

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

4.23. 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.

4.24. 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.

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

5. Specific requirement

5.1. Outpatient Medical Services

5.1.1. Practice:

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

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

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

5.1.1.3 The outpatient service shall be available for regular working hours,

5.1.1.4 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 outpatient service shall have consultation with functional intra and inter facility referral system which at least include:

- Procedure for identifying cases for referral,
- Procedure for referring patients directly to respective services,
- List of potential referral sites with contact address (referral directory),
- Referral forms and Documentation for referred clients,
- Referral tracing mechanism (linkage) and Feedback providing mechanism,
- Procedure to minimize delay for referral and managing referred patients

5.1.1.6 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), weight and pain assessment,
- Clinical examination pertinent to the illness,

(c) Diagnostics impression,
(d) Laboratory and radiographic (roentigenographic) workups when indicated.

5.1.1.7 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.

5.1.2. Premises

5.1.2.1 The outpatient layout shall include the following:

Rooms required	**# required**	**Area required**
• Reception, registration/ recording & waiting area	1	40sq. m
• Examination rooms	2	24sq. m
• Treatment/ injection room	1	9 sq. m
• Emergency room with 2 resuscitation couches	1	16sq. m
• Store		
• Staff room (for changing cloth)		
• Cleaners room/ closet		
• Toilet room (male & female) (OPD)	4	16 sq. m
• Minor OR/ procedure room,		

○ Minor operation theatre	1	20 sq. m
○ Patient changing room/ area	1	6sq. m
○ Nurse station & Recording room	1	12sq. m
○ Clean Utility room	1	6sq. m

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

5.1.2.3 Communication system shall be connected with major functional areas.

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

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

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

5.1.2.7 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).

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

5.1.2.9 Minor operation theatre shall be available with the followings:

a. It shall hall be located accessible to OPD, and shall be with low or no traffic area.
b. There shall be one operation room with two theatres,
c. There shall be two glass cabinets for orthopaedic surgical consumables in the OR,
d. There shall be two patient changing rooms,
e. There shall be mark on the floor restricting movement of unauthorized and/or person without OR suit,
f. Rest room
g. Utility room,
h. Store with shelves and cabinets,
i. Nurse station with table and chairs,
j. Toilet rooms for male female,
k. Cleaners room,

5.1.3 Professionals

5.1.3.1 At least one specialist shall be available to run the respective specialized outpatient service.

5.1.3.2 The outpatient service shall have the following professionals:

Professions required	**Number required**
Orthopaedic surgeon	2

Nurses,	4 (including minor OR)
GP as appropriate,	2
Receptionist	2
Cleaners,	
Runner/porter ,	

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

5.1.3.4 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.

5.1.4 Products

5.1.4.1 The following products shall be available for outpatient service. Products specific to particular specialty are indicated under the specific discipline.

a) Examination Coach
b) Weighing Scale
c) Vital Sign and Diagnostic Set
- Thermometer
- Stethoscope
- Sphygmomanometer
- Fundoscope
- Otoscope
- Pulseoxymeter
- Reflex hammer
- Snellen's chart

d) Refrigerator
e) Dressing Set
f) Minor Set
g) Catheterization set
h) Trolley
i) Folding Screen
j) X-Ray Film viewer
k) Gonometer
l) Hip spica tables (*For minor OR)*

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. Splint and immobilize multiple fractures ,
d. Detect and manage orthopaedic emergencies (e.g Bleeding control, compartment syndrome, cervical spine bleeding)
e. Fluid resuscitation (shock management),
f. 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.

5.2.1.3 The admission process for emergency orthopedic surgery shall be done by the emergency/ duty physician with consultation to the duty orthopedic surgeon.

5.2.1.4 There shall be written protocols for emergency services.

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

(a) Fever,
(b) Shock,
(c) Sever Bleeding,
(d) Sp

lint and immobilization of Multiple fracture and injuries, poly trauma, (e) Coma, (f) Burn, (g) Poisoning, (h) Tetanus, (i) Acute diarrhea (Severe dehydration), (j) Seizure disorder, (k) Airway obstruction, (l) Cardiac emergencies (m) Cerebrovascular accident (n) Hypertension emergencies (o) Psychiatric eme

rgencies
(p) Meningitis
(q) Burn
(r) Poisoning
(s) Acute abdomen

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

5.2.1.7 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.

5.2.1.8 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.

5.2.1.9 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.

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

5.2.1.11 There shall be policy that facilitates support from other services for emergency service.

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

5.2.1.13 There shall be a mechanism of quality improvement for the service at least by collecting feedback from clients and having a formal administrative channel through which clients place their complaints and grievances.

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 shall be labelled in bold.

5.2.2.2 The emergency premise shall be low traffic area and there shall be reserve parking place to accommodate at least two ambulances for receive multiple modalities.

5.2.2.3 The corridor to emergency rooms shall be stretcher friendly and spacious enough.

5.2.2.4 The emergency area shall be at least 60 sq.m 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 (2 beds).
c. Emergency medicines, supplies and equipments.
d. Staff/duty room (shared).
e. Toilet facilities separate for patients and staff (Male, female).

5.2.2.5 Observation beds 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 examination room or space.

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) Hand washing basin in each room

5.2.2.10 Waiting area for attendants and caregivers.

5.2.3 Professionals

5.2.3.1 The center shall have a orthopaedist surgeon or emergency medicine specialist or emergency trained GP available for emergency service.

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

(a) Orthopaedist surgeon / Emergency medicine specialist or emergency trained GP, (1)
(b) Orthopaedic nurses/ Nurses 2
(c) Cleaners
(d) Porter

5.2.3.3 After working hours, a specialist shall be available for emergency consultation on call basis.

5.2.3.4 At least a general practitioner shall be available for emergency services at all times.

5.2.3.5 The actual number of personnel required shall be adjusted based on Workload analysis.

5.2.3.6 The center shall arrange Drill-exercise of emergency case management on regular bases among the teams assigned in the emergency service.

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) Examination coach

(b) Stretcher

(c) Wheel chair

(d) IV Stand

(e) EKG (shared)

(f) Suction machine

(g) Defibrillator

(h) Trachea otomy set

(i) NG tube

(j) Chest tube

(k) Minor surgical set

(l) Different types of splints

(m) Skin traction

action

(n) POP with complete instruments (cutter, caster, different

nt POP, bandage scissor, POP/fiber glass, POP bandage, cast

stpad rowel bandage, cotton

(o) Mobile examination light

(p) Hot air oven

n (shared)

(q) Oxygen supply: oxygen, cylinder with flow meter, trol

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5.3. Orthopaedic operation services (orthopaedic surgical services)

5.3.1. Practice

5.3.1.1 Orthopedic surgical service shall be available 24 hours a day, 365 days a year,

5.3.1.2 There shall be written protocols and procedures for admissions and discharges with follow up.

5.3.1.3 There shall be protocols for the management of the orthopedic surgical conditions in the unit.

5.3.1.4 There shall be protocols for consultation and transfer of patients admitted to this unit.

5.3.1.5 There shall be a clear policy for handling emergency orthopedic surgical conditions.

5.3.1.6 The admission process for emergency orthopedic surgery shall be done by the emergency/ duty physician with consultation to the duty orthopedic surgeon.

5.3.1.7 The admission process for elective orthopedic surgery shall be done by the respective orthopedic surgeon in consultation with the anesthesia department and with the other departments as needed.

5.3.1.8 For admitted patients the orthopedic surgical service shall be organized

in such a way that it covers all the shifts.

5.3.1.9 There shall be a mechanism of interdepartmental consultations with orthopedic center for which the orthopedic surgeon on duty shall be responsible.

5.3.1.10 Adequate orthopedic center records shall be kept for each patient and the patient's.

5.3.1.11 All orthopedic surgical procedures (except in life-threatening emergencies) are performed only after appropriate history, physical examination, and indicated diagnostic tests are completed and documented in the patient's medical record.

5.3.1.12 The preoperative diagnosis shall be recorded in the medical record for all patients prior to orthopedic surgery.

5.3.1.13 The orthopedic surgeon shall explain the disease condition, possible orthopedic surgical intervention and outcome possibilities in clear, simple and understandable terms to the patient and/or family.

5.3.1.14 Except in life-threatening emergencies, the orthopedic surgeon shall obtain an informed consent and this must be documented in the patient's medical record. For the case with life threatening condition, consent shall be obtained from spouse, family, guardian or based on the orthopedic surgeon's clinical judgment.

5.3.1.15 If there is no body to sign the consent for the patient who is in life-threatening condition, the reason for not having the consent shall be stated.

5.3.1.16 The nursing care of patients undergoing orthopedic surgery shall be planned and documented in the medical record, directed by a trained nurse, and includes the following:

(a) Pre-operative care,
(b) Location of post-operative care,
(c) Type of post-operative care and monitoring needed,
(d) Pain management, and
(e) Patient's understanding of discharge instructions.

5.3.1.17 Operative reports shall be written in the patient's record and in the OR registration book immediately after orthopedic surgery and include at least the following:

(a) Patient identification,
(b) Pre-operative diagnosis,
(c) The procedure performed,
(d) Findings during orthopedic surgery,
(e) Post-operative diagnosis,
(f) Orthopedic surgical specimens removed,
(g) Date and time operation started and ended,
(h) Name of orthopedic surgeon, anesthesiologist/ anesthetist, scrub nurse, and any assistants,
(i) Signature of the orthopedic surgeon, and the scrub nurse
(j) Immediate post-operative orders explicitly in the order sheet.

5.3.1.18 There shall be policy that leads to positively identify the patient and ensure that the correct procedure and the correct side are confirmed prior to starting the orthopedic surgery.

5.3.1.19 There shall be processes and policies defining the appropriate safety before, during and immediately after orthopedic surgery, including at least the following:

(a) The orthopedic surgeon shall fill the pathology form and the specimen container shall be properly labeled. The container shall be filled with 10% formalin.
(b) The specimen shall be sent to the pathology department by the OR staff. It there no pathology department in the same center, the specimen shall be sent to another facility by a family member or a relative.

- Aseptic technique,
- Sterilization and disinfections,
- Selection of draping and gowning,
- Counting of sponges, instruments, and needles,

5.3.1.20 There shall be a protocol for patient transfer from operation theatre to recovery room. This includes;

(a) The handover and/or transfer of immediate post-operative patients shall be done between the anesthetist or anesthesiologist who

administered the anesthesia and the registered nurse in recovery room,

(b) The nurse in the recovery room shall immediately re-evaluate the condition of the patient in front of the anesthesiologist or anesthetist,

(c) The follow up of immediate post-operative patients in the recovery room shall be done by registered nurse with special training or similar experience until the anesthesiologist, anesthetist or other qualified physician makes the decision to transfer the patient from post-anesthesia care and this decision shall be based on the documented results of monitoring during anesthesia recovery,

(d) The transfer from recovery room shall be done after the transfer order is signed by the appropriate anesthetist, anesthesiologist, or other qualified physician,

(e) The nurse in the recovery room shall inform the ward and the ward nurse shall transfer the patient with the signed transfer note.

5.3.1.21 Post- operative patient in the wards shall get post operative care by qualified nurses. The post operative care includes to the minimum:

(a) Evaluation by the orthopedic surgeon or appropriate physician and ward nurses daily or whenever needed,

(b) Follow up of vital signs and carrying out of post-operative orders shall be done as per the order specified for individual patients. (special orders- NPO, positioning, exercise, drainages, etc.,)

5.3.1.22 The center shall have an Intensive Care Unit (ICU) with all requirements stipulated under ICU standards

5.3.1.23 The center shall provide anesthesia services as per the standards stipulated under the anesthesia services

5.3.1.24 The Center shall have clear protocol for orthopedic surgical activities to be done at outpatients level, orthopedic surgical referral clinics, follow up clinics, minor operations and orthopedic procedures

5.3.1.25 There shall be no time left without having general orthopedic surgeon or physician attending the orthopedic Center.

5.3.1.26 There shall be a policy or procedure that

clearly shows at least one orthopedic surgeon shall be on call/ on duty to respond for orthopedic surgical requests from emergency and/ or orthopedic ward physician.

5.3.1.27 All patients in orthopedic center shall be attended by registered nurse all the time with supervision by duty physician.

5.3.2. Premises

5.3.2.1 Orthopedics Operation Room / Suite:

a. The operation room shall be readily accessible to the orthopedic wards
b. An operating room shall have access- restricted environment where orthopedic surgical and invasive interventions are performed. It shall be organized and equipped so that OR trafficking shall be controlled and exercised over all persons and materials entering and leaving the area.

5.3.2.2 Operation Theatre:

a. At least one standard size operation theatre and one septic operation theatre shall be available.
b. The wall of the operation theatres shall be washable; the vicinity of plumbing fixtures shall be smooth and water resistant i.e., ceramic plated up to the ceiling.
c. The ceiling shall be monolithic, scrub-able and capable of withstanding chemicals. Cracks or perforation in these ceilings are not allowed.
d. Floors and walls penetrated by pipes, ducts and conduits' shall be tightly sealed.
e. The floor of the theatre shall be smooth, easily cleanable, non-slippery and non-staining and it shall not be affected by water or germicidal cleaning solutions; preferably made of marble or ceramic.
f. There shall be drainage on the floor,
g. There shall be at least six fixed electric outlets in each theatre with cover,
h. The entrance and exit doors to the theatre shall be fitted with self-closing double doors,
i. There shall be at least one operation table in each theatre,
j. At least one ceiling operation light and one

mobile operation light per theatre shall be available

k. Glass cabinet and shelves shall be available
l. The OR shall be thoroughly cleansed weekly.
m. Heater fixed on the wall shall be available in each theatre,

5.3.2.3 Scrub area:

a. There shall be a scrubbing-up area outside but adjacent to the operating theatre(s). The scrub area shall be in between the two self closing doors. If there is one common scrub area for the two theatres, it shall be wide enough to accommodate four staff scrubbing simultaneously.
b. This area shall have direct access to the operating room,
c. It shall be provided with multiple sinks or with wide sink and taps for running (warm) water. The taps for running water for scrubbing shall be hand free to be manipulated with elbow or knee joint.

5.3.2.4 Nurse station:

a. This is a room within the restricted access areas, which is so situated, constructed and equipped that it is possible for the nursing staff to observe patients directly and where necessary, to render assistance. This area need not be a room, but may form an integral part of the main patient corridor, recovery area or bed-receiving area.
b. There shall be a corridor or allocated area for keeping charged and empty Oxygen cylinders; the empty and charged oxygen cylinders shall be labeled clearly,

5.3.2.5 Entrance/Patient Transfer Area:

a. This area shall be large enough to allow for the transfer of patients from a bed to OR stretcher.
b. A line shall be clearly marked in red on the floor, beyond which no person shall be permitted to set foot without putting on protective clothing and OR shoes.
c. Holding bay: there shall be a space or corridor to keep and observe pre-operative patients until called to theatre.

5.3.2.6 Staff Change Rooms

a. Suitable two separate changing room facilities shall be available and clearly labeled for male and female.
b. Each changing rooms shall have two doors, one entrance and the second

door accessing into the restricted access area; the entrance is from outside the restricted access area.

c. Each changing room shall be provided with a locker for a minimum of 10 staff to keep personal clothes and belongings.
d. Each changing room shall be provided with shelves for Storage of clean theatre attire and inside shoes and operation theatre gum boots.
e. Separate storage bin shall be provided for used and soiled theatre apparels.
f. Wash hand basins: Toilets, showers,

5.3.2.7 Set-up Area (optional):

a. Store area for suture materials and other supplies from where necessary consumables could be stacked on a trolley that could be wheeled into theatre for subsequent procedure.
b. Doors into the operating room shall be big enough to wheel through the set trolleys from the set up room into the operating room without contact with doors or non sterile surfaces.
c. Packed instruments and other relevant materials shall be brought from the CSR and stored in this area according to the daily schedules one day prior to the scheduled operations.
d. Mayo table and dressing trolley to set up for the next case are kept in this area.
e. If there is no set up area the instruments can be set up within the operating theatre

5.3.2.8 Operating Theatre Equipment Store

a. There shall be equipment store area in the operating room that shall be supplied with a sufficient number of electrical plugs to keep the electrical equipments plugged in, charged and in case of power failure to work as back up electrical supply / or emergency electrical supply.
b. Equipments shall always be stored at the same space/location and properly labeled.
c. Shelves and cabinets

5.3.2.9 Operating Theatre Sterile Supply Store: This shall be a room which is used for the

storage of all sterile instrument sets, swabs and sterile renewable, consumables and it requires shelves.

5.3.2.10 Clean Utility, Orthopedic surgical Suite: There shall be a room allocated for storage of IV fluids, clean linen, medicines and other sundry items. Requirements:

a. Shall be situated where OR staff have easy access to the clean utility store.
b. Metallic washable rack for storage shall be available,
c. Equipments used for special procedures like splints shall be kept here thoroughly cleaned after use,
d. Refrigerator with thermometer shall be available for medicines requiring a temperature range of 4 to 8 °C.
e. Sink, cabinets and shelves

5.3.2.11 Soiled Utility/Sluice room shall be available with the followings:

a. This room shall be located at the back of the OR.
b. This room shall be for keeping contaminated materials until they are disposed.
c. Sharp containers, leak proof containers with lids shall be available, used sharps/safety boxes are to be stored here before being sent for incineration.
d. Container for temporary storage point for soiled linen,
e. Hand Washing basin,
f. Drainage on the floor,
g. Trolley for soiled materials and waste human tissues,

5.3.2.12 Cleaner's Room shall be available with the followings:

a. A room provided with 2 sets of cleaning equipments and materials,
b. Hand washing Basin,
c. Washing sink,
d. Detergent proof shelves and cabinets.

5.3.2.13 Central sterilization room shall be available with followings:

a. Direct access to OR,
b. Needs a minimum of three rooms:
    - One for reception, sorting of equipments; or clothes and documentation process;
    - One for inbuilt autoclaves;
    - One separate properly ventilated room for storing and shelving sterile clothes and instruments as per the guideline,
c. One staff room and
d. One cleaners' room

e. Shall have at least two inbuilt autoclaves, with small one as backup,
f. Continuous water supply with extra reservoir,
g. Shelves shall be washable ,corrosive free and metallic racks as per the guideline,
h. The date of sterilization & the name of the instruments shall be written after sterilization.
i. Staff toilets,

5.3.2.14 Recovery facilities shall be available with the followings:

a. It shall be close to OR, and shall be within the semi- restricted area.
b. ensures ease of communication and access for anesthesia department staff for close follow up
c. There shall be a minimum of 1.2 meter gap between beds for patient transferring stretcher,
d. Recovery beds shall have flexible side protections,
e. A minimum of two electric outlets shall be available for each bed,
f. resuscitation equipment including a defibrillator on trolley,
g. A minimum of 2 bed pans
h. A minimum of 2 patient screens shall be available,
i. There shall be sufficient light for each bed, one head light per bed,
j. oxygen source with face mask and or nasal catheter
k. There shall be a heater,

5.3.2.15 Premises requirement is summarized in the following table.

Rooms required
• Operation Room
○ Operation theatre
○ Scrub area
○ Staff Change area
○ Clean utility room
○ Soiled utility room
○ Nurse station
○ Anesthesia store
○ OR equipment store
○ Sterile supply room
○ Doctor's office/area
○ Duty room
○ Janitor's closet
○ Toilet rooms
○ Shower rooms
• Recovery room (with 2 beds)
• Sterilization room

5.3.3. Profession

5.3.3.1 professionals summary shall have the following

Professionals required
• Orthopedic surgeon
• Anaesthesiologists/Bsc Anaesthetist
• Anesthetist/ anesthesia nurse
• Nurses
○ OR: - Scrub nurse
- Circulating nurse
OR head nurse
- Recovery nurse

• CSR personnel(preferably nurse)
•
• Cleaner
• Porter/ runner
• General Technician

5.3.4. Product

5.3.4.1 Operating theatre:

Minimum equipment list for performing orthopedic procedures:

a. Basic Orthopedic set
b. Amputation set
c. Drill - electrical/ pneumatic, manual
d. Wire set
e. Rush pin
f. Hemiarthoplasty set and implant(optional)
g. Bone cutters
h. Different size of screws, plates, nails, wires)
i. Stenman pin
j. DHS set
k. K -wire and set
l. Different osteotomes: manual, electrical, compressed air
m. Large fragment and small fragment with plate and screw
n. Spine fixation-plate with joint sets(optional)
o. External fixatures, different types
p. Hand surgery sets with microsurgery instruments
q. Skin graft sets, manual, electrical
r. Plates (angle: 95° and 135°)
s. Fluoroscope, C-arm(optional)
t. POP with complete instruments(cutter, cast sprider, different POP, bandage scissor, POP/ fibber glass, POP bandage, cast pad rowel bandage, cotton)
u. Tourniquet, upper limb, lower limb, (pneumatic, manual)
v. Stools
w. Oxygen cylinders, different size
x. Tendon hammer
y. IV stands
z. Kick buckets
aa. Safety boxes
bb. Swab rack with drip trays
cc. Swab count record boards
dd. Bowls and stands

ee. Instrument tables/ tray
ff. White Framed boards with pencil marker
gg. Hammer and chisel
hh. Blankets, warming
ii. Coagulation unit, electro-cauthery, mobile, 200 W
jj. Lights, operating, 1 large copula, ceiling mounted
kk. Mobile operating lights
ll. 1 orthopedic Operating table, and 1 general operating table
mm. Suction machines
nn. Plastic Apron,
oo. protective shield if there is fluoroscopy

5.3.4.2 Surgery Equipment – OR sterile supply store:

a. General purpose trolleys, trays
b. General surgery-Suture set
c. Minor set including curates and rounger

5.3.4.3 Renewable/Consumables for orthopedic surgical service:

a. Tongue depressors
b. Guedel airways: size 0, 00, 3, 4 & 5
c. Disposable aprons
d. Bags - Refuse - All Colors and Sizes
e. Bags – Urine
f. Bandage -
g. Batteries - Medical & General
h. Bedpan Covers
i. Blood Administratio

n Sets

j. Blood Sampling
- Needles, disposable, sterile, 20 G, 21 G, 23 G
- Tube, Vacuum 5ml (Vacutainer)
- Tube, Vacuum EDTA 5ml (Vacutainer)
- Tube, Vacuum Heparinised 5ml (Vacutainer)
- Vacutainer Holder
- Vacutainer needle

k. Bottles - Suction - Glass/ Plastic

l. Braun Splints (Arm)

m. Bubble tubing box

n. Cannula - Nasal - Oxygen

o. Cannula, IV short, ster, disp, 18 G, 20 G, 22 G, 24 G

p. Caps - Mop/Bonnet Type

q. Catheter - Jacques

r. Chest, Electrode, Monitor

s. Cleansing Swabs – St

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cc. Foley Catheters – Latex/Silicone Size 10, 12 and 14
dd. Gauze Absorbent Ribbon
ee. Gloves:
- Househ old Large & Medium
- Orthopedic surgical Size 6, 6½, 7, 7½, 8
- Exam, latex, disp , larg e, med ium , sm all
ff. Handwash Antiseptic Liquid (Hibiscrub)
gg. Handwash Povidone (Betadine)
hh. Hot Packs
ii. I.V. Sets:
- I.V. Administration Sets – 15 Drop
- I.V. Administrati

on Sets - 60 Drop
- I.V. Set, Infusion “Y”, Luer lock, air inlet
jj. Intubation stylet, adult, 15 Ch
kk. IV Infusion set Burette roll
ll. K.Y. Jelly
mm. IV stands
nn. Drums
oo. Latex Tubing
pp. Linen Savers
qq. Nail Brush
rr. Needles:
- Spinal disp, (0.9 x 90 mm),sterile, 20G, 22G,
- Disp, 15G, 18G, 21G, 22G, 23G, 25G
- Butterfly 23G
ss. Oxygen Tubing Pieces 24G

tt. Oxygen Tubing
uu. Face Masks
vv. Razor Medical - Disposable - Single Edge
ww. Saf ety Pins Large & Med ium
xx. Sharps Container (Saf ety Box/ used syringes and needles)
yy. Shroud s
zz. Soap ,tow ile t,bar, appr ox .110 g, wrapped aaa. Spigots Large, Med ium and Small bbb. Spray Bottles - Plunger Oper ated ccc. Orth opedic Surgical Splints ddd. Syringes:

- Volume: 2ml, 5ml, 10ml, 20ml
- Syringes

50 ml Conical Tip
- Syringes 50 ml Luer Lock
- Syringes I nsulin eee. Tape:
  - Elastic Adhesive Plaster - White
5 cm and 10 cm
- Micropore tape
- Orthopedics
urgical Adhesive Hypo-Allergenic
- Adhesive

, zinc oxide, perforated, 10 cm x 5 m
- Adhesive, zinc oxide, 2.5 cm x 5 m

fff. Tourniquet, latex rubber, 75 cm

ggg. Tourniquet, pneumatic

hhh. Tubes:
- End-tracheal, disp. + connector, balloon, 6.5 mm, 7 mm, 7.5 mm, 8 mm
- End-tracheal, disp. + connector, neonate mm, w. balloon
- End-tracheal, disp. + connector, balloon, 6.5 mm, 7 mm, 7.5 mm, 8 mm
- Suction,

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er	2,
,d	C
is	H
p,	1
C	6

5.3.4.4 Operating Suite Renewable/Consumables :

a. Airway Guedel, pediatric & adult size
b. Plastic, reusable aprons
c. Urine bags, collecting, 2000 ml
d. 012 Band, Esmarch, 6 cm x 5 m
e. Survival blanket, 220x140cm
f. Blood Sampling:
    - Needle, disposable, sterile, 20G, 21G
    - Tube, Vacuum 5ml (Vacutainer)
    - Tube, Vacuum EDTA 5ml (Vacutainer)
    - Tube, Vacuum Heparinised 5ml (Vacutainer)
    - Vacutainer holder
    - Vacutainer needles, 18-24G
g. Bouffant Nurse Cap
h. Cannula, IV short, ster, disp, 18G, 20G, 22G, 24G
i. Catheters:
    - Sup-Pubic, CH 10, 1.65 cm, ster, disp adult with trocar
    - Urethral, CH6, ster, disp
    - Urethral, CH7, ster, disp
    - Foley, ster, disp, CH10, CH12, CH14
j. Compresses:
    - Abdominal compress, 40 x 40 cm
    - Compress, Swab, 20x 20 cm
    - Compress, gauze,10x10cm,n/ster/PAC-100
    - Compress, gauze,10x10cm,ster/PAC-5
    - Compress, paraffin,10x10cm,ster/BOX-10
    - Pelvic blinder
k. Connector, biconical, OD 7-11-7mm
l. Cotton wool,500g,roll,non-ster
m. Diathermy pencil/ball/blade
n. Disposable, dispersive, electrode(Diathermy pad)
o. Drain, corrugated sheet, 3 cm x 25 cm
p. Drain, wound, CH 12, ster, disp, CH12, CH16, CH6
q. Drawsheet,plastic,90x180cm
r. Elastoplasts, 10 cm x 3 m
s. Electrode, Chest, Monitor
t. Gauze:
    - Ball, Large (sterile)
    - Ball, Large (un-sterile)
    - Ball, Peanut (sterile)
    - Swabs RAYTEX® 10 X 10 cm
    - Swabs, Un-sterile (Green)
    - Roll,90cmx100m,non-ster
    - Vaseline gauze
u. Gloves,exam,latex,disp, large, medium & small
v. Gloves,surg,disp, 6.0, 6.5, 7.0, 7.5, 8, 8.5
w. Gum elastic bougie, CH 15, 60 cm

x. Intubation stylet, adult, 15 Ch
y. Mask, Clinical, Disposable (non-woven)
z. Mask, Protection, High Filtration
aa. Needle, spinal, 0.9x90mm),ster,disp, 20G, 22G, 24G
bb. Oxygen mask, adult
cc. Oxygen, nasal cannula
dd. Reusable, Diathermy, Cable
ee. Safety box for .used syrgs/ndls
ff. Set, Infusion "Y", Luer lock, air inlet
gg. Scalpel blade,ster,disp,no.10, no. 11, no. 15, no. 22, no. 23
hh. Shoe cover, disposable
ii. Silicone Rubber Tubing
jj. Orthopedic surgeon's Cap, Easy-Tie
kk. Wound vac(optional)
ll. Suturing materials: (Absorbable vicryl and variant non absorbable prolene, ethbond including different size
    - Wires, different size/thickness
    - Plates and screws, different size and shape
    - Implants, different types and size
mm. Tape,adhesive,Z.O,perforated,10cmx5m
nn. Tape,adhesive,Z.O.,2.5cmx5m
oo. Tubes:
    - Endo-tracheal, disp. + connector, 3 mm, w/o balloon
    - Endo-tracheal, disp. + connector, 3.5 mm, w/o balloon
    - Endo-tracheal, disp. + connector, 4 mm, w/o balloon
    - Endo-tracheal, disp. + connector, 4.5 mm, w/o balloon
    - Endo-tracheal, disp. + connector, 5 mm, balloon
    - Endo-tracheal, disp. + connector, 5.5 mm, balloon
    - Endo-tracheal, disp. + connector, 6 mm, balloon
    - Endo-tracheal, disp. + connector, 6.5 mm, balloon
    - Endo-tracheal, disp. + connector, 7 mm, balloon
    - Endo-tracheal, disp. + connector, 7.5 mm, balloon
    - Endo-tracheal, disp. + connector, 8 mm, balloon
    - suction,CH08,L50cm,ster, disp, CH08, CH10, CH14, CH16
    - N.G Tubes 12, 14, 16

5.3.4.5 Operating Room Linen:

a. Apron Orthopedic surgical, rubber
b. Trousers, Orthopedic surgical, woven, Small, Medium & Large
c. Top(shirts), Orthopedic surgical, woven, Small, Medium & Large
d. Gown, Orthopedic surgical, woven(Plain)
e. Cap, Orthope

dic surgical, woven

f. Masks, orthopedic surgical, woven

g. Drape:

- Orthopedic surgical, woven(1 x 1 m)
- Orthopedic surgical, woven(1 x 1.5 m)
- Orthopedic surgical, woven(1.5 x 1.5 m) (fenestrated
- Orthopedic surgical, woven(45 cm x 70 cm) (fenestrated)
- Orthopedic surgical woven (2 x 1.5 m)

h. Pillow case

i. Pillows

j. Sheet, Bed

k. Sheet, draw, white

l. Cellular Blanket

m. Mayo cover

n. Towel Bath

o. Towel Hand

5.3.4.6 Equipment recovery area:

a. Vacuum aspirator

b. Oxygen Flow meter, 0-15 l/min

c. Oxygen (one cylinder

d. Oxygen concentrater

e. Defebelator

r

f. Patient transfer, (stretchers)

g. Dressing trolley, trays

h. Bed with mattress

i. Stools

j. IV stands

k. Bed screen, 3 section, mobile

l. Pedal bin

m. Oxygen trolley, complete

n. Pulse

oximeter

o. Resuscitator, hand operated

p. Suction machines

q. Mobile examination light

r. Dual head stethoscope

5.3.4.7 Equipment-Central sterilization room

a. Auto claves, big and small
b. Drums, metallic shelves, cabinets, tables and chairs

5.4 Inpatient services

5.4.4 Practice

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

5.4.4.2 The specialty center shall have consultation and functional intra and inter facility referral system.

5.4.4.3 The admission process for elective orthopedic surgery shall be done by the respective orthopedic surgeon in consultation with the anesthesia department and with the other departments as needed.

5.4.4.4 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.

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

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

5.4.4.7 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.

5.4.4.8 The inpatient service shall have quality improvement mechanisms that at least constitutes of:

a) Collecting Feedbacks from clients,
b) Preparing a formal administrative channel through which clients lodge their complaints and present their grievances,
c) Conducting regular medical discussion sessions among health professionals across all clinical disciplines,

5.4.4.9 The specialty center shall have written protocol for admission and discharge.

5.4.4.10 A specialty center shall have at least ten inpatient admission beds. When two or more specialty centers combined together the number of inpatient beds shall be a minimum of twenty.

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

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

5.4.4.13 For admitted patients the orthopedic surgical service shall be organized in such a way that it covers all the shifts.

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

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

5.4.4.16 The Specialty center shall contact the municipality or responsible body for burial service if there is no family/guardian for the deceased.

5.4.5 Premises

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

Rooms required
• Surgical ward/ inpatient room
o Patient rooms for a minimum of 10 orthopedic beds {with maximum room capacity not more than 6 beds}
o Isolation rooms
o Nurse station
o Duty rooms with lockers (male/ female)
o Clean utility & linen room
o Soiled utility room
o Mini-Store
o Toilet rooms (can be in each patient room)

5.4.5.2 **Orthopedic ward** shall be available with the followings;

a. In addition to emergency and isolation beds, the specialty center shall have at least ten inpatient beds.
b. There shall be a minimum of one separate room, labeled “Septic Room” for septic patients
c. The number of beds per room shall not exceed six (6)
d. The beds shall be flexible and orthopedic beds,
e. Adult beds shall have 1m width and 2m length

a) Distance of bed from fixed walls shall be 0.9 m

f. In third class, space between beds shall be at least 1.2m.
g. Each bed room shall have alarm
h. The rooms shall have safe and continuous water supply, light and ventilation
i. The beds shall be equipped with fixtures for certain orthopedic surgical patients- orthopedic cases
j. Patient screens,

k. Patient toilets and showers with proximity to the ward, or covered walkways to the ablution facilities.

5.4.6 **Professionals**

5.4.6.1 Orthopaedic surgeon and/ or orthopaedic sub-specialist of related discipline shall be available with consultation bases during working hours at inpatient service unit.

5.4.6.2 At least one general medical practitioner shall be physically available in all the shifts in inpatient service unit.

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

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

5.4.6.5 Actual number of professionals shall be determined based on work load analysis.

5.4.6.6 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.

5.4.7 **Products**

5.4.4.1 The following products shall be available for inpatient services.

- Orthopaedics beds at least 2
- Beds with wheels
- Bed side cabinet
- Feeding table
- Bed pans
- Urinal (Male and Female)
- Bed Pan carriage
- Bed pan Racks
- IV Stand
- Stretcher
- Wheel chair
- Kidney basin, 475ml x 5
- Mobile Examination light,
- Plastic apron,
- Drapes,
- Rubber sheets,
- Connectors,
- Oxygen mask/ nasal catheters
- Oxygen cylinder,
- Oxygen trolley,
- Oxygen regulator/gauge
- Safety Box
- Suction machine
- Resuscitation set
- Thermometer
- Stethoscope
- Pulseoxymetry
- Sphygmomanometer
- Reflex hammer
- Refrigerators
- Minor operation set
- Dressing Set
- Lumbar puncture(LP) set

- Catheterization set
- Folding screens
- Dressing trolley
- X-ray Film Viewer

Optional products

- **Wound vac**
- **Browns spray**
- **Skin traction kit**

5.4.7.1 **Orthopedics ward Nurses' station** shall be available with the following;

a. located amidst of the wards
b. shall have table and chairs
c. shall have lockable cabinets,
d. shall have specimen collection station/ laminated table with racks
e. shall have hand washing basin,

5.4.7.2 **Orthopedic ward clean utility room (procedure room)** shall be available with the following;

a. Dressing trolleys ,beds
b. POP equipments sets,
c. Deep Sink,
d. Hand washing basin,
e. Worktable with laminated top,
f. Cabinets and shelves,

5.4.7.3 **Orthopedic ward clean linen room** with shelves and cabinets shall be available

5.4.7.4 Orthopedic ward in patient store with shelves, cabinets and fixed electrical plugs with protection shall be available

5.4.7.5 Orthopedic ward soiled utility products

a. shelves and leak proof containers with leads

b. Soiled linen trolley
c. Bin with lid
d. Worktable with laminated top
e. Wash tub (65L)
f. General purpose trolley, two trays

5.4.7.6 Orthopedic ward cleaner's room shall be available with the following

a. Hand washing basin,
b. Sinks and cleaning equipments,
c. Shelves and Cabinet,
d. One room for keeping patients belongings with lockers.

5.5 Anesthesia Services

5.5.4 Practices.

5.5.1.1 There shall be a written policy about administration of regional and general anesthesia in the specialty center,

5.5.1.2 Minor regional blocks shall be monitored in accordance with the specialty center's policy,

5.5.1.3 Anesthesia services shall be administered in accordance with written policies and procedures that are reviewed at least every three years, and revised more frequently as needed. They shall include at least the following :

(a) Anesthesia care, which includes moderate and deep sedation, is planned and documented in the patient's record.

(b) A pre-anesthesia/sedation assessment shall be done by anesthetist or anesthesiologist prior to the induction of anesthesia.

(c) The patient shall be reassessed immediately prior to induction of anesthesia by an anesthesiologist or anesthetist. The plan shall be consistent with the patient assessment and shall include the anesthesia to be used and the method of administration.

(d) Prior to administration of any pre-anesthesia medication, a written informed consent for the use of anesthesia shall be obtained and documented in the medical record.

(e) Each patient's physiologic status shall be continuously monitored during anesthesia or sedation administration and the results of the monitoring shall be documented in the patient's medical record on an anesthesia form, a minimum of :

- Pulse rate and rhythm.
- Blood pressure.
- Oxygen saturation.
- Respiratory rate.

(f) The anesthesia record includes:

- Fluids administered.
- Medications administered.
- Blood or blood products administered.
- Estimated blood loss.
- The actual anesthesia used.
- Any unusual events or complications of anesthesia.

- The condition of the patient at the conclusion of anesthesia.
- The time of start and finish of anesthesia.
- Signature of the anesthesiologist/ or anesthetists.

(g) The patient shall be monitored during the post-anesthesia/surgery recovery period and the results of monitoring shall be documented in the patient's medical record.

(h) The time of arrival and discharge from anesthesia recovery room shall be recorded.

(i) The observation at recovery room shall be done by qualified registered nurses with training of basic advanced cardio-pulmonary support.

(j) The decision of discharge shall be done by anesthesiologist, or anesthetist or other qualified physician based on the documented results of monitoring during the recovery.

(k) The discharge order from the recovery shall be documented on patients chart and signed by anesthesiologist or anesthetist or other qualified physician before transfer.

5.5.4.1 At all times, at least one anesthetist shall be on-site or on-call and available to reach the specialty center within 30 minutes.

5.5.4.2 The anesthetist shall visit the patient before the operation and assess the general medical fitness of the patient, receives any medication being taken, and assess any specific anesthesia problems.

5.5.4.3 The anesthetist shall discuss possible plans of management with the patient and explains any options available, to enable the patient to make an informed choice.

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

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

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

5.5.4.7 The anesthetist shall be present in the operating theatre around the patient throughout the operation and shall be present on-site until the patient has been discharged from the recovery room.

5.5.4.8 The conduct of the anesthesia and operation is monitored and recorded in line with the monitoring standards and formats, to a minimum these shall contain:

a) A continuous display of the ECG,
b) Continuous pulse oximeter, and

c) A written record of the anesthetic shall be kept as a permanent record in the case notes.

5.5.4.9 Pain shall be assessed in discussion with surgeon and/ or the patient and pain control shall be provided.

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

5.5.4.11 Written discharge criteria shall be in place, including satisfactory control of pain and nausea, spontaneous breathing, to determine when patients can be safely discharged from the recovery room, making it clear that the final responsibility is always with the anaesthetist or any qualified physician for transfer.

5.5.4.12 The protocols and guidelines used for anesthesia service shall be available and well understood by the surgical team.

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

5.5.4.14 There shall be a written protocol to assure that surgery shall not proceed when there are disabled alarms on the monitors,

5.5.4.15 The body temperature of each patient under general or major regional anesthesia lasting 45 minutes or more shall be continuously monitored and recorded at least every 15 minutes.

5.5.4.16 Pulse oximetry shall be performed continuously during administration of general anesthesia, regional anesthesia, and conscious sedation at all anesthetizing locations, unless such monitoring is not clinically feasible for the patient. Any alternative method of measuring oxygen saturation maybe substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness.

5.5.4.17 Blood pressure, pulse rate, and respiratory rates shall be determined and charted at least every five minutes for all patients receiving anesthesia at any anesthetizing location, except for local anesthesia and minor regional blocks.

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

5.5.5 Premises

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

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

5.5.5.3 Regarding the anesthesia store:

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

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

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

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

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

(f) There shall be separate place for keeping new and rechargeable Batteries and dry cells. Used batteries and cells shall be stored and discarded properly, refer to IP and waste disposal protocol,

5.5.6 Professionals

5.5.3.1 This standard allows to licensed Bsc anesthetist with a minimum of two years of experience to lead anesthesia service for short term until the country delivers adequate number of anesthesiologists

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

5.5.3.3 General or major regional anesthesia shall be administered and monitored only by the following:

a) An anesthesiologist/ Bsc Anesthetist or
b) A registered nurse anesthetist or registered anesthetist or physician resident (anesthesiology), a student nurse anesthetist, a student anesthetist under the supervision of an anesthesiologist.

5.5.3.4 The supervision of general or major regional anesthesia shall be provided by a registered anesthetist or nurse anesthetist or anesthesiologist who is immediately available. The supervising person may concurrently be responsible for patient care, with the exception of performing major surgery, administering general anesthesia, or major regional anesthesia.

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

a) An Anesthesiologist/Bsc Anesthetist, or
b) A nurse anesthetist, or

c) A physician, podiatrist (foot doctor);
d) A medical intern, a physician resident, , or a student nurse anesthetist, or student anesthetist, or a health officer, or a registered nurse, midwife, under the supervision of at least nurse anesthetist.

5.5.7 Products

5.5.4.1 Anesthesia supplies, equipment and safety systems shall include the following:

a) All medical gas hoses and adapters shall be color-coded and labeled according to current national standards.
b) An oxygen failure-protection device ("fail-safe" system) shall be used on all anesthesia machines to announce a reduction in oxygen pressure, and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of supply oxygen is reduced.
c) Vaporizer exclusion ("interlock") system shall be used to assure that only one vaporizer, and therefore only a single agent, can be actuated on any anesthesia machine at one time.
d) To prevent delivery of excess anesthesia during an oxygen flush, no vaporizer shall be placed in the circuit downstream of the oxygen flush valve.
e) All anesthesia vaporizers shall be pressure-compensated in order to administer a constant non-pulsatile output.
f) Accurate flow meters and controllers shall be used to prevent the delivery to a patient of an inadequate concentration of oxygen relative to the amount of nitrous oxide or other medical gas.
g) Alarm systems shall be in place for high (disconnect), low (sub atmospheric), and minimum ventilator pressures in the breathing circuit for each patient under general anesthesia.

5.5.4.2 Anesthesia supplies, equipment and patient monitoring shall include:

a) A respirometer (volumeter) measuring exhaled tidal volume shall be used whenever the breathing circuit of a patient under general anesthesia allows.
b) A difficult airway container or trolley shall be immediately available in each anesthesia department for handling emergencies. The following items are required to be included in the difficult airway container or trolley:

- resuscitation equipment like ambu bag, laryngoscope, defibrillator, laryngeal mask and endotracheal tube stylet
- Airway,
- emergency medicines,
- a laryngeal mask,
- endo-tracheal tube stylet,
- airway, and/or
- other items of similar technical capability.

c) A precordial stethoscope or oesophageal stethoscope shall be used when indicated on each patient receiving anesthesia. If necessary, the stethoscope may be positioned on the posterior chest wall or tracheal area.
d) Supplemental oxygen and a delivery system appropriate to the patient's condition shall be immediately available for patient transport from the operating room to the post anesthesia care /recovery unit.
e) Recording and reporting forms

5.5.4.3 Equipments:

a) Time clock
b) Anesthesia machine with ventilator, 2 vaporizers, and gas cylinders
c) Adult and pediatric anesthesia circuits with filters
d) Mechanical ventilators
e) Oxygen cylinders, oxygen trolley and oxygen regulator
f) Worktable with laminated top
g) Resuscitation equipments; Ambu bags (adult/ pediatric/ neonates), with inflatable bag,
h) Stools
i) Clips
j) Weight scale; adult & pediatric
k) Resuscitation trolley
l) Syringe pump
m) Blood gas analyzer
n) Dust bin
o) Blankets
p) Air conditioner and heater
q) Framed boards with pencil trays
r) IV stands, infusion pumps, IV fluid pressure bags, blood warmer and IV fluid warmer
s) Tourniquets, tongue depressors, disposable
t) Goggles and boots
u) Patient monitor
    - ECG monitor
    - 12 leads Electrode, Monitor
    - Pulse oximeter
    - Temperature monitor
    - Nerve stimulator
    - Dual head stethoscope

- BP apparatus with different size cuffs

v) Intubation gadgets:

- Airway Guedel, pediatric & adult size
- Laryngeal mask set
- Mask holder
- Cannula - Nasal-Oxygen,
- Masks – Oxygen 40 %
- Laryngoscope sets with different size blades (Mackintosh)
- Magill forceps (adult & pediatrics)
- Intubation stylet, adult, 15 Ch,/ Endo-tracheal tube guide
- Mouth gauge
- Guedel airways: size 0, 00, 3, 4 & 5
- Tube, Endo-tracheal:
    - disp. + connector, 3 mm, w/o balloon
    - disp. + connector, 3.5 mm, w/o balloon
    - disp. + connector, 4 mm, w/o balloon
    - disp. + connector, 4.5 mm, w/o balloon
    - disp. + connector, 5 mm, balloon
    - disp. + connector, 5.5 mm, balloon
    - disp. + connector, 6 mm, balloon
    - disp. + connector, 6.5 mm, balloon
    - disp. + connector, 7 mm, balloon
    - disp. + connector, 7.5 mm, balloon
    - disp. + connector, 8 mm, balloon
    - disp. + connector, neonate mm, w.o balloon
    - disp. + connector, balloon, 6.5mm, 7mm, 7.5mm, 8mm
- Tube:
    - Trachea, balloon, int.can, ster, size 6
    - Trachea, balloon, int.can, ster, size 8
    - Suction,CH08,L50 cm, ster,disp, CH08, CH10, CH14, CH16
- Extractor, mucus,20ml,ster,disp
- Safety Pins Large & Medium
- Connectors:
    - Biconical, Autoclavable
    - Connector, T/Y
    - Connectors - Plastic – Tapered
- Masks - Nebulizer/Oxygen
- Other accessories/ suppleis:
- Braun Splints (Arm)
- Draw sheet, plastic,90x180cm
- Clinical thermometer

- Fridge thermometer
- Tourniquet, latex rubber, 75cm

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

5.6 Intensive Care Services (optional)

5.6.4 Practices

5.6.1.1 The ICU is open 24 hours and 7 days a week with available medical personnel with Advanced Life Support (ALS) training available round the clock with shift.

5.6.1.2 The ICU shall have written policies and procedures that are reviewed at least once every 3 years and implemented. They shall include at least:

(a) Criteria for admission to ICU,
(b) Criteria for discharge and transfer;
(c) A list of procedures that registered physicians, who are certified/ accredited in intensive care, may or may not perform;
(d) Protocols for transfer and transport of patients within the specialty center or from the center to another facility including who shall accompany the patient being transferred or transported;
(e) Infection control procedures and/or protocols as indicated under infection prevention standards;
(f) A visitors policy that specifies visiting hours and number which subject to the discretion of the patient's physician or primary care nurse;
(g) A policy on the removal of a patient's life support system;
(h) A policy defining the physician, specialist and consulting physician to be called for patient emergencies, including a response time for physicians to respond to patient emergencies;
(i) Standing orders for patient emergencies;
(j) Policies and procedures which ensure that priority laboratory services will be available to critical care patients at all times if medically indicated;

5.6.1.3 Roles and responsibilities of specialists in management of ICU patients shall be available in written policy or protocol. All ICU patients shall be managed or co-managed by a dedicated trained internist or independent practitioner who is exclusively responsible for patients in one ICU.

5.6.1.4 Nursing functions shall be the responsibility of a licensed nurse and shall be accountable to the attending ICU physician,

5.6.1.5 Complete medical records shall be kept for each patient: pertinent history, physical examination, diagnosis, diagnostic procedures, medication administration, and treatment to facilitate continuity of care. And the

patient's medical service record shall be integrated with the patient's over-all specialty center's record,

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

5.6.1.7 There shall be a means of promoting harmony between critical care providers and families. This 5-part system, known by the mnemonic VALUE, includes:

(a) valuing and appreciating what the family members communicate,
(b) acknowledging their emotions by using reflective summary systems,
(c) listening to family members,
(d) understanding who the patient is as a person by asking open-ended questions and listening carefully to the responses, and
(e) Eliciting questions from the family more effectively than by simply asking "Any question?''.

5.6.1.8 There shall be portable life-support equipment for use in patient transport, both within the center and for transfer. All ventilators in use shall be equipped with an integral minimum ventilation pressure (disconnect) alarm. There shall be a system for obtaining immediate emergency replacement or repair of equipment in the critical care service.

5.6.1.9 There shall be a system in the specialty center of assuring the functionality of the ICU gadgets/ equipments at least every 3 years and labeling for the check service.

5.6.1.10 There shall be a mechanism in place for the critical care service to have access to nutritional support services for advice on both enteral and parenteral nutritional techniques.

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

5.6.5 Premises

5.6.2.1 The ICU shall be located in access restricted area of the center and well identified.

5.6.2.2 **ICU room**: The size of the room depends on the number of ICU beds. The ICU shall be at least 8m x 10m in size that accommodate a maximum of 2 electrically or manually

operated ICU patient beds fitted with full range of monitors and a screen.

a) The header of beds shall be 1 m away from the wall
b) There shall be a 2m wide free traffic area by side of beds and between any of two beds.
c) There shall be a nurse station within the ICU having a computer and a computer point, telephone and telephone point, cabinets and shelves, and lockers for controlled drugs.
d) There should be a separate physical area devoted to nursing management for the care of the intermediate patient (32 sq m area including nurse station).

5.6.2.3 Nurse station in the ICU:

a) Isolated with glass, full visual access to monitor admitted patients on monitors,
b) Equipped with chairs, working laminated top tables, drawers and computers, Linen boards, shelves, lockers
c) Telemetry monitoring for critical or post operative patients with transmitters,
d) Telephone end,
e) Medication boards, controlled drug locker,
f) Calculators,
g) Weight scale,
h) Ready to use CPR equipments with defibrillator on trolley,
i) Patient labeling for diet, allergy, etc.,

5.6.2.4 The ICU shall have easily accessible hand wash basin around the entrance-exit door.

5.6.2.5 In addition to the main ICU for critical care, the unit shall have the following spaces (rooms): toilets, nurse room, utility room, store, duty room, cleaner's room, staff tea room, and spacious corridor for stretchers and wheelchairs.

5.6.2.6 Toilet: ICU shall have staff and patient toilet and shower facilities.

5.6.2.7 The ICU shall be access to laboratory service, or it shall be equipped with side lab, dedicated and open for 24 hours a day and 365 days a year.

5.6.2.8 Nurse locker room: There shall be an ICU staff locker room in proximity with the ICU. The ICU area is generally regarded as a sterile zone and there shall be shoe and cloth change point for staff and attending families.

5.6.2.9 ICU Utility/ Sluice room: There shall be soiled utility/sluice room which acts as a storage area for contaminated materials until they are disposed off and temporary station for equipments until disinfected

and cleaned. The soiled utility room shall have a deep bowel sink, a hand wash basin with hot and cold water, plus cabinet and shelves.

5.6.2.10 Store room: There shall be an ICU supply room (store) at least 4m x 4m in size used for storage of consumables and spare equipments. It shall be equipped with cabinets and shelves. Materials shall be labeled, arranged in order, ready for use (charged) and there shall be ventilation and enough light.

5.6.2.11 Cleaner's room: There shall be an ICU cleaner's / janitor's room for an easy access to cleaning equipments and materials or the ICU floor. If there is a mobile cleaning service it can be optional.

5.6.2.12 Staff tea room (optional): There should be a staff tea room in close proximity to the ICU in order to ensure the availability of staff at all times and as rest room for visitors.

5.6.6 Professionals

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

5.6.3.2 The physicians working in the ICU shall be certified in either in internal medicine, anesthesia, surgery, paediatrician or general practice and/or have completed a formal training program in critical care approved by the licensing body in the country.

5.6.3.3 There shall be a registered professional nurse with administrative responsibility for the ICU or combination of units who is accountable for all critical care nursing rendered in the unit or units.

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

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

5.6.3.6 Nurse assistants assigned to ICU shall be oriented and trained on basic cardiac life support and critical care.

5.6.3.7 There shall be at least one registered ICU nurse in the ICU for 24 hours a day and 365 days a year.

5.6.3.8 At least the following professionals are required:

a) One anesthesiologist and/or ICU trained internist
b) Critical care nurses
c) Cleaners
d) Porters
e) General technician

5.6.7 Products

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

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

a) The ICU beds shall have removable side protections; functional wheels; shall be easily adjustable to multipurpose positions
b) mechanical ventilator to assist breathing through an endotracheal tube or a tracheotomy opening; at least 4; All ventilators shall be equipped with an integral minimum ventilation pressure (disconnect) alarm.
c) Different size endotracheal tubes and tracheotomy sets, at least 4 sets,
d) monitoring equipment, equipment for the constant monitoring of bodily functions;
e) cardiac monitors including telemetry,
f) Standard 12 lead EKG machines,
g) external pacemakers (optional),
h) defibrillators; at least 2,
i) Reliable Oxygen delivery systems: Oxygen cylinder or oxygen concentrator,
j) Oxygen regulator, at least 2
k) pulse oximeter,
l) end-tidal carbon dioxide monitoring,
m) Titrated therapeutic interventions with infusion pumps,
n) A web of intravenous lines for medicines infusions, fluids or total parenteral nutrition,
o) suction pumps,
p) infusion pump
q) Laryngoscopes with different size blades,
r) Ophthalmoscope,
s) Mouth gags, different size
t) Air ways, different size
u) Resuscitation trolleys,
v) Exam coaches,
w) Syringe pump,
x) Endotracheal tubes ,(different sets)
y) Wheel chair,
z) Patient transport stretcher,
aa) Sphygmomanometer, with adult and pediatric cuffs,
bb) Sthethoscopes: pediatric and adult,
cc) Electrical suction machine (at least 1 as a backup),
dd) Pedal suction machine,
ee) Nasal CPAP,
ff) Bed pan, plenty in number, different size
gg) Pacing boxes (at least 2)
hh) X-ray viewer per bed
ii) Wall clock (at least 2)
jj) Soiled cloth hampers
j) Patient screen per bed and
kk) IV stands, at least one per bed

5.7 Radiological Services

5.7.4 Practices

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

5.7.1.2 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.

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

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

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

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

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

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

5.7.1.9 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.

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

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

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

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

5.7.5 Premises

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

Rooms required
• CT or MRI room (Optional)
• Digital X-Ray room(s),
○ X-ray room
○ Fluoroscopy room
○ Dark room (If necessary)
○ Toilets
○ Patient dressing cubicles (inside X-ray room)
○ Sub waiting area
• Ultrasound room

5.7.6 Professional

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

5.7.3.2 A radiologist shall be available in the center during working hours all the time or if on call shall arrive within 30 minutes of being summoned

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

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

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

5.7.7 Products

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

a. Digital X-ray machine ,
b. Color Duplex Ultrasound,
c. Dexa scan (optional)
d. X-Ray viewing boxes,
e. Dark room film processing baths (if necessary),
f. Drier (if necessary),
g. MRI or CT scan machine (optional)
h. Radiation protection equipments:
   - lead gloves,
   - lead apron**,**
   - lead goggle,
   - gonad shield,

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

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

5.7.4.4 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

5.8 Medical Laboratory Services

5.8.4 Practices

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

5.8.4.2 The specialty center laboratory service shall provide Basic Hematology, Bacteriology, Clinical Chemistry, parasitology, urinalysis & Serology test profiles. Based on the type of the center, complexity of the test profiles varies.

5.8.4.3 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.** Quality assurance and control processes,
- **c.** Inspection, preventive maintenance & calibration of all equipment,
- **d.** Management of reagents including availability, storage, and testing for efficacy,
- **e.** Procedures for collecting, identifying, processing and disposing of specimens,
- **f.** All normal ranges for all tests shall be stated
- **g.** Laboratory safety program, including infection control
- **h.** Documentation of quality Assessment, calibration report and refrigerator readings.

5.8.4.4 The laboratory shall have procedures or (SOP) for specimen collection and/ or transport that address specific collection requirements.

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

5.8.4.6 The process of analysis shall be specified by validated written or electronic procedures maintained in and by the laboratory. Procedures may be written by the laboratory staff or may be adapted from previously published materials including, but not limited to, product inserts, procedure or instrument manuals, textbooks, journals, or international guidelines.

5.8.4.7 The Specialty center Laboratory staff shall prepare SOP or set criteria for acceptance and rejection of clinical specimens.

5.8.4.8 The Specialty center Laboratory shall monitor the transportation of samples to the laboratory such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual or SOP and in a manner that ensures safety for carrier.

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

5.8.4.10 The Specialty center Laboratory shall have a procedure for storage of clinical samples if it is not immediately examined.

5.8.4.11 Patient samples shall be stored only for as long as necessary to conduct the designated tests (or other permitted procedure) according to fixed storage times, and shall be destroyed safely and confidentially after storage.

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

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

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

a. All laboratory test result/reports shall have reference (normal) ranges.
b. Files of reported results shall be retained by the laboratory.
c. 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 policies and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic. Policies shall be established which define who may access patient data and who is authorized to enter and change patient results.

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

5.8.4.16 Safe disposal of samples shall be in line with standards prescribed under infection prevention

5.8.4.17 No eating, drinking, smoking or other application of cosmetics in laboratory work areas or in any area where workplace materials are handled.

5.8.4.18 No food or drink shall be stored in the laboratory.

5.8.4.19 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.

5.8.4.20 Where services are provided by an outside laboratory (contract), the conditions, procedures, and availability of services offered shall be in writing and available in the Specialty center.

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

Documentation shall be maintained.

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

5.8.4.23 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 labeled.

5.8.4.24 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,

5.8.5 Premises

5.8.5.1 The specialty center shall have a well organized, adequately supervised and staffed clinical laboratory with the necessary space, facilities and equipments.

Rooms required
• Laboratory room (can be 1 r open platform)
o Specimen collection
o Hematology & Clinical chemistry
o Parasitology, urinalysis & serology
o Disinfection & sterilization room (sha
o Blood bank/ storage room
o Duty room

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

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

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

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

5.8.5.6 The medical laboratory of the center shall fulfill all premises requirements described under each specialty center.

5.8.5.7 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.

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

5.8.6 Professionals

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

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

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

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

5.8.6.5 The medical laboratory of the center shall fulfill the minimum staffing requirements described under each specialty center.

5.8.7 Products

5.8.7.1 Specialty center medical laboratory shall have the following equipments:

a) Safety cabinet,
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) Water distillation apparatus,
l) Incubator,
m) Microhematocrit centrifuge,
n) WBC chamber,
o) Differential counter,
p) Hematology analyzer,
q) Clinical Chemistry analyzer (semi-automated*/ automated),
r) Water bath,
s) Assorted lab glassware s,
t) Biohazard bag,
u) Safety box,
v) Glucometer,
w) Hemoglobinometer,

5.8.7.2 **The minimum equipments for Clinical chemistry services:**

a) Autoclave
b) Clinical chemistry analyzer (Automated or semi automated)
c) Glucometer
d) Power surge protectors
e) Weighing balance
f) Micropipettes of different volumes
g) Timer with alarm
h) Water bath

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

a) Binocular Microscope,
b) Slides
c) Staining reagents, Gram stain, Giemsa stain, AFB stain,
d) CSF analysis reagents

5.8.7.4 **The minimum equipment for Hematology:**

a) Haemoglobinometer
b) Hematology analyzer (Automated)
c) Blood rocker
d) Refrigerator
e) Binocular microscope
f) Haemocytometer
g) Microrotohem
h) Microrotohem
i) Differential counter
j) Tally counter
k) Deep freezer
l) Centri

f u g e
m) T i m er
n) D is ti ll at io n u ni t
o) S h a k er / R ol le r
t a i n
e) F o r m a l i n
f) X y l e n e
g) O i l
i m m e r s i o n
h) C a r b o l f u c s i n
i) M e t h y l e n e b l u e
j) A c e t o n e
k) C r y s t a l v i o l e t
l) G r a

5.8.7.5 **Exception:** Internal medicine specialty center shall have viral load and CD4 machines.

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

a) H C l
b) S u l f u r i c A c i d
c) W r i g h t s t a i n
d) G i e m s a

m’s iodine

m) Absolute ethanol

n) Methanol

o) Safrani

p) Glacial acetic acid

q) Ether

r) 75% alcohol

s) 0.85% NaCl

t) Saval lone (chloroh exidine + cetrimide)

u) KOH

v) Glycerol

w) Urine strip of 10 parameter

x) HCG

Test kit

y) Occult blood reagents

z) Vacutainer

EDTA tube of 4ml

aa) Vacutainer plain tube of 10ml

bb) Vacutainer needled holder

cc) Vacutainer needle

dd) Syringe with needled of different size

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ee) Tourniquet

ff) Slide and cover slide

gg) Microscope

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mm) Stool cup

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oo) Cryo box es

pp) Past eur pipet tes

qq) Test tub es

rac ks

rr) Slide box es

ss) Lens paper

tt) Disposable glove s

uu) Cotton Roll

vv) Applicator sticks

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5.9 Pharmacy Services

5.9.4 Practices

Dispensing and Medication Use Counseling

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

5.9.4.2 Dispensers shall make sure that prescriptions are legible, written by authorized prescriber and complete. Prescription papers shall be standardized and must contain at least the following information and the prescriber shall complete all these information:

a) Name of patient, sex, age and medical record number,
b) Diagnosis and allergy, if any,
c) Name of the medicines, strength, dosage form, dose, frequency, and route of administration,
d) Duration of treatment,
e) Prescriber's name, qualification and signature,
f) Prescriber's address (name and address of Specialty center).

5.9.4.3 The pharmacist shall check the correctness of prescriptions in terms of appropriateness for patients and of dosage, strength and drug interactions based on approved standard treatment guidelines"

5.9.4.4 All medicines shall be dispensed with adequate and appropriate information and counseling to patients for correct use of their medications.

5.9.4.5 The pharmacist shall make an in-depth professional judgment to make sure that each medicines and its dosage form has all of its attributes of quality and an acceptable ratio of safety.

5.9.4.6 The containers used for dispensing shall be appropriate for the product dispensed and all containers intended for pharmaceuticals shall be protected and kept free from contamination, moisture and light.

5.9.4.7 All pharmaceuticals to be dispensed shall be labeled and the labels shall be unambiguous, clear, legible and indelible. The following minimum information

shall be indicated on the label/ sticker:

a) the generic name of the product or each active ingredient, where applicable;
b) the strength, dose, frequency of administration and total quantity;
c) the name of the person for whom the medicines are dispensed;
d) the name of the prescriber and patient card number;
e) the directions for use and route of administration tailored to patient or caregiver literacy and language;
f) the name and business address of the dispenser;
g) date of dispensing; and
h) Special precautions as applicable

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

5.9.4.9 Each Specialty center shall establish and implement policies, guidelines and procedures for reporting any errors or any suspicion in administration or provision of prescribed medications. Errors shall be reported to the prescriber in a timely manner upon discovery and a written report of the error prepared and documented. Any suspicion or error shall be communicated to the prescriber and clarified/corrected before dispensing without affecting patient's confidence on medical practices.

5.9.4.10 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.

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

5.9.4.12 The Pharmacist shall assess each patient's ability to understand the information imparted by question and answer and must be able to modify his/her approach

accordingly. Care shall be taken with counseling where understanding is likely to be a problem.

5.9.4.13 Cautionary instructions and ancillary information about medications shall be communicated in writing to the personnel responsible for administering medications.

Extemporaneous Pharmaceuticals Preparations (Optional):

5.9.4.14 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.

5.9.4.15 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.

5.9.4.16 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.

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

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

5.9.4.19 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

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

5.9.4.21 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.

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

5.9.4.23 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

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

5.9.4.25 A record of the stock on hand and of the dispensing of all these drugs shall be maintained

in such a manner that the disposition of any particular item may be readily traced.

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

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

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

5.9.4.28 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.

the administration of any quantity of the controlled substance

g) Day-ending or shift-evening verification of count of balances of controlled substances remaining and controlling substances administered shall be accomplished by two (2) designated licensed persons whose signatures shall be affixed to a permanent record.

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

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

5.9.4.31 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.

5.9.4.32 The Specialty center shall implement procedures whereby, on a periodic basis, a licensed Pharmacist shall reconcile quantities of controlled substances dispensed in the Specialty center against the controlled substance record. Any discrepancies shall be reported to the head of the center. Upon completion, all controlled substance records shall be returned to the pharmacy by the designated responsible person.

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

Clinical Pharmacy Services (optional):

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

5.9.4.35 The pharmacist for clinical pharmacy services shall have access to patient specific

medication therapy information.

5.9.4.36 Patient-specific medication therapy information must be evaluated and a drug therapy plan shall be developed by the pharmacist mutually with the patient, the prescriber and nurse as appropriate.

5.9.4.37 The pharmacist shall review, monitor and propose for modification of the therapeutic plan in case of adverse effects, patient noncompliance and evidence- based efficacy problem and as appropriate, in consultation with the patient, prescriber and nurse.

5.9.4.38 Through prescription and medication history monitoring, the pharmacist shall identify problems or opportunities for optimizing treatment and hence safeguard the patient and ensure the optimal use of medicine

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

information and knowledge necessary to carry out the drug therapy plan.

5.9.4.41 As a member of the specialty center team, the pharmacist shall attend and participate at patient visits and contribute to patient care through the provision of medicine information, dose calculations and adjustment, assisting in the rational prescribing decision, alternative regimens & combinations and reducing the frequency and duration of medication errors.

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

Emergency Pharmacy Services

5.9.4.43 The specialty center shall have emergency pharmacy service for 24 hours a day.

5.9.4.44 The center shall have emergency medicines list and continuous availability of such medicines shall be ensured at all times,

5.9.4.45 The center shall have the mechanism to ensure appropriate use of

medicines for emergency purposes

5.9.4.46 Orders received by words of mouth or through telephone during emergency (in case of immediate administration is necessary, no appropriate alternative treatment is available and when it is not reasonably possible for the physician to provide a written prescription prior to dispensing) shall latter be endorsed by the prescriber and be documented in writing within 24 hours. The quantity shall be limited to emergency period only.

Adverse Drug event, ADE/ Pharmacovigilance

5.9.4.47 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 FMHACA.

responsible to report suspected ADE cases to the ADE focal person.

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

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

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

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

5.9.4.53 The reporting of ADE shall be done by the national ADE prepaid yellow form prepared by FMHACA

Pharmaceutical Supply and Management

5.9.4.54 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

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

5.9.4.56 The center shall have procurement policy to ensure the continuous supply of safe, quality and effective medicines

5.9.4.57 A pharmacist shall not purchase any medicinal product where he/she has any reason to doubt its safety, quality or efficacy and he/she should notify this to the appropriate organ .

5.9.4.58 The pharmacist shall ensure that both the supplier and the source of any medicine purchased are reputable and registered by the FMHACA.

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

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

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

5.9.4.62 There shall be a responsible pharmacy personnel assigned for receiving, storage, issuing, recording, monitoring and reporting.

5.9.4.63 The storage condition shall provide adequate protection to the medicines from all environmental factors until the medicines are delivered to the patient.

5.9.4.64 The responsible pharmacist must ensure that all areas where pharmaceuticals are stored are of acceptable standards (palletized or shelved, ventilated, rodent free, temperature and moisture controlled and others) for medicines store.

5.9.4.65 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

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

5.9.4.67 Firefighting equipment or system shall be installed to pharmaceutical storage places

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

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

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

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

5.9.4.72 The responsible pharmacist shall ensure that adequate control procedures are in place for all stock circulating at all outlets within the center.

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

5.9.4.74 There shall be a pharmacist assigned as medicine Supply Management Officer that is responsible for the procurement, stock management, warehouse management, distribution of medicines and disposal of medicine waste. There shall be also a responsible pharmacy personnel assigned for receiving, storage, issuing, recording, monitoring and reporting

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

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

Medicines Waste Management and Disposal

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

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

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

5.9.4.80 Cleaners or anybody to handle hazardous pharmaceutical wastes shall wear protective devices like apron, plastic shoes, gloves,

head gears and eye glasses when the need arises.

5.9.4.81 General wastes shall be collected daily from the pharmacy and placed in a convenient place outside the pharmacy to facilitate coordinated disposal by the center.

5.9.4.82 Solid wastes from the pharmacy shall be categorized as "hazardous" and 'non-hazardous" and shall be collected separately for proper treatment.

5.9.4.83 All hazardous chemicals spills shall be immediately reported to head of the pharmacy or responsible person for safety (if available) to minimize the risk and take immediate action.

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

5.9.4.85 Medicines in single dose or single use containers which are open or which have broken seals, medicines in containers missing medicines source and exact identification (such as lot number), and outdated medications shall be collected to the pharmacy for disposal.

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

5.9.4.87 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

5.9.4.88 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.

5.9.4.89 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.

5.9.4.90 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.

5.9.4.91 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

5.9.4.92 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,

5.9.4.93 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.

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

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

5.9.4.96 The Specialty center shall ensure that each customer has the right to get receipt which has the following minimum information about medicines dispensed.

a) Name of patient,

b) Name and dosage form of medicines dispensed,

c) Unit of measurement and quantity,

d) Unit and total price,

e) Date,
f) Signature of dispenser and cashier,
g) Address of the Specialty center.

Organization Management and Quality Improvement

5.9.4.97 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.

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

5.9.4.99 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.

5.9.4.100 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.

5.9.4.101 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.

5.9.4.102 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.

5.9.4.103 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

5.9.5 Premises

5.9.5.1 The design and layout of the pharmacy shall permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimize the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of medicines and service delivery.

5.9.5.2 The area(s) of counseling shall be arranged or constructed in such a manner that it provides adequate space, have professional look and ensure reasonable privacy to the patient at all times and eliminate background noise as much as possible.

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

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

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

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

5.9.5.7 The pharmacy premises shall be clearly demarcated and identified from the premises of any other business or practice. The pharmacy shall be secure from theft & any other disaster like fire & flood.

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

5.9.5.9 The ceiling height of the pharmacy store shall not be less than 2.6m. This height requirement shall increase depending on the climatic condition of the area

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

5.9.5.11 Medicines shall be shelved a minimum of 20cm above the floor, 1m wide between shelves and 50cm away from the wall and ceiling. If pallets are used, there shall be 20cm above the floor, one meter between pallets and 50cm away from the wall.

5.9.5.12 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)

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

5.9.6 Professional

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

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

5.9.6.3 The center shall have one additional pharmacist

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

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

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

5.9.7 Products

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

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

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

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

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

Equipment and facilities

a) Refrigerator

b) Desk free

c) Refrigerator Thermometer

d) Table clock

e) Scientific thermometer

f) Table lean and clean towel

g) Scissors

h) Adult weighing scale

i) Room thermometer

j) Balance

k) Telephone line

l) Access to water

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5.9.7.6 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

5.10 Medical Recording

5.10.4 Practices

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

5.10.4.2 The Specialty center shall maintain individual medical records in a manner to ensure accuracy and easy retrieval. A patient shall have only one medical record in the Specialty center.

5.10.4.3 If the patient received medical intervention while on ambulance, the medical information of a patient during ambulance service including medication administered shall be documented properly and attached into the medical record,

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

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

5.10.4.6 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.

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

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

5.10.4.9 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.

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

5.10.4.11 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.

5.10.4.12 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.

5.10.4.13 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.

5.10.4.14 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.

5.10.4.15 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.,

5.10.4.16 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.

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

5.10.4.18 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.

5.10.4.19 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.

5.10.4.20 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.

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

5.10.4.22 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.

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

5.10.5 Premises

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

5.10.5.2 The medical record room shall have adequate space to accommodate the following:

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

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

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

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

5.10.6 Professionals

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

medical records management.

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

5.10.7 Products

5.10.7.1 The Medical record room shall have:

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

5.11 Physical therapy Services

5.12.1 Practices:

5.12.1.1 There shall be specific treatment and/or procedure protocols for each service available and rendered in the unit,

5.12.1.2 There shall be a protocol for patient referral and inter discipline consultation,

5.12.1.3 There shall be a protocol that the physiotherapist shall document the entire plan in the patient's medical records. A progress note shall be entered into the medical record.

5.12.1.4 The physiotherapist shall discuss the plan of care with the patient and family,

5.12.1.5 The physiotherapy service shall be available during working time.

5.12.1.6 Visual and Auditory privacy shall be offered and provided to all patients during evaluation and treatment.

5.12.1.7 There shall be a protocol that states written orders shall be given to patients when patients are discharged with exercise or treatment to continue at home.

5.12.1.8 There shall be a protocol for safety and ethical practice of physiotherapy, identifying six precepts for health care, namely, that the health care system must be: safe, effective, patient-centered, timely, efficient, and equitable.

5.12.1.9 There shall be patient education on prevention for possible complications like

a) pressure sores in clients with sensory loss,
b) contractures in clients with limb and/or trunk paralysis,
c) phantom limb pain and sensations for amputees
d) gait training
e) walking aid usage
f) other

5.12.2 Professionals:

5.12.2.1 The physiotherapy service shall be directed by a licensed doctor of physiotherapy or physiotherapy specialists or physiotherapy professionals.

5.12.2.2 The center shall have one of the following:

(a) Doctor of physiotherapy
(b) Physiotherapy specialist (MSc PT)
(c) Physiotherapy professional
(d) Physiotherapy technicians(optional)

5.12.2.3 The physiotherapists must keep their updates with current best evidence-based practice and