

CES 232
Ethiopian Standard

Compulsory

Second Edition
2019

Specialty Centre-Obstetrics & Gynecology
Specialty center

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Foreword

This Ethiopian Standard has been prepared under the direction of the Technical Committee for HealthCare Practices (TC 90) and published by Ethiopian Standards Agency (ESA).

This Compulsory Ethiopian Standard cancels and replaces ES 3619:2012. Application of this standard is COMPULSORY with respect to Obstetrics & Gynecology Specialty Center.

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 XX December 2019.

Specialty Centre-Obstetrics & Gynecology Specialty Center

1. Scope

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

1.1. Requirements of a specialty center are stipulated under section two to eight of this standard.

2. Normative References

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

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

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

3. Terms and Definitions

For this standards the following terms and definition shall apply

3.1.

Clinic

a health facility which delivers outpatient services .

3.2.

Speciality clinic

a health facility which provides delivers outpatient services emphasising on specific special services .

3.3.

Specialty Center

a health facility which provides a minimum of curative, preventive and promotion **emphasising on specific special** 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 for inpatient services per specialty. The center shall have 24 hour service in its respective specialty.

3.4.

Hospital

A hospital is a residential establishment which provides short-term and long-term medical care consisting of observational, diagnostic, therapeutic and rehabilitative services for persons suffering or suspected to be suffering from a disease or injury and for parturients. It may or may not also provide services for ambulatory patients on an out-patient basis'.

3.5.

Cross-Cutting Services

services which rendered in all types of the specialty centers except those services exempted under the specific specialty service standards.

4. General Requirements- Cross cutting service for specialty clinics**4.1. General**

- 4.1.1. All specialty centers shall have and fulfill all the requirements stated under the cross cutting services section of this standard. Cross cutting services which are not applicable for a given specialty center are indicated under respective cross cutting service standards
- 4.1.2. The range of treatment options and the clinical impression shall be fully described to client and/or their families and/or next of kin and shall be documented accordingly
- 4.1.3. Diseases under national surveillance shall be notified to the FMOH through the proper reporting channel
- 4.1.4. The center shall have updated reference materials, treatment guidelines and manuals like National TB and leprosy, pain management, Malaria treatment, ART
- 4.1.5. The center shall use standard prescriptions as per pharmacy standards and different request forms for investigation like laboratory and x-ray
- 4.1.6. Medicines shall be prescribed with generic names only and dispensing shall be made according to patient choice
- 4.1.7. With regard to quality assurance and transparency. The specialty center shall have a range system at outpatient center to collect feedback from clients. The specialty center shall have formal administrative channel through which clients lodge their complaints and grievances
- 4.1.8. The specialty center shall display the following at visible place:
- 4.1.9. List of Services available in the specialty center during working hours & after working hours
- 4.1.10. List of Professionals and specialties working in the center during & after working hours

4.2. Outpatient Medical Services**4.2.1. Practice**

- 4.2.1.1. The Specialty center outpatient service shall provide the following core functions:
- 4.2.1.2. Care of ambulatory patients with outpatient service
- 4.2.1.3. Examination and management of preadmission patients
- 4.2.2. Follow up of discharged and ambulatory patients, Pharmacy service, and Diagnostic services (Laboratory & Imaging-optional)
- 4.2.3. The outpatient service shall have guidelines regarding access and availability of quality service that includes:
 - available for regular working hours
 - 4.2.3.1. 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
 - 4.2.3.2. The outpatient service shall have consultation with functional intra and inter facility referral system which at least include
 - 4.2.3.3. Procedure for identifying cases for referral

- 4.2.3.4. Procedure for referring patients directly to respective services
- 4.2.3.5. List of potential referral sites with contact address (referral directory)
- 4.2.3.6. Referral forms and Documentation for referred clients
- 4.2.3.7. Referral tracing mechanism (linkage) and Feedback providing mechanism
- 4.2.3.8. Procedure to minimize delay for referral and managing referred patients
- 4.2.3.9. There shall be medical assessment at outpatient services which includes at least
- 4.2.3.10. Comprehensive medical and social history
- 4.2.3.11. Physical examination including at least
- 4.2.3.12. Vital sign (BP, PR, RR, To), weight and pain assessment
- 4.2.3.13. Clinical examination pertinent to the illness, Diagnostics impression
- 4.2.3.14. Laboratory and radiographic (roentigenographic) workups when indicated

4.3. Premises

- 4.3.1. All outpatient rooms shall have adequate light, water and ventilation
- 4.3.2. The room arrangements of outpatient services shall consider proximity between related services
- 4.3.3. The outpatient clinical setup shall have easy access to pharmacy laboratory and other diagnostic services
- 4.3.4. The outpatient clinic shall be well marked and easily accessible for disabled clients, elderly patients, under five children and pregnant mother
- 4.3.5. The outpatient service shall be located where access for ambulatory patients is the easiest and where incoming client would not have to pass through other care service outlets (in-patient, laboratory etc)
- 4.3.6. The outpatient clinics shall have fire extinguishers placed in visible area

4.4. Professionals

- 4.4.1. The actual number of personnel shall be determined by workload analysis
- 4.4.2. The staff shall have regular supportive supervision by senior staff or peer review or case conferences at least every three months and it shall be documented

4.5. Emergency Services

4.5.1. Practice

- 4.5.1.1. 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: Airway management and/or oxygen supply, Cardiopulmonary resuscitation (CPR), Bleeding control, Fluid resuscitation (shock management), and Prevention of further damages
- 4.5.1.2. On top of the above article (4.5.1.1), the specialty center shall avail advanced emergency services specific to the specialty
- 4.5.1.3. There shall be written protocols for emergency services
- 4.5.1.4. Emergency services shall follow MoH guideline to bind all healthcare practice services
- 4.5.1.5. Infection prevention standards shall be implemented in the emergency room as per the IP standards stated under this standard
- 4.5.1.6. Every life saving emergency service shall be given to patients without any prerequisite and discrimination

4.5.1.7. 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

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4.5.1.8. 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 arrange an ambulance and shall assign a health personnel to accompany & assist patient

4.5.1.9. 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

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

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

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

4.5.1.13. 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

4.5.2. Premises

4.5.2.1. The emergency room shall be located in a place where it is easily recognizable to the public and shall be labeled in bold

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

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

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

4.5.2.4.1. Triage, Accepting, triaging and providing immediate care including emergency procedures

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

4.5.2.4.3. Emergency medicines, supplies and equipments, Staff/duty room (shared)

4.5.2.4.4. Toilet facilities separate for patients and staff (Male, female)

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

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

4.5.2.7. The emergency premise shall allow patient dignity and privacy

4.5.2.8. 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

4.5.2.9. The emergency room shall have the following facilities: Adequate water, light and ventilation, Fire extinguishers placed in visible area, Telephone, and Hand washing basin in each room

4.5.2.10. Waiting area for attendants and caregivers

4.5.3. Professionals

4.5.3.1. Specialist and/or sub-specialist of related disciplines shall be physically available during working hours at inpatient service unit

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

4.5.3.3. One nurse for a maximum of six (6) patients per shift shall be available to provide nursing care services

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

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

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4.5.3.6. 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

4.5.4. Equipments, Materials & Supplies

4.5.4.1. The following equipments shall be available for inpatient services: Beds with wheels, Bed side cabinet, Bed pans, Urinal (Male and Female), Bed Pan carriage, Bed pan Racks, IV Stand, Stretcher, Wheel chair, Safety Box, Suction machine, Resuscitation set, Thermometer, Stethoscope, Sphygmomanometer, Fundoscope, Otoscope, Reflex hammer, Refrigerators, Minor operation set, Dressing Set, Enema Set, Lumbar puncture(LP) set, Catheterization set, Folding screens, X-ray Film Viewer

4.6. Nursing Services

4.6.1. Practice

4.6.1.1. 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

4.6.1.2. Written copies of nursing procedure manual shall be made available to the nursing staff. The manual shall be used at least to:

4.6.1.2.1. Provide a basis for induction of newly employed nurses

4.6.1.2.2. Provide a ready reference on procedures for all nursing personnel

4.6.1.2.3. Standardize procedures and practice

4.6.1.2.4. Provide a basis for continued professional development in nursing procedures/ techniques

4.6.1.3. The Specialty center shall have established guidelines for verbal and written communication about patient care

4.6.1.3.1. Written communication includes proper use of clinical forms, nursing Kardex, progress notes, and/or nursing care plan for each patient and discharge instructions

4.6.1.3.2. 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)

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

4.6.1.5. The nursing care plans shall be initiated upon admission of the patient and shall include discharge plans as part of the long-term care provision goals

4.6.1.6. The nurses shall assess and document the holistic needs of admitted patients:

4.6.1.6.1. formulate, implement goal-directed nursing interventions, evaluate the plan of nursing care and

4.6.1.6.2. Involve patients, their relatives or next of kin in decisions about their nursing care

4.6.1.7. Nurses' documentation shall include:

4.6.1.7.1. Medication/ treatment/ other items ordered by authorized attending, physician, Nursing care needed, Long-term goals and short-term goals, Patient/ family teaching and instructional programs, The psycho- social needs of the patient, and Preventative nursing care

4.6.1.7.2.

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

4.6.1.9. 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

4.6.1.10. 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

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

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

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

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

4.6.1.15. 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

4.6.1.16. 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

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

4.6.2. Premises

4.6.2.1. The specialty center shall have the following premises for nursing services: Nurse's station located in the middle of the inpatient room(s) with free access to all rooms, Hand washing basin and toilet room at nurse station, Procedure room for nursing procedures and Nurse changing room with cabinet, chairs, cupboard

4.6.3. Professional

4.6.3.1. Nursing care service at different service delivery areas shall be directed by a licensed BSC nurse with work experience

4.6.3.2. The center shall have in place a nursing workforce plan that addresses nurse staffing requirements including, at a minimum:

4.6.3.3. A nurse representative in each patient care unit responsible for the operation of the professional nursing service 24 hours per day and 365 days a year

4.6.3.4. A provision that direct patient care for 24 hours in inpatient unit be provided by licensed nursing personnel

4.6.3.4.1. A method for assessing each unit's additional nursing needs for each shift

4.6.3.4.2. All nursing staff shall receive orientation, training and/or update at least annually including at least:

- 4.6.3.4.3. Center's policies and procedures, Routine nursing procedures, Emergency procedures and Infection prevention and control
- 4.6.3.5. Professional Quality assurance: On-going internal institutional evaluation of outcome-based quality indicators related to nursing care shall be in place to assess and provide a safe and adequate level of patient care including at least:

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- 4.6.3.5.1. Patient injury rate, Medication process errors, Maintenance of skin integrity, Control of cross infections and nosocomial infection rates, Centre -wide patient satisfaction with overall nursing care and Patient satisfaction with pain management

4.6.4. Equipments, Materials & Supplies

- 4.6.4.1. The following equipments shall be available for nursing care services:
 - 4.6.4.1.1. Specimen collection set, Rubber Sheets, Restraining equipment as appropriate, Patient Chart Folders, Vital Sign Equipments, Trolley for vital sign monitoring, Thermometer, BP apparatus, stethoscope, measuring tape, sphygmomanometer with stethoscope, wrist watch/ wall clock, bedside weighing scale, Pulseoxymetry
 - 4.6.4.1.2. Nursing procedure equipments: dressing trolley, dressing set, minor set, enema set, iv stand, oxygen trolley, oxygen cylinder, oxygen regulator/gauge, oxygen mask/ nasal catheters
 - 4.6.4.1.3. suction machine: electrical/pedal waste basket, safety boxes, bed screens, kidney basin, 475ml x 5, bed pan, urinal, mobile examination light, plastic apron, drapes, rubber sheets, connectors, cushion bags
 - 4.6.4.1.4. Soiled utility room: soiled linen trolley, bin with lid, worktable with laminated top, wash tub (65l), general purpose trolley, two trays
 - 4.6.4.1.5. Furniture and fixtures: table, chair, stackable, without armrests, basket, waste-paper, metal, cabinet, patient chart holder, refrigerator, bedside cabinet, feeding table

4.7. Anesthesia Services

4.7.1. Practices

- 4.7.1.1. This standard are applicable to the following specialty centers: Surgery specialty center, Orthopedics specialty center, Neurology specialty center, Renal specialty center and Other centers which apply general or major anesthesia for surgical interventions
- 4.7.1.2. Anesthesia Services shall follow MoH& regional guidelines
- 4.7.1.3. At all times, at least one anesthetist shall be on-site
- 4.7.1.4. The conduct of the anesthesia and operation shall be monitored and recorded in line with the monitoring standards and formats
- 4.7.1.5. The protocols and guidelines used for anesthesia services shall be available and follow national guidelines
- 4.7.1.6. Anesthetic agents administered with the purpose of creating conscious sedation, deep sedation, major regional anesthesia, or general anesthesia shall be in accordance with anesthesia policies and procedures
- 4.7.1.7. The general anesthesia service shall be provided in the Operation theatre (OR), together with the surgical services

4.7.2. Premises

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

- 4.7.2.2. There shall be central oxygen system or a system where there is a continuous supply of charged Oxygen cylinders
- 4.7.2.3. The anesthesia store can be optional
- 4.7.2.4. Recovery Room shall be sited within the operating suit and has a minimum of:
 - 4.7.2.4.1. two beds with side protection,

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- 4.7.2.4.2. resuscitation equipment including a defibrillator on trolley, oxygen source with face mask and or nasal catheter,
- 4.7.2.4.3. ensures ease of communication and access for anesthesia department staff for close follow up

4.7.3. Professionals

- 4.7.3.1. All anaesthesia providers who administer and/or supervise the administration of general anaesthesia, major regional anaesthesia, or conscious sedation anaesthesia shall maintain current training in Advanced Cardiac Life Support
- 4.7.3.2. General or major regional anaesthesia shall be administered and monitored only by the following:
 - 4.7.3.2.1. An anaesthesiologist/ Bsc Anaesthetist or registered nurse anaesthetist or registered anaesthetist or physician resident, (anaesthesiology), a student nurse anaesthetist, a student anaesthetist under the supervision of an anaesthesiologist
- 4.7.3.3. Minor regional blocks shall be administered by the following registered professionals:
 - 4.7.3.3.1. An Anaesthesiologist/MSC Anaesthetist or A nurse anaesthetist, or A physician
 - 4.7.3.3.2. A medical intern, a physician resident, , or a student nurse anesthetist, or student anesthetist, or a health officer, or a registered nurse, midwife, or under the supervision of at least nurse anesthetist

4.7.4. Equipments, Materials & Supplies

- 4.7.4.1. shall have Anaesthesia supplies, equipment and safety systems
- 4.7.4.2. Time clock, Anaesthesia machine with ventilator, 2 vaporizers, and gas cylinders, Adult and paediatric anaesthesia circuits with filters, Mechanical ventilators, Worktable with laminated top, by oxygen source & portable oxygen machine, Resuscitation equipments, Refrigerator, Stools
- 4.7.4.3. Clips, pediatric, Resuscitation trolley, Syringe pump or infusion pump, Blood gas analyzer- optional fluid warmer-optional, Goggles and boots Patient monitor, ECG monitor, 3 leads electrode, Pulse oximeter, Temperature monitor, BP apparatus with different size cuffs
- 4.7.4.4. All medicines and supplies shall be available as per the national medicines list for this level of health facility

4.8. Intensive Care (Ic) Services-optional

4.8.1. Practices

- 4.8.1.1. This service standard shall be applicable to the following specialty centers: Surgery specialty center, Neurology specialty center, Renal specialty center, Cardiac specialty center
- 4.8.1.2. The ICU shall open 24 hours and 7 days a week with a available medical personnel with Advanced Life Support (ALS) training available round the clock with shift
- 4.8.1.3. The ICU shall have written policies and procedures that are reviewed at least once every 3 years and implemented. They shall include at least:

- 4.8.1.3.1. Criteria for admission to ICU, Criteria for discharge and transfer
- 4.8.1.3.2. list of procedures that registered physicians, who are certified/ accredited in intensive care, may or may not perform
- 4.8.1.3.3. 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
- 4.8.1.3.4. Infection control procedures and/or protocols as indicated under infection prevention standards

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- 4.8.1.3.5. A visitors policy that specifies visiting hours and number which subject to the discretion of the patient's physician or primary care nurse
- 4.8.1.3.6. policy on the removal of a patient's life support system
- 4.8.1.3.7. 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
- 4.8.1.3.8. Nursing functions shall be the responsibility of a licensed nurse and shall be accountable to the attending ICU physician
- 4.8.1.3.9. the patient's medical service record shall be integrated with the patient's over-all specialty center's record
- 4.8.1.3.10. A ratio of 2 patients to 1 nurse shall be available at a general ICU
- 4.8.1.3.11. 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
- 4.8.1.3.12. There shall be a mechanism in place based on professional type for the critical care service to have access to nutritional support services for advice on both enteral and parenteral nutritional techniques

4.8.2. Premises

- 4.8.2.1. The ICU shall be located in access restricted area of the center and well identified
- 4.8.2.2. The ICU shall be at least 6m x 7m in size that accommodate a maximum of 2 electrically or manually operated ICU patient beds fitted with full range of monitors and a screen
 - 4.8.2.2.1. The header of beds shall be 1 m away from the wall
 - 4.8.2.2.2. There shall be a 2m wide free traffic area by side of beds and between any of two beds
 - 4.8.2.2.3. 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
 - 4.8.2.2.4. There should be a separate physical area devoted to nursing management for the care of the intermediate patient (12 sq m area including nurse station)
- 4.8.2.3. Nurse station in the ICU shall include:
 - 4.8.2.3.1. full visual access to monitor admitted patients on monitors
- 4.8.2.4. The ICU shall have sanitizer hand wash basin around the entrance-exit door
- 4.8.2.5. 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 (need further discussion)
- 4.8.2.6. ICU shall have 2 toilet 1 for staff & 1 for patient

4.8.3. Professionals

4.8.3.1. The specialty center ICU shall be directed by a licensed anesthesiologist or intensivist or ICU trained internist (suggested-additional professional emergency & critical care/intensive professional by referring their scope to be addressed)

4.8.3.2. The physicians working in the ICU shall have been 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

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4.8.3.3. All practicing nurses in the ICU shall be trained and certified in basic cardiac life support and Nurse assistants assigned to ICU shall be oriented and trained on basic cardiac life support and critical care

4.8.4. Equipments, Materials & Supplies

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

4.8.4.1.1. The ICU beds shall have removable side protections; functional wheels; shall be easily adjustable to multipurpose positions

4.8.4.1.2. mechanical ventilator at least 2

4.8.4.1.3. Different size endotracheal tubes and tracheotomy sets, at least 4 sets, monitoring equipment, cardiac monitors including telemetry, Standard 12 lead EKG machines, external pacemakers (optional), defibrillators (minimum 1), Reliable Oxygen delivery systems, Oxygen regulator, at least 2 pulse oximeter, end-tidal carbon dioxide monitoring (optional), infusion pump, Laryngoscopes with different size blades, fundoscope, Mouth gags, different size Air ways, different size Resuscitation trolleys Endotracheal tubes, (different sets), Wheel chair Patient transport stretcher, Sphygmomanometer, with adult and pediatric cuffs, Stethoscopes: paediatric and adult, functional suction machine at minimum 1 as a backup, Nasal CPAP, Bed pan, Pacing boxes (at least 2) (for further discussion), minimum 1 Wall clock, Soiled cloth hampers, Patient screen per bed and IV stands, at least one per bed

4.9. Radiological Services (Optional)

4.9.1. Practices

4.9.1.1. Basic Radiology service should be available for specialty center, at a minimum includes X-Ray & ultrasound (Mandatory)

4.9.1.2. The radiology service shall have written policies and procedures that are reviewed regularly and implemented. These policies and procedures shall include at least:

4.9.1.2.1. Safety practices, Management of the critically ill patient, Infection control, including patients in isolation, Timeliness of the availability of diagnostic imaging procedures and the results, Quality control program covering the inspection, maintenance, and calibration of all equipment, emergencies in the radiological suite

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

4.9.1.4. There shall be documentation of the report for periodic radiation exposure dose readings for Radiation workers by the use of exposure meters or badge tests

4.9.1.5. Signed reports shall be filed with the patient's medical record and duplicate copies kept in the service unit and there shall be registration log book

- 4.9.1.6. Requests for x-ray examinations shall contain a concise statement of reason for the examination
- 4.9.1.7. X-ray films shall be labelled with minimum information such as date, name, age, sex, right/left marks, name of institute
- 4.9.1.8. Reporting forms shall have minimum information such as date, patient's name, age, sex, findings and name and signature of radiologist

4.9.2. Premises

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

4.9.3. Professional

- 4.9.3.1. The radiology service of the center shall be directed by a licensed radiologist and qualified /licensed radiology technologist
- 4.9.3.2. 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
- 4.9.3.3. A licensed radiology technologist or radiographer shall be present in the center at all times
- 4.9.3.4. A licensed professional nurse may be available in the radiology service to administer medications and perform other nursing care
- 4.9.3.5. A receptionist, cleaners shall be available in radiology service as full time

4.9.4. Equipments, Materials & Supplies

- 4.9.4.1. All medical equipments which shall be available for radiology services at Specialty center are indicated below:
 - 4.9.4.1.1. X-ray machine, Ultrasound, X-Ray viewing boxes, Dark room film processing baths (optional), Drier(optional),
 - 4.9.4.1.2. Radiation protection equipments: lead gloves, lead apron, lead goggle, and gonad shield
- 4.9.4.2. The X-Ray machine shall be regularly inspected, maintained, and calibrated; appropriate records of maintenance shall be maintained
- 4.9.4.3. Installation and un-installation of X-Ray machine shall follow the safety procedures set by the Ethiopian Radiation Protection Authority during all procedures

4.10. Medical Laboratory Services

4.10.1. Practices

- 4.10.1.1. The specialty center shall have a minimum of basic laboratory service working for 24 hours a day & 365 days a year
- 4.10.1.2. The specialty center laboratory service shall provide Basic Hematology, Bacteriology, Clinical Chemistry, parasitology, urinalysis & Serology test profiles
- 4.10.1.3. The specialty center laboratory shall have policies & procedures with respect to QMS & safety
- 4.10.1.4. The Specialty center laboratory shall maintain a record of all samples received
- 4.10.1.5. The laboratory for specialty center should establish an external quality control system with accredited agencies and shall participate nationally or internationally in EQA at least once yearly
- 4.10.1.6. The specialty center Laboratory shall produce report which shall contain the following:

- 4.10.1.6.1. All laboratory test result/reports shall have reference (normal) ranges
- 4.10.1.6.2. Files of reported results shall be retained by the laboratory
- 4.10.1.6.3. In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be contained in the medical record
- 4.10.1.6.4. test results shall be reported on standard forms to the following minimum information:
- 4.10.1.6.5. Patient identification (patient name, age, gender)
- 4.10.1.6.6. Date and time of specimen collection and the test performed and date of report

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- 4.10.1.6.7. 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
- 4.10.1.6.8. Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them
- 4.10.1.6.9. 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
- 4.10.1.6.10. When reports altered, the records shall show the time, date and name of the person responsible for the change
- 4.10.1.6.11. Safe disposal of samples shall be follow national lab safety guideline
- 4.10.1.6.12. No eating, drinking, smoking or other application of cosmetics in laboratory work areas or in any area where workplace materials shall be handled
- 4.10.1.6.13. No food or drink shall be stored in the laboratory & there shall be shall have PPE
- 4.10.1.6.14. There shall be a policy and procedure for regular calibration and running of control tests for laboratory equipments: semi-automated/ automated machines. Documentation shall be maintained
- 4.10.1.6.15. Laboratory shall have a documented and recorded programme of preventive maintenance which at a minimum follows the manufacturer's recommendations

4.10.2. Premises

- 4.10.2.1. The laboratory working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste materials
- 4.10.2.2. The laboratory shall have lighting, ventilation, water, waste and refuse disposal
- 4.10.2.3. The laboratory shall have monitored temperature room refrigerator. For which recordings shall be documented
- 4.10.2.4. Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access
- 4.10.2.5. The laboratory facilities shall meet at minimum the following general requirements:
 - 4.10.2.5.1. Reliable supply of running water
 - 4.10.2.5.2. The laboratory rooms shall have two separate sinks, one for general laboratory use and the other reserved for hand washing
 - 4.10.2.5.3. Continuous power supply
 - 4.10.2.5.4. Fitted with laboratory benches, Working surface covered with appropriate water proof, corrosive resistance materials, Laboratory stools(ergonomical chair)
 - 4.10.2.5.5. Laboratory furniture shall be capable of supporting anticipated loading and uses

- 4.10.2.5.6. Spaces between benches, cabinets, and equipment shall be accessible for cleaning
- 4.10.2.5.7. Lockable doors and cupboards, Closed drainage from laboratory sinks (to a septic tank or deep pit) and Separate toilets for staff and patients
- 4.10.2.6. 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.

FOR PUBLIC COMMENT