ETHIOPIAN STANDARD

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First edition

# **Comprehensive Specialized Hospital - Requirements**

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**FOREWORD** 

This Ethiopia Standard has been prepared under the direction of the Technical

Committee for Medical Care Practices (TC90) and published by the Ethiopian

Standards Agency (ESA).

The draft document (Working Draft, WD) has been submitted to the Secretariat by

the Ethiopian Food, Medicine & Healthcare Administration and Control Authority

(FMHACA).

A comprehensive specialized hospital shall provide services in accordance with this

standard and shall comply with the requirements. The standard shall enter into

force starting from the day of approval as Ethiopian Standard. This standard is

approved by the convention of ...... made on....Application of this standard is

MANDATORY with the intention to ensure the quality and public safety of health

services through standardized licensure and inspection procedures, to promote

access to quality health services and encourage health investment.

The Ethiopian Standard Agency recommends fulfilling all the requirements

stipulated under this document. It has to be noted that the fruition of fulfilling these

requirements will ensure the quality and safety of public health services through

availing appropriate infrastructure, deployment and retention of qualified and

competent health professionals that deliver best practices and by generating

innovative ideas and methodologies to solve healthcare problems.

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to the effort of developing Ethiopian Standards for Health Facilities.

Ato..... or W/0.....

Director General, Ethiopian Standard Agency

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## **SECTION ONE: GENERAL**

## 1. Scope

- 1.1. This Ethiopian standard shall be applicable for all comprehensive specialized hospitals 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 comprehensive specialized hospitals.
- 1.3. Requirements of a comprehensive specialized hospital are stipulated under section two to eight of this standard.

### 2. Normative References

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

- 2.1. Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No. 661/2009
- 2.2. Ethiopian Food, Medicine and Healthcare Administration and Control Regulation No 189/2010
- 2.3. Federal Hospitals Administration Council of Ministers Regulation No. 167/2009
- 2.4. The Ethiopian Hospital Reform and Implementation Guidelines, Mar 2010
- 2.5. Health Policy of Ethiopia
- 2.6. Drug Policy of Ethiopia
- 2.7. Commercial Code of Ethiopia
- 2.8. Criminal Code of Ethiopia
- 2.9. Medicines Waste Management and Disposal Directive No 2/2011
- 2.10. Ethiopian National Guideline for Health Waste Management, 2008
- 2.11. Ethiopian Building Proclamation, No. 624/2009

# 3. Terminologies and Definitions

#### 3.1

# **Appropriate Organ**

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

#### 3.2

## Authority

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

#### 3.3

#### **Proclamation**

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

#### 3.4

## **Appropriate Law**

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

#### 3.5

#### Person

Shall mean any physical or juridical person

#### 3.6

#### **Authorized Person**

Shall mean any hospital staff who is responsible for a given service

#### 3.7

## **Comprehensive Specialized Hospital**

Shall mean a health facility at tertiary level of healthcare which provides curative and rehabilitative services with a minimum capacity of 110 beds and provides at least gynecology and obstetrics, pediatrics, internal medicine, surgery, orthopedics, psychiatry, ophthalmology, ENT, dentistry, dermatology specialty services and emergency services that require advanced diagnostic facilities and therapeutic

interventions and shall have a minimum of additional two sub-specialties. It shall also provide promotive and preventive services including medical laboratory, imaging and pharmacy services and other related services stated under this standard. In case of government owned comprehensive specialized hospitals, the minimum bed capacity shall be 300 beds with at least four subspecialty services.

## **SECTION TWO: LICENSURE**

#### 2.1 General

- 2.1.1 This standard provides minimum requirements for the establishment and maintenance of comprehensive specialized hospital in order to protect the public interest by promoting the health, welfare, and safety of individuals.
- 2.1.2 No comprehensive specialized hospital shall be built or be functional by any person without prior permission of the appropriate organ.
- 2.1.3 The requirements set by this standard may not be waived unless otherwise for public interest and there is a substantial need for waiver. There shall be an assurance that the waiver will not create a hazard to the health and well-being of patients or others than the public interest.

## 2.2 Application for Licensure

- 2.1.1. No person shall operate a specialized hospital in Ethiopia, whether governmental, nongovernmental or private, without being licensed as required by Proclamation No 661/2009 and this standard.
- 2.2.1 Any person desiring to operate a specialized hospital shall:
  - (a) Apply to the Authority for a new license on forms prescribed by the Authority;
  - (b) Pay the prescribed license fee; and
  - (c) Provide additional information or document upon written request by Authority.
- 2.2.2 A person desiring to operate a specialized hospital shall consult the Authority on the plant design conformity with this standard before starting construction or renovation work.
- 2.2.3 An application for the initial licensure of specialized hospital shall be submitted to the Authority no later than ninety (90) days prior to the stated date of operation.
- 2.2.4 The first pre-licensing inspection shall be conducted by the Authority upon application without service fee. In case of failure to comply with this standard during the first pre-licensing inspection, the applicant has the right to reapply not more than two times upon paying service fee. If the

- applicant fails to comply with this standard for the third time, its application for licensure shall be suspended for three months.
- 2.2.5 The application for a specialized hospital license shall state each service for which the applicant undertakes to furnish hospital care and the number of beds allocated, and shall submit other information required including:
  - (a) Hospital location and address;
  - (b) Name and address of the applicant (if the applicant is an authorized delegate, written delegation letter shall be submitted);
  - (c) Previous owner, license number for existing specialized hospital;
  - (d) Name, qualification and address of the licensee/CCO;
  - (e) Total bed capacity;
  - (f) Surrounding environment/location;
  - (g) Number, type, work experience and original release of all technical staff;
  - (h) Number of administrative staff;
  - (i) Physical plant/Hospital design and its description;
  - (j) Proposed use of idle space;
  - (k) CEO of the hospital;
  - (l) Chain organization (organizational structure);
  - (m)Owner of the building;
  - (n) Professional license and registration certificate of the licensee and all other health professionals responsible for each service in the hospital;
  - (o) Any other requirements set by the Authority
- 2.2.6 All applicants shall demonstrate that they have the capacity to operate a hospital in accordance with this standard.
- 2.2.7 An application for a license or change in service shall be denied if the applicant cannot demonstrate that the premises, products, personnel and healthcare services are fit and adequate in accordance with this standard.
- 2.2.8 The Authority shall consider an applicant's prior history in operating a healthcare facility either in Ethiopia or in other countries in making licensure decision. Any evidence of licensure violations representing serious risk of harm to patients shall be considered by the Authority, as well as any record of criminal convictions representing a risk of harm to the safety or welfare of patients.

### 2.3 Initial/New Licensure

- 2.3.1 Every specialized hospital shall have a separate license. The authority shall issue each license in the name of the owner and chief clinical officer only for the premises and person named as applicant in the application and the license shall not be valid for use by any other person or at any place other than the designated in the license.
- 2.3.2 A specialized hospital license shall specify the following:
  - (a) Name and address of the specialized hospital;
  - (b) The name and professional license and registration number of the licensee;
  - (c) Ownership of the specialized hospital;
  - (d) Name of the owner;
  - (e) License number, issuance and expiration dates of the license;
  - (f) Signature and stamp of the Authority and
  - (g) Notices/reminders prepared by the Authority.
- 2.3.3 Prior to initial licensure of the hospital, the Authority shall conduct an on-site inspection to determine compliance with the applicable laws and standards governing specialized hospitals.
- 2.3.4 The Authority shall send a written report of the findings to the applicant no later than five (5) working days from the conclusion of the inspection.
- 2.3.5 A specialized hospital with deficiencies shall correct them within ninety (90) days upon receipt of the written report prior to the issuance of a license. The hospital shall submit written proof of correction of deficiencies.
- 2.3.6 The Authority may require the hospital to submit a written, signed and dated plan of correction to abate deficiencies cited no later than ten (10) working days following the receipt of the written report of findings.
- 2.3.7 The Authority shall conduct a follow-up inspection to determine correction of deficiencies cited within ten (10) days following the ninety (90) day correction period or upon notification from the hospital if the deficiencies have been corrected before the specified date.
- 2.3.8 The Authority shall deny the application for licensure to a specialized hospital that has not corrected deficiencies. The applicant shall reapply for licensure when deficiencies are corrected.
- 2.3.9 The Authority shall conduct an on-site inspection of the specialized hospital to assess the hospital's continued compliance with the laws and standards governing the hospital.

- 2.3.10 The Authority shall issue a replacement license where the originally issued license has been lost or destroyed upon the application supported by affidavit.
- 2.3.11 The original license shall be posted in a conspicuous place at reception at all times.

## 2.4 License Renewal Requirements

- 2.3.1 A license, unless suspended or revoked or under consideration in pending case, shall be renewable annually and the specialized hospital shall submit an application for license renewal to the Authority no later than sixty (60) days before the expiration date of the current license.
- 2.3.2 Without prejudice to article 2.3.1;
  - (a) Subsequent to submitting renewal application, the owner shall pay the prescribed license fee
  - (b) License renewal shall be made during the first quarter of each fiscal year (Hamle 1 to Nehassie 30) based on routine inspection findings over the year
  - (c) In case of failure to renew license within the prescribed period, license may be renewed upon paying penalty (50% of renewal fee) within one month
  - (d) In case of failure to renew license as per article 2.3.2 (c), license shall be considered as cancelled
  - 2.4.1 Every applicant who needs to renew a license shall:
    - (a) Apply to the Authority in the prescribed form;
    - (b) Pay the prescribed license renewal fee; and
    - (c) Provide additional information or document upon written request by the Authority.
  - 2.4.2 The Authority may conduct background checks on the applicant or licensee to determine his or her suitability or capability to operate or to continue operating a health care facility. Background checks shall consist of, but not be limited to, the following:
    - (a) Verification of licensure status;
    - (b) Verification of educational credentials;

- (c) Verification of residency status;
- (d) Verification of solvency; and
- (e) Contacts with Ethiopia and other country to determine outstanding warrants, complaints, criminal convictions, and records of malpractice actions.
- 2.4.3 The Authority shall renew a license for a specialized hospital in substantial compliance with the applicable laws and this standard.

# 2.5 Removal Permits, Change of Operation and Forfeiture of License

- 2.5.1 No specialized hospital or part thereof shall move from the premises for which a license has been issued to any other premises without first having obtained from the Authority a permit to move to the premises not covered by the license issued to the specialized hospital.
- 2.5.2 Without the prejudice to article 2.4.1, permit in change of address shall indicate the special conditions governing the moving of the specialized hospital or part of it as the Authority may find to be in the interest of the public health.
- 2.5.3 Without prior permission of the Authority, change of owner and/or licensee shall not be made
- 2.5.4 The hospital shall inform the Authority about the issue of change in operation or profession within thirty (30) days before the change. Change of operation means any alteration of services that is different from that reported on the specialized hospital's most recent license application.
- 2.5.5 The license shall not be assignable or transferable to any other person or place without the prior approval of the Authority and shall be immediately void if the specialized hospital ceases to operate, if its ownership or licensee changes, or if it is relocated to a different site.
- 2.5.6 When change of ownership or licensee of a hospital is contemplated, the hospital shall notify the Authority in writing at least thirty (30) days prior to the proposed date of change of ownership, giving the name and address of the proposed new nominee.

### 2.6 Suspension and revocation of a license

- 2.6.1 The Authority is authorized to suspend or revoke a license or order closure of a service/ unit within the specialized hospital or order removal of patients from the hospital where it finds that there has been a substantial failure to comply with this standard.
- 2.6.2 Without prejudice to grounds of suspension provided under relevant laws, the Authority shall suspend the license for 3 to 12 months in any of the following grounds:
  - (a) Where the specialized hospital is legally suspended;
  - (b) Where the specialized hospital Fails to practice medical ethics;
  - (c) Where the specialized hospital engages in rendering services which are outside the scope of the hospital for which the license is obtained;
  - (d) Where the specialized hospital fails to allow inspection pursuant to relevant law and this standard;
  - (e) Where the specialized hospital allows a practitioner, who has been suspended by Authority from practicing his profession;
  - (f) Where members of the Governing Board, the Chief Executive Officer, a Chief Clinical Officer, department head, or other key staff member are convicted of a serious offence involving the management or operation of a specialized hospital, or which is directly related to the integrity of the facility or the public health or safety;
  - (g) Where the specialized hospital fails to implement or fulfill comments and corrections given by the authority;
  - (h) Where the specialized hospital has shown any act which constitutes a threat to the public health or safety;
  - (i) Where the specialized hospital fails to observe laws relating to health services and this standard;
  - (j) Where the specialized hospital fails to submit relevant information required under this standard.
- 2.6.3 Without prejudice to grounds of revocation provided under relevant laws, the appropriate organ shall revoke the primary hospital license from one to two years on any of the following grounds;

- a. Where the license is proved to have been obtained by submitting false information;
- Allows a practitioner, who is not licensed pursuant to the appropriate law or who has been revoked by appropriate organ from practicing his profession;
- c. Where any of its permanent health personnel is found registered/ employed as a permanent staff in any other facility;
- d. Where the faults referred to in Article 2.5.2 have been committed for the second time;
- e. Where the license is found transferred or rented to another person;
- f. Where the specialized hospital changes types of services, name, address and the licensee without obtaining permission from the Authority;
- g. Where the license is not renewed in accordance with section 2.3 of this standard;
- h. Where the specialized hospital is legally closed or ceases operation;
- i. Where the specialized hospital is found operating while suspended by the Authority;
- j. Where the specialized hospital is found operating outside the scope of services stated under this standard;
- 2.6.4 At least 30 days prior to voluntary surrender of its license where approved by the Authority, or order of revocation, refusal to renew, or suspension of license, the specialized hospital must notify each patient and the patient's physician the intended closure.
- 2.6.5 Each license in the licensee's possession shall be the property of the Authority and shall be returned to the Authority immediately upon any of the following events:
  - (a) Suspension or revocation of the license;
  - (b) Refusal to renew the license;
  - (c) Forfeiture of a license; or
  - (d) Voluntary discontinuance of the operation by the licensee.

- 2.6.6 The license shall be returned to the Authority within five (5) working days from voluntary surrender, order of revocation, expiration, or suspension of license.
- 2.6.7 If the Authority determines that operational or safety deficiencies exist, it may require that all admissions to the specialized hospital cease. This may be done simultaneously with, or in lieu of, action to revoke license and/or impose a fine. The Authority shall notify to the hospital in writing of such determination.
- 2.6.8 The Authority shall order and ensure in collaboration with appropriate local health authorities the immediate transfer of patients from the specialized hospital whose license is revoked or suspended to a similar level health facility whenever it determines there is imminent danger to the patients' health or safety.
- 2.6.9 The Authority shall issue to the specialized hospital a written notification on reasons for denial, suspension or revocation of the license.

#### 2.7 Right to Fair Hearing

- 2.7.1 Any applicant made subject to action by the Authority for denial or suspension or revocation of license or who is assessed a fine under terms of this standard shall have the right to a fair hearing in accordance with relevant laws.
- 2.7.2 Fair hearing shall be provided/arranged by the authority whenever there is an official compliant submitted to this body.

#### 2.8 Information to be disclosed

- 2.8.1 Evidence based information received by the Authority through inspection and other true sources about the specialized hospital shall be disclosed to the public in such a way to indicate the public a decision maker or self regulator for its own health.
- 2.8.2 Whenever public disclosure is necessary, the Authority shall forward inspection reports to the specialized hospital at least 15 days prior to public disclosure.
- 2.8.3 Any citizen has the right to obtain information on the official profile of services of any licensed specialized hospital from the Authority.
- 2.8.4 Anyone who is interested in establishing a specialized hospital shall have the right to be provided with information concerning the standards required by the Authority at any working time.

### Section 3: Governance

## 3.1 Governing Board

- 3.1.1 A governmental comprehensive specialized hospital shall have Governing Board, Chief Executive Officer (CEO), Chief Clinical Officer (CCO) and necessary staffs indicated in this standard.
- 3.1.2 Except for Share Company where its Board of Directors shall be deemed as Governing Board, other private comprehensive specialized hospitals licensed otherwise under the Commercial Code shall not be required to have such organizational structure.
- 3.1.3 The Board of Management of nongovernmental specialized hospitals licensed according to Charities and Societies Proclamation No. 629/2009 shall be deemed as Governing Board.
- 3.1.4 The Board shall have the authority and responsibility for the direction and policy of the specialized hospital.
- 3.1.5 The Board of the hospital may issue its own rules and regulation of procedures.
- 3.1.6 Without prejudice to powers and duties provided by the relevant laws, the Board responsibilities shall include:
  - (a) Approve all policies and guidelines to be used in the hospital;
  - (b) Maintaining the specialized hospital's compliance with all applicable laws, its policies, procedures and plans of correction;
  - (c) Systems are in place for ensuring the quality of all services, care and treatment provided to patients;
  - (d) Designating and defining duties and responsibilities of the CEO save for the provision of relevant laws;
  - (e) Notifying the Authority in writing within thirty (30) working days when a vacancy in the CEO position occurs, including who will be responsible for the position until another person is appointed;
  - (f) Notifying the Authority in writing within thirty (30) working days when the CEO vacancy is filled indicating effective date of the appointment and name of person appointed;
  - (g) At least once a year, reviewing the medical care provided and the utilization of the hospital resources; and

- (h) Establishing a means for effective communication and coordination among the CEO, the medical staff and the various hospital departments.
- 3.1.7 Minutes of the Board Meeting shall be recorded, signed, and retained in the hospital as a permanent record.
- 3.1.8 The CEO shall be the secretary and non voting members of the Board.
- 3.1.9 The Board shall at least develop the following policies and procedures that are revised at least every three years:
  - (a) For human resource management;
  - (b) For ensuring the hospital is smoke- free area;
  - (c) For the declaration of death of patients which shall accommodate the patient's religious beliefs with respect to declaration of death. Such policies shall also include indicating the cause of death, medication given, examinations done, and practitioner who cares of the patient.
  - (d) For transfer of dead body to its family. If a patient dies in the facility, the body shall be handed over to the family with in a day unless conditions dictate otherwise.
  - (e) For patient visit which shall be in the best interest of patients, staffs, visitors and the hospital environment, including, but not limited to, protection from communicable diseases, exposure to deleterious and hazardous substances and equipments
- 3.1.10 The hospital shall develop and implement a complaint procedure for patients, families, visitors, and others. The procedure shall include, at least, a system for receiving complaints, a specified response time, assurance that complaints are referred appropriately for review, development of resolutions, and follow-up action.
- 3.1.11 There shall be an organizational chart of the specialized hospital and each service that shows lines of authority, responsibility, and communication between and within services.
- 3.1.12 There shall be a formal mechanism for communication among the Board, CEO, CCO and the necessary medical staff.
- 3.1.13 The specialized hospital shall establish a mechanism for involving consumers in the formulation of the hospital policy and implementation of activities.
- 3.1.14 The specialized hospital shall develop and implement a complaint procedure for patients, families, visitors, and others.

#### 3.2 Chief Executive Officer

- 3.2.1 The Manager of Specialized Hospitals formed as Charities and business organization shall be deemed as CEO.
- 3.2.2 The CEO shall be responsible for planning, organizing, and directing and controlling the day to day operation of the hospital. The CEO shall report and be directly responsible to the Board in all matters related to the maintenance, operation, and management of the hospital.
- 3.2.3 The CEO shall be responsible to ensure the operation of the hospital twenty-four (24) hours per day, seven (7) days per week.
- 3.2.4 Without prejudice to powers and duties provided in relevant laws, the CEO shall be responsible for:
  - (a) Providing for the protection of patients' health, safety, and well-being;
  - (b) Maintaining staff appropriate to meet patient needs;
  - (c) Developing and implementing procedures on collecting and reporting information on abuse, neglect and exploitation;
  - (d) Ensuring that investigations of suspected abuse, neglect or exploitation are completed and that steps are taken to protect patients; and
  - (e) Ensuring appropriate response to reports from the Authority;

#### 3.3 Chief Clinical Officer

- 3.3.1 Each specialized hospital shall have a Chief Clinical Officer who shall be accountable to the CEO.
- 3.3.2 The CCO shall oversee the clinical care provided by the hospital. In particular, the function of the CCO shall include:
  - (a) Facilitating communication among the medical staff members and with the hospital;
  - (b) Implementing the hospital and medical staff policies and procedures;
  - (c) Recommending the appointments to the medical staff and scope of clinical privileges;
  - (d) Ensuring the provision of continuing medical education;
  - (e) Taking other necessary actions necessary to govern the medical staff and relate to the hospital board.

### 3.4 Management Committee

- 3.4.1 A department head shall be assigned to each of the medical and administrative departments. The responsibility of department heads includes at least the following:
  - (a) Providing a written description of the services provided by the department
  - (b) Ensuring coordination and integration of these services with other departments when relevant
  - (c) Recommending space, staffing, and other resources needed to fulfill the department's responsibility
  - (d) Defining the education, skills, and education needed by each category of employee in the department
  - (e) Ensuring that there is an orientation and continuing education program for the department's employees
  - (f) Developing and implementing a department quality improvement program.
- 3.4.2 Any specialized hospital shall establish a Management Committee consisting of heads of the medical and administrative departments. The CEO shall be the chairperson of the Committee.
- 3.4.3 The Committee shall be an adviser of the CEO on the day to day management of the hospital.
- 3.4.4 The Committee shall meet upon regular basis. The minutes of the meeting shall be recorded and available to the Authority upon request.

# Section 4: Patient Rights and Responsibilities

#### 4.1 Informed Consent

- 4.1.1. Each hospital shall protect and promote each patient's rights. This includes the establishment and implementation of written policies and procedures for the patient right.
- 4.1.2. For undertaking any type of procedures and treatments an informed consent shall be required from the patient or patient's next of kin or guardian.
- 4.1.3. An informed consent may not be required during emergency cases or life threatening situations where the patient is not capable of giving an informed consent and his or her next of kin or guardian is not available.
- 4.1.4. Unless provided by the law or this standard or by the hospital policies and procedures that an informed consent shall be given in written form, an informed consent of the patient can be given orally or inferred from an act. A written consent shall be needed at least for the following:
  - (a) Surgery and invasive procedures;
  - (b) General anesthesia;
  - (c) Blood donation and transfusion;
  - (d) Clinical trials/Research;
  - (e) High-risk procedures or treatments (including Electro Convulsive Treatment, radiation therapy, chemotherapy).
- 4.1.5. The specialized hospital shall comply with relevant laws, national and international codes of ethics in the cases of vulnerable groups like children, women, geriatric patients etc when someone other than the patient can give consent.
- 4.1.6. Patient consent forms shall be available in all applicable locations at the hospital. The locations include at least the following:
  - (a) All nursing inpatient units
  - (b) All areas where surgery or invasive procedures are done
  - (c) Radiation therapy
  - (d) Outpatient chemotherapy area
  - (e) Psychiatry units where electroconvulsive treatment is done
  - (f) In the Blood or genetic testing laboratory

- 4.1.7. No photographic, audio, video or other similar identifiable recording is made of without prior informed consent of a patient or next of kin.
- 4.1.8. A specialized hospital shall establish and implement a process to provide patients and/or their designee appropriate education to assist in understanding the identified condition and the necessary care and treatment.
- 4.1.9. A specialized hospital shall document its assessment of each patient's ability to understand the scope and nature of the diagnosis and treatment needed.

## 4.2 Patient Rights

Every specialized hospital patient shall at least have the following rights:

- 4.2.1 To receive reasonable, respectful and safe access to health services by competent personnel that the hospital is required to provide according to this standard;
- 4.2.2 To receive treatment and medical services without discrimination based on race, age, color, religion, ethnicity, national or social origin, sex, sexual preferences, disabilities, diagnosis, source of payment or other status;
- 4.2.3 To retain and exercise to the fullest extent possible all the constitutional and legal rights to which the patient is entitled by law;
- 4.2.4 To be informed of the names and functions of all physicians and other health care professionals who are providing direct care to the patient. These people shall identify themselves by introduction or by wearing a name tag;
- 4.2.5 To receive, to the extent possible, the services of a translator or interpreter to facilitate communication between the patient and the hospital's health care personnel if the patient cannot understand the working language;
- 4.2.6 To receive from the patient's physician(s) or clinical practitioner(s) an explanation of his or her complete medical condition, recommended treatment, risk(s) of the treatment, expected results and reasonable medical alternatives in terms that the patient understands. If this information shall be detrimental to the patient's health, or if the patient is not capable of understanding the information, the explanation shall be provided to his or her next of kin or guardian and be documented in the patient's personal medical record;

- 4.2.7 To give informed, written consent prior to the start of specified non-emergency procedures or treatments only after a physician or clinical practitioner has explained specific details about the recommended procedure or treatment, the risks involved, the possible duration of incapacitation, and any reasonable medical alternatives for care and treatment in terms that the patient understands. If the patient is incapable of giving informed, written consent, consent shall be sought from the patient's next of kin or guardian or through an advance directive, to the extent authorized by law. If the patient does not give written consent, a physician or clinical practitioner shall enter an explanation in the patient's medical record;
- 4.2.8 To refuse medication and treatment and to be informed of the medical consequences of refusing treatment provided that he/she is mentally clear except conditions which are threatening the public health. The hospital shall develop a procedure on the management of the cases of patients who refuse treatment.
- 4.2.9 To be informed if the specialized hospital has authorized other health care and educational institutions to participate in the patient's treatment. The patient also shall have a right to know the identity and function of these institutions, and may refuse to allow their participation in the patient's treatment;
- 4.2.10 To be informed of the hospital's policies and procedures regarding life-saving methods and the use or withdrawal of life-support mechanisms. Such policies and procedures shall be made available promptly in written format to the patient, his or her next of kin or guardian, and to the public, upon request;
- 4.2.11 To be informed by the attending physician and other providers of health care about any continuing health care requirements after the patient's discharge from the hospital. The patient shall also have the right to receive assistance from the physician and appropriate hospital staff in arranging for required follow-up care after discharge;
- 4.2.12 To receive sufficient time before discharge to have arrangements made for health care needs after hospitalization;
- 4.2.13 To be informed by the hospital about any discharge appeal process to which the patient is entitled by law;

- 4.2.14 To be transferred to another facility only for one of the following reasons, with the reason recorded in the patient's medical record:
  - (a) The transferring hospital is unable to provide the type or level of medical care appropriate for the patient's needs. The hospital shall make an immediate effort to notify the patient's primary care physician and the next of kin, and document that the notifications were received; or
  - (b) The transfer is requested by the patient, or by the patient's next of kin or guardian when the patient is mentally incapacitated or incompetent;
- 4.2.15 To receive from a physician an explanation of the reasons for transferring the patient to another facility, information about alternatives to the transfer, verification of acceptance from the receiving facility, and assurance that the movement associated with the transfer will not subject the patient to substantial, unnecessary risk of deterioration of his or her medical condition. This explanation of the transfer shall be given in advance to the patient, and/or to the patient's next of kin or guardian except in a life-threatening situation where immediate transfer is necessary;
- 4.2.16 To be treated with courtesy, consideration, and respect for the patient's dignity and individuality i.e. the right to care that respects the patient's personal values and beliefs:
- 4.2.17 To be free from physical and mental abuse, neglect, sexual harassment, sexual violence and exploitation;
- 4.2.18 To be free from chemical and physical restraints that are not medically necessary, unless they are authorized by a physician for a limited period of time to protect the patient or others from injury;
- 4.2.19 To have personal and physical privacy during medical treatment and personal hygiene functions, such as bathing and using the toilet, unless the patient needs assistance for his or her own safety. The patient's privacy shall also be respected during other health care procedures and when hospital personnel are discussing the patient;
- 4.2.20 Confidential treatment information in the patient's records shall not be released to anyone except upon the following conditions;
  - (a) If the patient has approved the request,

- (b) If another health care facility to which the patient was transferred requires the information,
- (c) If the release of the information is required and permitted by law.
- (d) If the patient's identity is masked, the hospital may release data about the patient for studies containing aggregated statistics.
- 4.2.21 To know the price of services and procedures;
- 4.2.22 To receive a copy of the hospital payment rates, regardless of source of payment. Upon request, the patient or responsible party shall be provided with an itemized bill and an explanation of the charges if there are further questions. The patient or responsible party has a right to appeal the charges. The hospital shall provide the patient or responsible party an explanation of procedures to follow in making such an appeal;
- 4.2.23 To have prompt access to the information contained in the patient's medical record as per the medical record section stated under this standard, unless a physician prohibits such access as detrimental to the patient's health, and explains the reason in the medical record. In that instance, the patient's next of kin or guardian shall have a right to see the record. This right continues after the patient is discharged from the hospital for as long as a copy of the record is kept;
- 4.2.24 To obtain a copy of the patient's medical record, as per the standards set under the medical record section of this standard.
- 4.2.25 To have access to individual storage space in the patient's room for the patient's private use. If the patient is unable to assume responsibility for his or her personal items, there shall be a system in place to safeguard the patient's personal property until the patient or next of kin is able to assume responsibility for these items:
- 4.2.26 To receive a medical certificate in English or Amharic or in working language of the place where the hospital is located.
- 4.2.27 To present his or her suggestion or grievances, without fear of retribution, to the hospital staff member designated by the hospital to respond to questions or grievances about patient rights and to receive an answer to those grievances within a reasonable period of time without discrimination. The hospital shall post the names, addresses, and telephone numbers of ethical officers of the

- hospital and relevant external government agencies to which the patient can lodge their complaints and ask questions.
- 4.2.28 To be given a summary of these patient rights, as approved by the Authority, and any additional policies and procedures established by the hospital involving patient rights and responsibilities. The hospital shall be obliged to ensure that,
  - (a) The patient is informed of his or her rights during the admission process;
  - (b) This summary include the name and phone number of the hospital or hospital staff member to whom patients can complain about possible patient rights violations;
  - (c) This summary is provided in the patient's native language if 10 percent or more of the population in the hospital's service area speak that language;
  - (d) A summary of these patient rights is posted conspicuously in the patient's room and in public places throughout the hospital;
  - (e) Complete summary copies of the patient right is available at nurse stations and other patient care registration areas in the hospital.
- 4.2.29 To be informed and participate in decisions relating to their care and participates in the development and implementation of a plan of care and any changes.

#### 4.3 Patient Responsibilities

- 4.3.1 Every patient shall have the following responsibilities:
  - (a) To provide, to the best of the patient's knowledge, accurate and complete information regarding past medical history and issues related to the patient's health, including unexpected changes, to the health professional responsible for the patient's care;
  - (b) To follow the course of treatment and instructions proposed by the physician or an authorized health personnel or to accept the consequences if treatment instructions is refused;
  - (c) To report any changes in his/her condition or anything that appears unsafe to the responsible health professional;

- (d) To be considerate of the rights of other patients and to respect their privacy;
- (e) To respect their caregivers;
- (f) To fulfill the financial obligations as promptly as possible;
- (g) To keep all appointments and notify hospital or the appropriate person when unable to do so;
- (h) To observe the hospital policies and procedures, including those on smoking, alcohol or drug addiction, cellular phones, noise and visitors;
- (i) Be considerate of the hospital facilities and equipment and to use them in such a manner so as not to abuse them;
- (j) Not to litter the hospital premises.
- (k) To sign on "Against Medical Advice Notice" if he / she refuses the recommended treatment or intervention.
- 4.3.2 The list of a patient's rights and responsibilities shall be posted at various places of the hospital premises.

# **Section 5: Human Resource Management**

#### **5.1.** General Requirements

- 5.1.1. The hospital shall have Human Resource Department (HRD) which carries out the major functions of Human Resource Management (HRM).
- 5.1.2. Each service units of the hospital shall maintain a sufficient number of staff with the qualifications, training and skills necessary to meet patient needs as per this standard. The hospital shall be staffed twenty-four (24) hours a day and 365 days a year.
- 5.1.3. All recruitment and selection shall follow consistent approach using the recruitment and selection manual approved by the hospital management/governing board.
- 5.1.4. No health professional shall practice his/her profession in the hospital without having professional license from the appropriate organ. The hospital shall ensure that all health professionals recruited by the hospital are licensed as per the registration and licensing requirement of the appropriate organ
- 5.1.5. The hospital shall ensure that all health professionals have received a copy of professional code of ethics and scopes of practice
- 5.1.6. Each hospital shall ensure and maintain evidence of current active licensure, registration, certification or other credentials for employees and contract staff prior to staff assuming job responsibilities and shall have procedures for verifying that the current status is maintained.
- 5.1.7. Whenever a licensed health-care professional is terminated as a result of a job-related incident, the hospital shall refer a report of the incident to the appropriate organ.
- 5.1.8. Every health professional shall report to the hospital whenever he/she is infected with contagious diseases. The hospital shall also establish a mechanism for screening health professionals with contagious diseases. The health professional shall not practice his/her profession during the

- period of such infection and his/her rights provided under the relevant employment law and the hospital's HR manual shall be respected.
- 5.1.9. Each person involved in direct patient care shall have an occupational health screening by a physician or other qualified health professional prior to entering active status and at least once every five (5) years thereafter. A health professional shall not conduct health examination for himself/ herself.
- 5.1.10. Each health screening shall include a medical history, physical examination, and any indicated laboratory work and investigations.
- 5.1.11. A report, signed by an examining physician or other qualified health professional, shall be made of each examination.
- 5.1.12. The report of each examination shall be kept on file in the hospital and shall be open to inspection by the appropriate organ.
- 5.1.13. Each person who is involved in direct patient care and who acquires notifiable illness shall, prior to returning to duty, obtain certificate of fitness, as provided in the hospital's policies, that he or she may return to duty without apparent danger to any patient.
- 5.1.14. Immunization against communicable disease shall be required of all employees and all other persons who routinely come in contact with patients or patient areas. Immunizations shall be in accordance with current national immunization guidelines.
- 5.1.15. Each hospital shall maintain a current employment record for each staff. The record shall contain, at a minimum, information on credentials, health examination (fitness for duty), work history, current job description, evidence of orientation, in-service education/training and copies of annual evaluation.
- 5.1.16. All health professionals shall abide with health professionals Code of conduct and respective scope of practice.
- 5.1.17. There shall be a policy or procedures for all health professionals to report any suggestive signs of child abuse, substance abuse and /or abnormal psychiatric manifestations by the patients under their care.

## 5.2. Staffing Plan

- 5.2.1. The hospital shall avail as a minimum the staff requirement stated under this standard.
- 5.2.2. For additional staff a staffing plan shall be developed collaboratively by the different service units and management, which identifies the number and types of the staff
- 5.2.3. The planning process shall use recognizable process for estimating the staffing need like Workload Indicator for Staffing Need (WISN) method.
- 5.2.4. The staffing plan shall be reviewed on an ongoing basis and updated as necessary
- 5.2.5. The staffing plan shall define the following elements:
  - (a) The total number and types of staff needed for the hospital as a whole and for each service unit
  - (b) The total number and types of staff currently available for the hospital as a whole and each service unit
  - (c) The required education, skills, knowledge, and experience required for each position
  - (d) The process and time period for reviewing and updating the plan shall be indicated. (The plan is periodically reviewed and updated as required, but it shall be done at least every two years.)
  - (e) Expected/existing workload
- 5.2.6. The hospital shall have in effect a contingency plan for assuring adequate staffing at all times. The plan shall detail policies and procedures to regulate closure of available beds or services, if actual staffing levels fall below specified levels.
- 5.2.7. The Specialized hospital shall have at least the following summary of professionals and staffing:

Professionals required	Minimum number required
CEO	1
MD-Specialist (Licensee)	1
MD Specialist	(At least 26)

C 10	2
General Surgeon	3
Anaesthesiologist	2
Obstetrician and Gynaecologist	2
Internist	2
Pediatrician	3
Accident/ Emergency specialist	2
Orthopaedic surgeon	2
Psychiatrist	1
<ul> <li>Ophthalmologist</li> </ul>	1
<ul> <li>Pathologist</li> </ul>	1
<ul> <li>Dental specialist/ Dental surgeon</li> </ul>	1
<ul> <li>Radiologist</li> </ul>	2
Dermatologist	2
ENT specialist	2
MD Sub- Specialist	((At least 4 including Neonatologist))
Oncologist	1
Neurosurgeon	1
Uro-surgeon	1
GI- surgeon	1
Plastic surgeon/ trauma	1
Thoraxic surgeon	1
Pediatric surgeon	1
Cardiologist	1
Nephrologist	1
Neonatologist	1(mandatory)
Neurologist	1
Gastroenterologist	1
Endocrinologist	1
MD (General Practioner)	26
Midwives	24
Nurses (BSc) [ER (8), OPD (15), IPD (32), OR	81
(20), ICU (6)]	01
Nurse (Diploma) [ER (6), OPD (27), IPD (30),	89
OR (20), ICU (6)]	
BSc anaesthetist	10
Nurse anaesthetist	4(Optional)
Specialized nurses	
Ophthalmic nurse	3
Optometrist/refractionist	1
Intensive trained nurse	12
Nurse psychiatrist	1
Neonatology trained nurse	2
reoriatology damed harbe	-

• Others	
Dental professional	2
•	10
BSc in radiology	
Radiographer	4(optional)
Physiotherapist	4
Speech therapist	2
Occupational therapist	2
MSc in medical laboratory	1
Laboratory technologist	11
Laboratory technician	10(optional)
Pharmacist	10
Pharmacy technician	4(optional)
Nuclear medicine professionals	Refer nuclear medicine service standard
Environmental Health professional	2
Compliant handling officer	2
Health Information	4
Cleaners	40
Reception/Archive	20
Maintenance personnel (plumbing, electricity,	4
general maintenance services)	
Bio-Medical Engineer	4
Food and dietary	24
Morgue attendant	2
Social workers	2

NB: Human resource minimum requirement has been determined based on the mandatory services to be licensed as a comprehensive specialized hospital. In addition for detail requirements please refer the standard of each service unit.

## 5.3. Job Description and Orientations

- 5.3.1. All staffs shall be provided with current written job descriptions and be oriented to their specific job responsibilities at appointment
- 5.3.2. The job description shall include the title and grade of the position, specific function of the job, job requirement, reporting mechanism, evaluation criteria and description of job site and work environment.
- 5.3.3. The orientation program for all employees shall include three levels of orientation: hospital wide, service unit and job specific:
- 5.3.4. Orientation to hospital structure and administration shall be provided by hospital management.

- 5.3.5. Orientation to hospital policies, including all environmental safety programs, infection control, and quality improvement shall be provided
- 5.3.6. Staff members who are not licensed to independently practice shall have their responsibilities defined in a current job description.
- 5.3.7. Each hospital shall provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments.

  The orientation program shall include:
  - (a) Job duties and responsibilities
  - (b) Hospital's sanitation and infection control programs;
  - (c) Organizational structure within the hospital;
  - (d) Patient rights;
  - (e) Patient care policies and procedures relevant to the job;
  - (f) Personnel policies and procedures;
  - (g) Emergency procedures;
  - (h) The Disaster preparedness plan; and
  - (i) Reporting requirements for abuse, neglect or exploitation

#### **5.4.** Staff Education:

- 5.4.1. The hospital shall ensure that staffs receive training in order to perform assigned job responsibilities.
- 5.4.2. Each staff member shall receive ongoing Continuing Professional Development (CPD) to maintain or advance his or her skills and knowledge
- 5.4.3. The CPD shall be relevant to the setting in which they work as well as to the continuing advancement of the hospital
- 5.4.4. The hospital shall decide the type and level of training for staff in accordance with National CPD guideline and then carry out and document a program for this training and education.
- 5.4.5. The hospital shall provide and maintain evidence of CPD for staff. A record shall be maintained including dates, topics and participants
- 5.4.6. The hospital shall periodically tests staff knowledge, skill and attitude through demonstration, mock events and other suitable methods. This testing is then documented

#### 5.5. Medical Staff

- 5.5.1. There shall be a policy of verifying qualifications, restrictions to practice and professional registration of all new employees and have a system in place to check re-registration details. There shall be documentation of staff licenses and training certificates.
- 5.5.2. There shall be a policy that strengthens involvement of medical staff to take part in the ongoing Continuing Medical Education (CME).
- 5.5.3. Any medical service shall be organized under the directorship of a licensed professional who is a medical specialist in that medical service.
- 5.5.4. The medical staff shall be responsible to the governing authority for medical care and treatment provided in the hospital in accordance with the standards stipulated under the hospital administration and shall:
  - (a) Participate in a Quality Assurance/Performance Improvement program to determine the status of patient care and treatment;
  - (b) Abide by hospital and medical staff policies;
  - (c) Establish a disciplinary process for infraction of the policies
- 5.5.5. The medical staff shall see that there is adequate documentation of medical events by a review of discharged patients that shall insure that medical records meet the required standards of completeness, clinical pertinence and promptness or completion of following discharge
- 5.5.6. The medical staff shall actively participate in the study of hospital associated infections and infection potentials and must promote preventive and corrective programs designed to minimize their hazards
- 5.5.7. There shall be regular medical staff meetings to review the clinical works of the members and to complete medical staff administrative duties
- 5.5.8. The hospital shall have physicians available on the premises during working hours. The physician on call shall be duty bound to respond to calls.
- 5.5.9. Each patient shall be under the care of a physician, regardless of whether the patient is also under the care of an allied health professional practitioner authorized to practice.

### 5.6. Employee's Health

- 5.6.1. The hospital shall institute systems and processes that minimize employees' risks, protect employees and provide access to care when needed.
- 5.6.2. A comprehensive Occupational Health and Safety (OHS) program shall have the following components:
  - (a) Staff dedicated to coordinate OHS activities
  - (b) Policies and Procedures that define components of the program
  - (c) Training for staff on program components
- 5.6.3. The hospital shall have a designated individual qualified (occupational health and safety officer) to coordinate and develop the hospital's occupational health and safety activities full-time.
- 5.6.4. The standards outlined below define the core elements of an OHS program and specify minimum requirements needed to address OHS issues.
  - (a) The hospital shall have an occupational health and safety policy and procedures in place to identify, assess and address identified health and safety risks to staff and prevent those risks that will potentially compromise their health and safety.
    - The hospital assesses and documents safety risks through formalized, structured assessments that are done at regular intervals.
    - The assessments shall be logged in some format—for example a register or report
    - The information gathered from the assessment shall be documented and reported to the management (management committee and boards).
    - Interventions shall be designed and implemented to address the risks that are identified.
  - (b) The hospital shall establish a means of communicating to staff their risks and prevention measures or interventions.
  - (c) The hospital shall regularly monitor its occupational health and safety activities to assess how effective it has been in reducing risk.
  - (d) The hospital shall have written policies and procedures to manage manual handling risks.

- (e) The hospital shall have written policies and procedures which define how harassment, physical violence and/or aggression against staff (from patients, caregivers, other staff etc) are addressed.
- (f) The hospital shall provide services to staff to minimize work-related stress.
- (g) The hospital shall ensure all employees have access to full pre-employment health screening, covering Hepatitis B (including other relevant vaccine), TB status and are declared fit for their respective roles prior to employment. This shall include having:
  - Written instructions for health care workers to follow in notifying the hospital's administration of infectious status.
  - Documentary evidence of vaccination records for all health care workers employed, including Hepatitis B status for all health care workers who perform exposure-prone procedures. All staff are tested for and vaccinated against Hep B, if there is no evidence of previous vaccination produced.
- (h) The hospital shall ensure that all employees are provided with immunization services to protect against infectious/communicable diseases.
- (i) The hospital shall have a program in place to address injuries that could lead to the transmission of blood-borne viruses (needle stick and other injuries). The program shall include:
  - Measures to prevent needle stick and other injuries
  - Training on infection prevention techniques
  - Sharps risk reduction
  - Provision of post-exposure prophylaxis
  - Working hours and duty hours
- 5.6.5. The hospital shall provide personal protective equipment as per the sections of Infection Prevention and Control, and Sanitation and waste management of this standard
- 5.6.6. The hospital shall provide the following facilities to employees
  - (a) Cafeteria
  - (b) Break room (equipped with a television and other recreational equipments)
  - (c) Green area
  - (d) Library (equipped with books and computers with internet)
  - (e) Adequate toilet and shower facilities

# 5.7. Dress Code and Employee Identification Badge

For areas involving direct patient contact:

- 5.7.1. Footwear shall be safe, supportive, clean, and non-noise producing.
- 5.7.2. No open toe shoes shall be worn.
- 5.7.3. Artificial nails are prohibited. Natural nails must be kept short and jewelry must be kept to a minimum.
- 5.7.4. Hair must be worn in a way that prevents contamination and does not present a safety hazard
- 5.7.5. The dressing shall not interfere in any way the service provision
- 5.7.6. The hospital shall specify a particular style and/or color of uniform with different style/color code; separate for each human resource category, employee and trainees
- 5.7.7. The employee shall keep the uniform neat, wrinkle free and in good repair
- 5.7.8. The hospital shall be responsible for providing employee identification badges
- 5.7.9. The identification badge shall be worn at all times while at work and be easily visible, with name, profession and department facing outward.

# Section 6: Service Standards

# 6.1 Nursing Services

## 6.1.1 Practice

- 6.1.1.1 There shall be written policies and procedures of nursing services for routine taking and documenting vital signs, carrying out prescribed medication and nursing care to be rendered. Such policies and procedures shall be reviewed at least once every three years.
- 6.1.1.2 There shall be regulations that ensure nurses access to clinical supervision, support and participation in regular clinical services audit and reviews.
- 6.1.1.3 There shall be current clinical and administrative nursing policies and procedures available to all nursing personnel on each patient care unit at all times.
- 6.1.1.4 Nursing care service at different service delivery areas shall be directed by a licensed nurse with a minimum of BSc from recognized university and has at least two years of relevant experience.
- 6.1.1.5 Written copies of nursing procedure manual shall be available to the nursing staff in every nursing care unit. The manual shall be used at least to:
  - (a) Provide a basis for training programs to enable new nursing personnel to acquire local knowledge and current skills
  - (b) Provide a ready reference on procedures for all nursing personnel.
  - (c) Standardize procedures and equipment.
  - (d) Provide a basis for evaluation and study to insure continued improvements in techniques.
- 6.1.1.6 The hospital shall have established guidelines for verbal and written communication about patient care that involves nurses.
  - (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 includes reporting to physicians; nurse-to-nurse reporting; communication with other service units (laboratory, pharmacy, X-Ray, social work service), with patient and family education.

- 6.1.1.7 There shall be a procedure for standardized, safe and proper administration of medications by nurses or designated clinical staff including regular checks of patients' medications and proper documentation of administered medicines.
- 6.1.1.8 There shall be a system/ protocols in place to handle comatose or patients on life support system and also patients diagnosed to have communicable diseases.

## Nursing care: general patient services

- 6.1.1.9 Assessment and documentation of the holistic needs of patients; formulating, implementing goal-directed nursing interventions and evaluating the plan of nursing care and involvement of patients, their relatives or next of kin in decisions about their nursing care shall be done by licensed nurses.
- 6.1.1.10 All patients shall be under the supervised care of a licensed nurse at all times.
- 6.1.1.11 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; see the infection prevention section of this standard.
- 6.1.1.12 Nurses shall work with others to protect and promote the health and wellbeing of patients under their care.
- 6.1.1.13 Nurses shall be open and honest, act with integrity and uphold the reputation of their profession.
- 6.1.1.14 All nursing staff shall wear easily readable name tags that include their name and status, (such as licensed nurse, student, etc). The hospital shall have a policy to identify nursing unit exceptions to this procedure where necessary.
- 6.1.1.15 Nurses providing care and service at specific units like OR, ICU, Recovery, cardiac unit, etc., shall have proper orientation and minimum basic training on related nursing activities in each unit.
- 6.1.1.16 The nursing care plan shall be initiated upon admission of the patient and, as a part of the long-term goal, shall include discharge plans.
- 6.1.1.17 Each patient shall receive nursing care that is organized around ongoing, patient-specific care planning which is consistent with medical care planning. The planning shall include setting measurable goals with the patient and

- family to the extent possible. This planning, nursing interventions and patient responses shall be documented in the medical record.
- 6.1.1.18 There shall be a policy that empowers nurses to restrict number of visitors and/ or care takers based on the condition of the patient.
- 6.1.1.19 Documentation and completion of all patient's recording, registers, and reporting formats shall be the responsibility of licensed nurses in the unit.
- 6.1.1.20 A nurse shall write brief and pertinent nursing care plan and activity for each patient. It shall include at minimum:
  - (a) Medication, treatment, and other items ordered by authorized staff.
  - (b) Nursing care needed.
  - (c) Long-term goals and short-term goals.
  - (d) Patient and family teaching and instructional programs.
  - (e) The socio-psychological needs of the patient.
  - (f) Preventative nursing care.
- 6.1.1.21 Nurses shall not disclose confidential information relating to their patients.
- 6.1.1.22 Nurses shall explain and seek informed consent from their patients or their relatives/next of kin (for incompetent patients) before carrying out any procedure.
- 6.1.1.23 Nurses shall find solutions to conflicts caused by deep moral, ethical and other beliefs arising from a request for nursing service through dialogue with patients.
- 6.1.1.24 Patient discharge instructions shall be documented in the patient's medical record at the time of discharge.
- 6.1.1.25 Allergies shall be listed on the front cover of the patient's chart or, in a computerized system, highlighted on the screen.
- 6.1.1.26 Patients who require assistance in feeding shall be identified, and there shall be a mechanism in place to assure that assistance is provided.
- 6.1.1.27 For admitted patients, the nursing staff shall take and document the necessary vital signs as ordered and communicate to treating /attending physician immediately if abnormal findings observed.
- 6.1.1.28 Patients who required/prescribed to have special diet/ care shall be identified, labeled and there shall be a mechanism in place to ensure this procedure.

- 6.1.1.29 There shall be clear policy that state general and oral hygiene in particular of admitted patients as part of the nursing care.
- 6.1.1.30 There shall be written policies that state the procedures for communicating with laboratory, laundry and food service. The nurse shall communicate and follow up food orders, laboratory orders and specimens and patient transfers.
- 6.1.1.31 There shall be a policy that state reporting of any signs suggestive of child abuse, substance abuse and /or abnormal psychiatric manifestations by the nursing staff.
- 6.1.1.32 There shall be a policy or guideline that assigns nurses to different specific disciplines such as ENT, OR, ophthalmic clinic and others.

## Nursing care services related to pharmaceutical services

- 6.1.1.33 All medications administered by nursing personnel shall be prescribed by physician and/or any other authorized health professional and shall be administered in accordance with the prescriber orders.
- 6.1.1.34 Medications for individual patients shall not be removed from their original prescription containers by nursing personnel until the time of medicine administration.
- 6.1.1.35 Medicines packaged in unit dose containers shall not be removed from the containers by nursing personnel until the time of medicines administration. Such medicines shall be administered immediately after the dose has been removed from the container, and by the individual who prepared the dose for administration.
- 6.1.1.36 Each patient shall be identified prior to medicine administration. Medicines dispensed for one patient shall not be administered to another patient.
- 6.1.1.37 The nurse shall observe administration of prescribed medicines for those patients under nursing care who are taking oral medications.
- 6.1.1.38 Regarding self-administration of medicines, nursing personnel shall directly observe self-administration and implement policies and procedures developed by the drug and therapeutics committee.
- 6.1.1.39 There shall be a policy of reporting and documenting medication errors, product quality and adverse drug reactions by attending nursing personnel immediately to the prescriber and ADE focal person.

- 6.1.1.40 Medicines in patient care areas shall be maintained under proper conditions, as indicated under pharmaceutical service standards of this standard.
- 6.1.1.41 Medicines, needles and syringes in patient care areas shall be maintained under proper conditions as per the pharmaceutical service standards stated under this standard.
- 6.1.1.42 Nursing personnel shall return unfit-for-use medicines to the central medical store of the hospital for disposal.
- 6.1.1.43 Nursing personnel shall store and use needles and syringes in accordance with the infection prevention standards of this standard
- 6.1.1.44 There shall be a protocol that guides nurses copying the prescription of prescriber's order.

# Nursing care: use of restraints

- 6.1.1.45 The hospital shall have written policies and procedures regarding the use of physical restraints that are reviewed at least once every three years and implemented. They shall include at least the following:
  - (a) Protocol for the use of alternatives to physical restraints, such as staff or environmental interventions, structured activities, or behavior management. Alternatives shall be utilized whenever possible to avoid the use of restraints;
  - (b) A delineation of indications for use, which shall be limited to:
    - Prevention of imminent harm to the patient or other persons when other means of control are not effective or appropriate; or
    - Prevention of serious disruption of treatment or significant damage to the physical environment;
  - (c) Contraindications for use, including at least clinical contraindications, convenience of staff, or discipline of the patient;
  - (d) Protocols for notifying the family or guardian of reasons for use of restraints, and for informing the patient and requesting consent when clinically feasible; and
  - (e) Protocol for removal of restraints when goals have been accomplished.

- 6.1.1.46 Except in an emergency, a patient shall be physically restrained only after the attending physician or another designated physician has personally seen and evaluated the patient and has executed a written order for restraint.
- An emergency restraint procedure, beginning with the least restrictive alternative that is clinically feasible, shall be initiated by a licensed professional nurse only when the safety of the patient or others is endangered or there is imminent risk that the patient will cause substantial property damage. The attending physician or a licensed psychiatry nurse or other authorized professional shall be notified immediately and shall respond within one hour. An order shall be given if the use of restraints is to continue beyond one hour. The clinical condition of the patient shall be evaluated and documented by medical or licensed nursing personnel at least once every two hours.
- 6.1.1.48 In all cases, the attending physician or licensed psychiatry nurse or other authorized professional shall observe the restrained patient at least once every 24 hours to evaluate any changes in the patient's clinical status. This evaluation shall be documented in the patient record. If a physician has ordered the use of restraints, a subsequent order for the use of restraints shall not be required so long as its use is in compliance with the intent of the original order and hospital policy.
- 6.1.1.49 Interventions while a patient is restrained, except as indicated at (g) below, shall be performed by nursing personnel in accordance with nursing care policy. They shall include at least the following and shall be documented:
  - (a) Assessment for clinical status and reevaluation of need for restraints at least every two hours;
  - (b) Toileting at least every two hours with assistance if needed;
  - (c) Monitoring of vital signs; and
  - (d) Release of restraints at least once every two hours in order to:
    - Assess circulation and skin integrity;
    - Perform skin care; and
    - Provide an opportunity for exercise or perform range of motion procedures for a minimum of five minutes per limb.

- (e) Continuous or periodic visual observation based upon an evaluation of the patient's clinical condition.
- (f) Administration and monitoring of adequate fluid intake;
- (g) Adequate nutrition through meals at regular intervals, snacks, and assistance with feeding if needed;
- (h) Assistance with bathing as required, occurring at least once a day; and
- (i) Ambulation at least once every four hours if clinically feasible.
- 6.1.1.50 Licensed professional nursing staff shall evaluate and ensure appropriate monitoring and documentation of the effects of all psychotropic medications. These medications shall be administered only upon written physician orders as part of the patient's treatment plan and shall not be used as a method of restraint, discipline, or for the convenience of staff.

# Nursing care: Dying patient

- 6.1.1.51 There shall be a policy or a protocol that state the procedure to be followed for dead body care which at least contain:
  - (a) Confirmation of death by at least attending physician or any independent practitioner and the nurse giving care (at least 2 medical personnel),
  - (b) Care for the body shall be carried out according to the religion and culture of the patient as per the hospital protocol,
  - (c) If there is need of pathologic examination the request shall be sent to morgue,
  - (d) If there is document of consent for organ donation (i.e. cornea), the consent shall be sent to morgue
  - (e) The body shall be taken to morgue immediately,
  - (f) The time of death shall be documented on the patients chart,

### 6.1.2 Premises

- 6.1.2.1 Private room /space: for isolation or special care, with toilet room and shower,
- 6.1.2.2 Hand washing basin at each room,
- 6.1.2.3 Toilet rooms,

- 6.1.2.4 Procedure room: for nursing procedures,
- 6.1.2.5 Nurse changing room:
- 6.1.2.6 Nurses station: located in the middle of the wards with free access to all wards,

## 6.1.3 Professional

- 6.1.3.1 The nursing staff shall have a minimum of diploma from accredited college or university.
- 6.1.3.2 There shall be written discrete job descriptions that detail the roles and responsibilities of each nursing staff members at specific units like ICU, OR, CSR.
- 6.1.3.3 The hospital shall have in place a nursing workforce plan that addresses nurse staffing requirements, including, at a minimum:
  - (a) A nurse representative in each patient care unit or case team responsible for the operation of the professional nursing service 24 hours per day and 365 days a year.
  - (b) A daily staffing schedule that ensures at least one licensed nurse in charge and assigned exclusively to each patient care unit or case team on each shift;
  - (c) A provision that at least 100 percent of direct patient care for 24 hours in inpatient units on a hospital wide average be provided by licensed nursing personnel,
  - (d) A method for assessing each unit's additional nursing needs for each shift.
- 6.1.3.4 There shall be at least one licensed nurse in charge of each patient care unit at all times and this shall be indicated in the hospital's organizational plan. Additional staff shall be assigned by the hospital as required by the acuity levels.
- 6.1.3.5 Nurse staffing for inpatient patient care service within the hospital shall be in accordance with not more than 6 patients under one nurse for general inpatient care. However, for ICU and emergency there shall be one nurse for a maximum of two patients

- 6.1.3.6 There shall be effective policy that control nursing care by junior nurses, health assistants and nursing students shall be under direct supervision of a licensed nurse; all being accountable.
- 6.1.3.7 All nursing staff shall receive orientation, training and/or update at least annually including at least:
  - (a) Hospital's policies and procedures,
  - (b) Routine nursing procedures,
  - (c) Emergency procedures and
  - (d) Infection prevention and control.
- 6.1.3.8 **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:
  - (a) Patient injury rate;
  - (b) Medication process errors;
  - (c) Maintenance of skin integrity;
  - (d) Control of cross infections and nosocomial infection rates;
  - (e) Hospital-wide patient satisfaction with overall nursing care;
  - (f) Patient satisfaction with pain management.

## 6.1.4 Products

- 6.1.4.1 The following products shall be available for nursing care services.
  - (a) Specimen collection set
  - (b) Rubber Sheets
  - (c) Restraining equipment in accordance with the standards under the use of restraints and mental health services. E.g., cushion, belt, vest, long sleeve pullover, etc.,
  - (d) Patient Chart Folders
  - (e) Emergency resuscitation sets: airway, ambu bag of different size,
  - (f) 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
- (g) Nursing procedure equipments:
  - Dressing trolley
  - Dressing set,
  - Minor set,
  - Chest tubes and bottles,
  - Enema set,
  - IV stand,
  - Oxygen trolley,
  - Oxygen cylinder,
  - Oxygen regulator/gauge,
  - Oxygen face mask/ nasal catheters,
  - Suction machine: electrical/pedal,
  - Wheel chair,
  - Waste basket,
- (h) Soiled utility room:
  - Soiled linen trolley
  - Bin with lid
  - Worktable with laminated top
  - Wash tub (65L)
  - General purpose trolley, two trays

- Safety boxes,
- Bed screens,
- Kidney basin, 475ml x 5
- Bed pan
- Urinal
- Mobile Examination light,
- Plastic apron,
- Drapes,
- Rubber sheets,
- Connectors,
- Cushion bags,
- NG tube, Catheter
   (different type, poly, plain, etc), canuala of different gauge

- (i) Furniture and fixtures;
  - Table
  - Chair, stackable, without armrests
  - Basket, waste-paper, metal
  - Cabinet
  - Patient chart holder,

- Refrigerator,
- Bedside cabinet,
- Feeding table,
- IV stands

# 6.2 Patient flow

## 6.2.1 Practices

- 6.2.1.1 The hospital shall have a written protocol of patient flow which at least describes the following:
  - (a) How to refer patients to different level of health facilities
  - (b) How to handle patients referred from other health facilities
  - (c) The presence, roles and responsibility of a receptionist at the gate
  - (d) Triaging of patients
  - (e) How to get into emergency and delivery services
  - (f) How to get into regular outpatient case teams and chronic illness case teams
  - (g) How to be admitted if admission is needed
  - (h) How to get pharmacy, laboratory and other diagnostic services
  - (i) The process of discharge
  - (j) The procedures of payment for services
- 6.2.1.2 The hospital shall follow its written patient flow procedures
- 6.2.1.3 Except for laboring mothers, Central triage shall be carried out by a team of qualified professional as soon as a patient arrives at the hospital. Emergency cases shall be transferred directly to emergency service.
- 6.2.1.4 There shall be separate triaging for children and persons with disability within the central triage.
- 6.2.1.5 Triage at emergency service shall be carried out before any administrative procedures such as registration.

6.2.1.6 Patients identified as nonemergency cases in emergency service unit shall be transferred to central triage.

# 6.2.2 Premises

- 6.2.2.1 Service areas shall be labeled in bold at a recognizable location
- 6.2.2.2 The office layout shall be arranged in a way that ensures patient independence by labeling in bold and making related service provided in adjacent rooms
- 6.2.2.3 There shall be a clearly labeled reception and triage room.

# 6.2.3 Professionals

- 6.2.3.1 The hospital shall have runners to facilitate patient flow
- 6.2.3.2 Receptionists

# 6.2.4 Products

The following equipment are required

- (a) Wheelchairs
- (b) Stretchers with wheels

# 6.3 Outpatient Services

## 6.3.1 Practices

- 6.3.1.1 The outpatient services shall comply with the standards prescribed under patient rights and responsibilities standard
- 6.3.1.2 The hospital outpatient service shall have a central triage system
- 6.3.1.3 The outpatient service shall have policies and procedures regarding access, availability of service and networking
- 6.3.1.4 The outpatient service shall be available in working days for at least eight hours a day
- 6.3.1.5 The hospital may have a system for providing after-hour (non-working hour) follow up service.
- 6.3.1.6 Follow up clinic services, which shall be led by a specialist or sub-specialist, shall be available at least once a week for eight hours per discipline.
- 6.3.1.7 The hospital shall have a system to make follow up of patients by the same physician
- 6.3.1.8 The outpatient service shall have consultation, and functional intra and inter facility referral system which include at least:
  - Procedure for referring and receiving referral
  - List of potential referral sites with contact address (referral directory)
  - Referral forms
  - Referral tracing mechanism (linkage)
  - Feedback providing mechanism
  - Documentation of referred clients
  - Consultation forms
- 6.3.1.9 The medical assessment at outpatient services shall at least includes comprehensive medical and social history, physical examination, diagnostics impression as well as laboratory and other medical workups (x-ray, ultrasound, CT scan etc) when indicated.
- 6.3.1.10 The outpatient clinic shall have clinical protocols for management of at least common disease entities and locally significant diseases in line with the national and international guidelines.

6.3.1.11 The range of relevant treatment options and the clinical impression shall be fully described to client and/or their families and documented accordingly

## 6.3.2 Premises

- 6.3.2.1 The outpatient layout shall include the following:
  - a) Dedicated entrance
  - b) Waiting area: room /lobby preferably with public telephone, TV area, drinking fountain and gender specific toilet
  - c) Reception and recording area/desk
  - d) Dedicated patient consultation and examination rooms /cubicles for each specialty services
  - e) Room for minor procedures
  - f) Room for providing injections
  - g) Storage place for sterile supplies
  - h) Soiled utility
  - i) Staff room (for changing cloth)
  - j) Janitors closet
- 6.3.2.2 All rooms shall have adequate light, water and ventilation
- 6.3.2.3 Communication system shall be connected with major functional areas
- 6.3.2.4 The room arrangements of outpatient services shall consider proximity between related services
- 6.3.2.5 The outpatient clinical setup shall have easy access to pharmacy, laboratory and other diagnostic services.
- 6.3.2.6 The outpatient clinic shall be well marked and easily accessible for disabled clients, elderly patients, under five children and pregnant mother.
- 6.3.2.7 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 (inpatient, laboratory etc)
- 6.3.2.8 The outpatient clinics shall have fire extinguishers placed in visible area

### 6.3.3 Professionals

6.3.3.1 At least one general medical practitioner per discipline (Internal Medicine, Pediatrics, Surgery, Gynecology and Obstetrics) for the general outpatient service shall be assigned for eight hours in each working day

- 6.3.3.2 One specialist or sub-specialist per discipline (specialty) to run the respective specialized outpatient service shall be assigned
- 6.3.3.3 The actual number of personnel shall be determined by workload analysis using recognizable methods
- 6.3.3.4 The staff shall have regular supportive supervision by senior staff or peer review or case conferences every three months and it shall be documented

### 6.3.4 Products

- 6.3.4.1 Products that are specific to particular department are indicated under the specific discipline
  - a) Weighing Scale
  - b) Vital Sign and Diagnostic Set
    - Thermometer
    - Stethoscope
    - Sphygmomanometer
    - Fundoscope
    - Otoscope
    - Pulseoxymeter
    - Reflex hammer
    - Snellen's chart

- c) Refrigerator
- d) Dressing Set
- e) Minor Set
- f) Examination Coach
- g) Catheterization set
- h) Trolley
- i) Folding Screen
- j) X-Ray Film viewer

# 6.4 Inpatient Services

# 6.4.1 Practices

- 6.4.1.1 The inpatient service delivery shall comply with the patient rights section of this standard
- 6.4.1.2 The inpatient service shall be available 24 hrs of a day and 365 days a year.
- 6.4.1.3 The inpatient service shall have consultation and functional intra and inter facility referral system as prescribed under the outpatient service standards.
- 6.4.1.4 The inpatient service shall include at least the following services for admitted patients:
  - a) Taking comprehensive medical and social history, comprehensive physical examination and performing important laboratory & other medical workups upon admission and when indicated.

- b) Nursing care service over the 24 hrs of each day of admission until discharge
- c) Detailed round visits at least twice a week and daily business round by the attending physicians
- 6.4.1.5 The inpatient nursing care shall comply with the nursing service section of this standard
- 6.4.1.6 The inpatient service shall have clinical protocols for management of at least common causes of admission in the hospital
- 6.4.1.7 The hospital shall have a system to make follow up of patients by the same physician
- 6.4.1.8 The range of relevant treatment options, plans and the clinical impression shall be communicated to client and/or their families and documented accordingly
- 6.4.1.9 The inpatient service shall have quality improvement mechanisms that at least include conducting regular morning sessions among relevant health professionals
- 6.4.1.10 The hospital shall provide dietary service for patients who are admitted
- 6.4.1.11 The hospital shall provide a clean gown to admitted patients
- 6.4.1.12 The hospital shall secure the properties of admitted patients in a cabinet or room with shelves
- 6.4.1.13 The inpatient service shall have easy access to laboratory, diagnostic and pharmacy services as per their respective sections of this standard
- 6.4.1.14 Religious support shall be provided for admitted patients upon patient request and this shall not disturb the privacy, dignity and right of other admitted patients.
- 6.4.1.15 The inpatient service shall arrange the appropriate post discharge instructions and follow up for the patient
- 6.4.1.16 The hospital shall provide a post mortem care and morgue service to deceased
- 6.4.1.17 The hospital shall contact the municipality or responsible body for burial service if there is no family/guardian of the deceased.

#### 6.4.2 Premise

- 6.4.2.1 Inpatient service shall have the following rooms
  - (a) Wards separate for male and female
  - (b) Nursing Station per ward

- (c) Doctors office
- (d) Bathroom for patients per ward
- (e) Staff bathroom
- (f) Duty room
- (g) Clean utility room
- (h) Soiled utility room
- (i) Store
- 6.4.2.2 The number of beds per room shall not exceed six (6) with the following specifications
  - (a) Distance of bed from fixed walls shall be 0.9 m
  - (b) Distance between beds shall be 1.2 m
  - (c) Adult beds shall have 1m width and 2m length
  - (d) Each bed room shall have alarm
  - (e) The rooms shall have safe and continuous water supply, light and ventilation
  - (f) There shall be washing basins for each room

### 6.4.3 Professionals

- 6.4.3.1 Specialists and sub-specialists of the related discipline with a minimum of one shall be physically available during working hours in respective wards.
- 6.4.3.2 At least one general medical practitioner per discipline shall be physically available in all the shifts in respective wards.
- 6.4.3.3 One nurse for a maximum of six (6) patients per shift shall be available to provide nursing care services
- 6.4.3.4 Support staff such as runner, cleaner and telephone operator shall be available for 24 hrs a day
- 6.4.3.5 Actual number of professionals shall be determined based on the case load analysis of the hospital
- 6.4.3.6 Engineers/Technicians 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

## 6.4.4 Products

- 6.4.4.1 The following products shall be available for inpatient services. Products peculiar to specialty services are indicated in respective specialty standards stated in this document.
  - Beds with wheels
  - bed side cabinet
  - Bed pans
  - Urinal (Male and Female)
  - Bed Pan carriage
  - Bed pans washer and sterilizer
  - 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

# 6.5 Emergency Services

### 6.5.1 Practices

- 6.5.1.1 The emergency service including emergency surgical interventions shall be available 24hrs a day and 365 days a year.
- 6.5.1.2 The hospital shall have an emergency triage system. Triage shall be carried out before any administrative procedures such as registration.
- 6.5.1.3 Patients identified as nonemergency cases in emergency service unit shall be transferred to the central triage or respective outpatient services.
- 6.5.1.4 Infection prevention standards shall be implemented in the emergency room as per the IP standards stated under this standard
- 6.5.1.5 Every emergency patient shall get the service without any prerequisite and discrimination.
- 6.5.1.6 The hospital shall provide a complete emergency service at least to the level of its specialization

- 6.5.1.7 The emergency service shall have functional intra and inter facility referral system which encompasses SOP for selection of referral cases, referral directory, referral forms, referral tracing mechanism, feedback providing mechanism, documentation of referred clients and consultation forms.
- 6.5.1.8 If referral is needed it shall be done after providing initial stabilization and after confirmation of the required service availability in the facility where the patient is to be referred to.
- 6.5.1.9 If the patient to be referred needs to be accompanied by a physician or other professional on the way to another hospital, the hospital shall arrange an ambulance service and accompanying professionals to transfer the patient.
- 6.5.1.10Every procedure, medication and clinical condition shall be communicated to the patient or family member after responding for urgent resuscitation measures
- 6.5.1.11There 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
- 6.5.1.12The emergency service shall have a procedure for easy access to intensive care unit, pharmacy, laboratory and radiological diagnostic services 24hrs a day and 365 days a year as per their respective standards stated under this standard.
- 6.5.1.13For labor and delivery emergencies, the emergency service of the hospital shall have direct access with the delivery facility.
- 6.5.1.14There shall be a written protocol for emergency services and the provision of this service shall be done in accordance with the clinical protocols of the service
- 6.5.1.15The emergency service shall have clinical protocol for the initial management of at least the following emergency cases:
  - (a) Shock
  - (b) Bleeding
  - (c) Fracture and injuries
  - (d) Coma
  - (e) Seizure disorder
  - (f) Air way obstruction
  - (g) Cardiac emergencies
  - (h) Hypertension emergencies

- (i) Psychiatric emergencies
- (j) Acute diarrhea
- (k) Tetanus
- (l) Meningitis
- (m)Burn
- (n) Poisoning
- (o) Cerebrovascular accident
- (p) Acute abdomen

- 6.5.1.16Emergency referral system shall be strictly chained, controlled & managed by the emergency team of the hospital.
- 6.5.1.170ther service that assist the emergency service shall be available for 24 hrs with adequate staffing

## 6.5.2 Premises

- 6.5.2.1 The emergency room shall be located in a place where it is easily recognizable to the public and shall be labeled in bold.
- 6.5.2.2 The emergency premise shall be low traffic area and there shall be reserve parking place for ambulances.
- 6.5.2.3 The corridor to emergency rooms shall be stretcher friendly and spacious enough.
- 6.5.2.4 The emergency area shall be spacious enough ( $\geq$  193 m<sup>2</sup>) to provide a space for the following tasks:
  - (a) Triaging
  - (b) Accepting and providing immediate care including emergency procedures
  - (c) Admitting for a maximum of 24 hrs to provide emergency care (8 beds) equivalent to 67 square meters.
  - (d) Emergency pharmacy for emergency medicines, supplies and equipments
  - (e) Staff/duty room
  - (f) Toilet facilities separate for patients and staff
- 6.5.2.5 Beds shall be arranged as the description of inpatient beds' arrangement
- 6.5.2.6 The size of the door for the emergency room shall not be less than 1.5 meter
- 6.5.2.7 The emergency premise shall allow patient dignity and privacy.
- 6.5.2.8 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
- 6.5.2.9 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
- 6.5.2.10 Waiting area for attendants and caregivers

### 6.5.3 Professionals

- 6.5.3.1 The emergency service shall be directed by emergency medicine specialist or emergency medical service trained physician.
- 6.5.3.2 The team of emergency shall be changed every eight hours and the team composition during working and non-working hours shall have similar staffing pattern.
- 6.5.3.3 The emergency service shall be opened for 24hrs a day and 365 days a year being run by an emergency team. Each team for all the shifts shall contain a minimum of:
  - (a) Emergency trained physician or emergency medicine specialist
  - (b) Nurses
  - (c) Cleaners
  - (d) Runner
  - (e) Regarding pharmacy, laboratory and x-ray see their respective standards stated under this standard
- 6.5.3.4 At least one specialist or sub-specialist for each major discipline shall be available for emergency consultation on call bases.
- 6.5.3.5 The actual number of personnel required shall be adjusted based on Workload analysis.
- 6.5.3.6 All health professionals working in the emergency room shall be trained on at least cardio-pulmonary resuscitation
- 6.5.3.7 Rotation of staff shall not be a routine exercise for the emergency service.
- 6.5.3.8 Drill-exercise of emergency case management shall be conducted on regular bases among the teams working in the emergency service.
- 6.5.3.9 The staff shall have regular supportive supervision by senior staff or peer review or case conferences every three months and it shall be documented
- 6.5.3.10The hospital shall have personnel manual which also covers staff at the emergency services

### 6.5.4 Products

- 6.5.4.1 The emergency service shall have readily arranged emergency medicines and supplies on trolley.
- 6.5.4.2 There shall be at least two coaches at emergency room

- 6.5.4.3 There shall be at least eight beds to be used only for emergency admission
- 6.5.4.4 The emergency service shall have at least the following products.
  - (a) Emergency Bed with wheel
  - (b) Stretcher with wheel
  - (c) Wheelchair
  - (d) IV Stand
  - (e) EKG
  - (f) Suction machine
  - (g) Defibrillator
  - (h) Tracheotomy set
  - (i) NG tube
  - (j) Minor surgical set
  - (k) Different types of splints

- (l) Mobile examination light
- (m)Hot air oven
- (n) Oxygen supply: Oxygen cylinder with flow meter, trolley and nasal prongs
- (o) Examination Lamp
- (p) Resuscitation set on trolley
- (q) Intubation set
- (r) Ambu bags
- (s) Examination coach

## 6.6 Internal Medicine Services

### 6.6.1 Practices

- 6.6.1.1 There shall be written protocols and procedures which shall be enforced that establish the management of the medical conditions in the unit as well as consultation and transfer of patients admitted to this unit or other departments
- 6.6.1.2 For non-emergency medical condition the medical service shall be available during the regular working hours
- 6.6.1.3 For admitted patients the medical service shall be organized in such a way that it covers all the shifts.
- 6.6.1.4 Nursing functions shall be the responsibility of licensed nurses and shall be supervised by a nurse assigned by the licensed internist. Nurses practicing in the internal medicine service shall be accountable to the licensed internist.
- 6.6.1.5 The service shall have written policies and procedures that shall include
  - (a) Admission and discharge criteria specific to the service;
  - (b) Visitors policy that allows for 24 hour visitation by designated visitors and specifies the number of visitors permitted for each patient at any time
  - (c) Infection control specified under this standard and National and or Hospital IP guideline
  - (d) Transfer and referral of patients
  - (e) Monitoring and follow-up of patients
- 6.6.1.6 Every medical records shall be kept for each patient as specified in the medical records of this standard
- 6.6.1.7 Information contained in the medical record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis, diagnostic procedures, medication administration, and treatment. Refer to the medical record section of this standard.
- 6.6.1.8 The medical unit shall have a follow-up service for patients with chronic ailments.
- 6.6.1.9 Notifiable diseases shall be notified through the proper channel (to chief clinical officer or chief executive officer and hence to the FMOH)

- 6.6.1.10 The unit shall avail updated reference materials, treatment guidelines and manuals (e.g. National TB and leprosy, pain management, Malaria treatment, ART etc)
- 6.6.1.11 The patients and/or caretakers shall be included in the development of the nursing patient plan of care.
- 6.6.1.12 There shall be a system for clinical staff to refer patients directly to the social works unit.

### 6.6.2 Premises

- 6.6.2.1 The maximum capacity of inpatient room shall not exceed six patients or beds per room
- 6.6.2.2 Patient rooms shall be constructed to meet a minimum of 9 meter squares for single bed room
- 6.6.2.3 In case of multiple beds per room, the area per bed shall be 80 sq. ft
- 6.6.2.4 Dimensions and clearances- the dimensions and arrangements of rooms shall be such that there is a minimum of 0.9m (90cm) between the sides and foot of the bed and any wall or any other fixed wall construction. In multiple bed rooms a clearance of 1.2 meter shall be available at the foot of each bed or between beds to permit the passage of equipments and beds
- 6.6.2.5 The number of rooms and beds shall be as per the load, volume and nature of work performed.
- 6.6.2.6 The inpatient rooms for medical service shall be organized into different wards, the number of which depends upon the size and the degree of specialization of the medical service, available facilities, and the service needs.
- 6.6.2.7 The medical service unit shall have at least three isolation rooms for treatment of conditions that require isolation.
- 6.6.2.8 Patients in acute care shall be under direct observation in a room near the nurses' station.

- 6.6.2.9 In addition to the ward rooms, the internal medicine service shall have the following rooms and facilities:
  - a) A private area for counseling (examination room/office for physician);
  - b) Duty room/Station;
  - c) Meeting room;
  - d) Nurse station;
  - e) Utility rooms;
  - f) Procedure room,
  - g) Care after death room
  - h) Rooms for follow-up clinics
  - i) Store
  - j) Staff Toilets, showers and changing room and
  - k) Patient Toilet and shower at least one each per room.

### 6.6.3 Professionals

- 6.6.3.1 The internal medicine services shall be directed by a licensed internist.
- 6.6.3.2 There shall be qualified medical and nursing personnel in the medical service unit available at all times to meet the service needs
- 6.6.3.3 The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis)
- An internist or licensed independent practitioner shall be available (physically present) at all times in the adult medical service unit
- An internist or licensed independent practitioner shall be on duty or on call at all times. The physician on call shall be duty bound to respond to calls.
- 6.6.3.6 A licensed nurse shall be available at all times to assess, evaluate, and supervise the nursing care provided.
- 6.6.3.7 An internist or licensed independent practitioner shall be responsible for the follow-up clinics.
- 6.6.3.8 The internal medicine service shall have support staff such as cleaners and others available as per the service need

#### 6.6.4 Products

- 6.6.4.1 The hospital shall prepare an emergency medicine list in accordance with the hospital medicines and ensure their availability.
- 6.6.4.2 The medical OPD shall have the following supplies and functional equipment in addition to office furniture's
  - a) Torch, Otoscope, ophthalmoscope
  - b) Weighing scales for adults
  - c) Measuring board for measuring length and height
  - d) Tape meter, thermometer
  - e) Stethoscopes
  - f) Sphygmomanometer
  - g) X-ray viewer
  - h) Examination couch
  - Lumbar puncture, bone marrow aspiration (and biopsy) set, pleural ( peritoneal) biopsy set, liver biopsy set, renal biopsy set, cut down set, pericadiocentesis set, wide bore needles for thoracentesis
  - j) Hand washing basin
  - k) Spatula, K-Y jelly, surgical and disposable gloves, antiseptics, cotton, gauze
- 6.6.4.3 The inpatient service shall have the following supplies and functional equipments
  - a) Torch, Otoscope, ophthalmic diagnostic set with Snellen's chart
  - b) Weighing scales
  - c) Tape meter, thermometer, patella hammer
  - d) Stethoscopes and Sphygmomanometer
  - e) X-ray viewer
  - f) Examination couch, medicine trolley, Cup board
  - g) Lumbar puncture, Bone marrow aspiration set, pleural biopsy set, tracheostomy set, chest tube
  - h) EKG machine, defibrillator
  - i) Suction machine
  - j) Drip counters/Infusion pump, Tourniquets and IV stands
  - k) Oxygen cylinder, Flow-meters for oxygen, Nasal prongs catheters

- 1) Self inflating bags for respiratory support, Masks, endotracheal tubes,
- m) Laryngoscope
- n) Cannulas, Nasogastric tube
- o) Beds for patients and hand washing basin
- Nebulisers for administration of salbutamol (electricity driven, or oxygen driven or footpump driven)
- q) Equipment for pleural tapping and biopsy, pericardiocentesis, and paracentesis and drainage of ascites,
- r) Equipment for skin scrapings and biopsy of dermatological lesions, bone marrow trephine needles and slides and others
- s) Gastroscope, Colonoscope and Proctoscope
- t) Pulse oxymeter and Defibrillator
- u) Glucometer and glucostick
- v) Wheelchair
- w) Over bed table (for feeding)
- x) Bed side cabinet and bed curtain fixed with the roof and the ground
- y) Waste paper basket
- 6.6.4.4 The service shall have at least a general follow-up clinic that shall have the following supplies and functional equipments:
  - a) Torch, Otoscope, ophthalmic diagnostic set with Snellen's chart
  - b) Weighing scales
  - c) Tape meter, thermometer, patella hammer
  - d) Stethoscopes and Sphygmomanometer
  - e) X-ray viewer
  - f) Examination couch
- 6.6.4.5 Medicines and supplies shall be available in line with national medicines list

## 6.7 Pediatric Services

## 6.7.1 Practices

- 6.7.1.1 Pediatric emergency care shall be available 24 hours a day and 365 days a year.
- 6.7.1.2 Pediatric services shall have in-patient, out-patient and neonatal services
- 6.7.1.3 The hospital shall have pediatric intensive care services with full-fledged neonatal unit and this service unit shall have written protocols and procedures
- 6.7.1.4 The pediatric services shall have a plan to deal with internal disasters such as the arrival of one or more seriously injured patients
- 6.7.1.5 For non-emergency conditions of pediatric patients the service shall be available during regular working hours
- 6.7.1.6 Admitted patients shall receive services for 24 hours a day which shall be covered through rotation of health care providers
- 6.7.1.7 The service shall have written policies and procedures that shall include
  - (a) The age below which all patients must be admitted to a pediatric service;
  - (b) Admission and discharge criteria specific to the service;
  - (c) A visitors policy that allows for 24 hour visitation by designated visitors and specifies the number of visitors for each patient at any one time;
  - (d) Infection control as per the standard prescribed under this standard
  - (e) Transfer and referral of patients
  - (f) Safety measures for the purpose of preventing electrical and bodily injury to pediatric patients.
  - (g) Monitoring and follow-up of pediatric patients
- 6.7.1.8 There shall be an adult supervising when children under seven years of age are present in the recreation room or playroom.
- 6.7.1.9 The nursing assessment and care of each pediatric patient shall consider the patients developmental needs
- 6.7.1.10 The parents or guardians of pediatric patients shall be included in the development of the nursing patient plan of care

- 6.7.1.11 Immunization services shall be available in the pediatric unit and all children shall have their immunization status checked before discharge
- 6.7.1.12 The unit shall avail updated reference materials, treatment guidelines and manuals (eg. National TB, Malaria, ART etc.)
- 6.7.1.13 Medical records shall be kept in line with standards
- 6.7.1.14 Information contained in the medical record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis, diagnostic procedures, medication administration, and treatment.
- 6.7.1.15 Growth monitoring activities and nutritional advice and management shall be there.
- 6.7.1.16 The pediatrics unit shall have a follow-up service for patients with chronic ailments.
- 6.7.1.17 All children with notifiable diseases shall be notified through the proper channel (to chief clinical officer or chief executive officer and hence to the FMOH)
- 6.7.1.18 There shall be a system for clinical staff to refer patients directly to the social works unit.

### 6.7.2 Premises

- 6.7.2.1 Inpatient room capacity shall not exceed six patients (or beds) per room.
- 6.7.2.2 The hospital shall have pediatric intensive care unit that accommodate a minimum of four ICU beds.
- 6.7.2.3 Patient rooms shall be constructed to meet a minimum of 9 meter squares for single bed room
- 6.7.2.4 In case of multiple beds per room, the area per bed shall be 80 sq. ft
- 6.7.2.5 Dimensions and clearances- the dimensions and arrangements of rooms shall be such that there is a minimum of 0.9m (90cm) between the sides and foot of the bed and any wall or any other fixed wall construction. In multiple bed rooms a clearance of 1.2 meter shall be available at the foot of each bed to permit the passage of equipments and beds
- 6.7.2.6 Windows-each patient room shall have at least one window
- 6.7.2.7 Each room shall have a hand washing station, toilet and bath room

- 6.7.2.8 The pediatric premises shall include at least emergency unit, outpatient, inpatient and neonatal units.
- 6.7.2.9 The pediatric outpatient shall have a functional oral rehydration therapy corner
- 6.7.2.10 A minimum of 10 percent of the beds used for pediatric care shall be capable of functioning as isolation rooms.
- 6.7.2.11 Each pediatric unit shall have at least one playroom with recreation equipment and child-size tables and chairs.
- 6.7.2.12 The number and size of the rooms shall be adequate in relation to the volume and nature of the activity in the unit
- 6.7.2.13 Patients in acute care shall be under direct observation in a room near the nurses' station.
- 6.7.2.14 The following premises setup shall be available in the pediatric service.
  - (a) Neonatal unit: shall have at least the following rooms
    - Room for care of critical newborns
    - isolation room for infectious cases
    - Procedure room
    - Nurses station
    - Room for mothers
    - Milk preparation room
    - Kangaroo mother care room
    - Toilet and bath for Staff
    - Toilet and bath for mothers
    - Store room
    - Office for physicians
    - The arrangement of the rooms for the neonatal care shall avoid wind draft and shall be access limited.
  - (b) Pediatric OPD: shall have at least the following rooms:
    - Waiting area with safe playing ground
    - Examination Room(s)
    - Procedure room
    - Room(s) for follow-up clinic
    - Nurse station
    - Store

- Toilets for patients and staff
- (c) Pediatric emergency shall have at least the following rooms:
  - Space for triaging/ reception
  - Examination room
  - Resuscitation room with beds for initial management of patients and
  - ORT corner,
- (d) Pediatric in-patient shall have at least the following rooms:
  - Inpatient rooms
  - Procedure room
  - Room for severely malnourished patients
  - Nutritional supplement preparation room
  - Nurses station
  - Dark room
  - Isolation room,
  - Staff toilet and bath
  - Toilet and bath for patients and care takers
  - Store room
  - Office for physicians
- (e) Pediatric ICU shall have the following premises:
  - ICU room with 4 ICU beds,
  - Hand washing facility by entrance,
  - Nurse station,
  - Staff change room,
  - Toilet with shower,
  - Store,
  - The premises shall fulfill the requirements stated under general ICU section in this standard.

- (f) In addition, pediatrics services shall have:
  - Counselling room
  - Duty room
  - Meeting hall and
  - Room for inpatient pharmacy (shared)

### 6.7.3 Professionals

- 6.7.3.1 The pediatric service shall be directed by a licensed pediatrician.
- 6.7.3.2 There shall be adequate qualified medical and nursing professionals in the pediatric unit available at all times
- 6.7.3.3 The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis)
- 6.7.3.4 A physician or licensed independent practitioner shall be available (physically present) at all times in the pediatric unit
- 6.7.3.5 A licensed pediatrician shall be available at all times. The pediatrician on call shall be duty bound to respond calls.
- 6.7.3.6 The neonatal unit shall have at least the following professionals:
  - (a) Neonatologist,
  - (b) Pediatrician,
  - (c) Nurses with experience in neonatal care,
  - (d) Neonate caretakers/Feeders with training or experience and
  - (e) Others as required.
- 6.7.3.7 The pediatric ICU shall have at least the following professionals:
  - (a) Pediatrician (pulled),
  - (b) Nurse with ICU training or experience per two beds,
  - (c) Clinical nurse(s),
  - (d) Cleaners,
  - (e) Runner (pulled)
- 6.7.3.8 The nurse with administrative responsibility for nursing care in pediatrics shall be a licensed professional nurse with at least two years of experience in pediatrics.
- 6.7.3.9 There shall be adequate support staff available as per the service need.

### 6.7.4 Products

- 6.7.4.1 The pediatric emergency unit shall have the following equipment and supplies:
  - a) Resuscitation stretcher, examination couches, beds for emergency services,
  - b) X-ray viewer,
  - c) Sphygmomanometer (pediatric and adult sizes), stethoscope, thermometer, weight scale, tape meter, Torch, Otoscope, ophthalmoscope, patella hammer,
  - d) Oxygen cylinder with flow meter,
  - e) Nasal prongs catheters,
  - f) Self inflating bags for respiratory support,
  - g) Masks (infant size, child size, adult size),
  - h) endotracheal tubes (pediatric and adult sizes),
  - i) laryngoscope
  - j) Equipment for intra-osseous fluid administration
  - k) Glucometer with glucosticks,
  - l) pulse oximetery,
  - m) EKG machine and its supplies,
  - n) Cardiac monitor (optional),
  - o) lumbar puncture set,
  - p) minor set,
  - q) chest tube set,
  - r) tracheostomy set
  - s) Suction machine,
  - t) medicine trolley, Cup board
  - u) Hand washing basin
  - v) Nebulizers (electricity driven, or oxygen driven or manual)
  - w) Spacers with masks for sprays,
  - x) Consumables:
    - Butterflies and/or cannulas of paediatric size,
    - NG-tubes and urinary catheters (pediatric size),
    - Gloves (surgical and disposable),
    - antiseptics (alcohol, savlon, iodine), cotton, gauze, K-Y jelly,

- Spatula,
- y) Emergency medicines as per the national medicine list.
- 6.7.4.2 The pediatric OPD shall have the following functional equipment and supplies:
  - a) Diagnostic equipment: Torch, Otoscope, ophthalmoscope, reflex hammer,
  - b) Weighing scales for children and infants,
  - c) Measuring board for measuring length (lying for infants) and height (standing for older children),
  - d) Measuring tape, thermometer,
  - e) Stethoscopes,
  - f) Sphygmomanometer (pediatric and adult sizes),
  - g) X-ray viewer,
  - h) Examination couch,
  - i) Lumbar puncture, Bone marrow aspiration set, pleural biopsy set,
  - j) Hand washing basin,
  - k) Consumables: Spatula, KY Jelly, Surgical and disposable gloves, antiseptics, cotton, gauze
- 6.7.4.3 The pediatric inpatient shall have the following functional equipment and supplies:
  - a) Diagnostic equipment: Torch, Otoscope, ophthalmoscope, reflex hammer,
  - b) Weighing scales for children and infants,
  - Measuring board for measuring length (lying for infants) and height (standing for older children),
  - d) Measuring tape, thermometer,
  - e) Stethoscopes and Sphygmomanometer (pediatric and adult sizes),
  - f) X-ray viewer,
  - g) Examination couch, medicine trolley, Cupboard,
  - h) Lumbar puncture, Bone marrow aspiration set, pleural biopsy set,
  - i) EKG machine and its supplies,
  - j) Suction machine,
  - k) Drip counters,
  - l) Infusion pump,
  - m) Tourniquets,
  - n) IV stands,

- o) Radiant or Heat source,
- p) Beds for patients, mothers and croup tents
- q) Oxygen cylinder, Flow-meters for oxygen
- r) Nasal prongs catheters
- s) Self inflating bags for respiratory support,
- t) Masks (infant size, child size, adult size)
- u) endotracheal tubes (pediatric and adult sizes), laryngoscope
- v) Equipment for intra-osseous fluid administration
- w) Nebulizers for administration of salbutamol (electricity driven, or oxygen driven or foot pump driven)
- x) Spacers with masks for administration of metered doses (spray) of salbutamol
- y) Consumables: Spatula, K-Y jelly, Surgical and disposable gloves, Butterflies and/or cannulas of pediatric size, NG-tubes-pediatric size, antiseptics, cotton, gauze,
- z) Emergency mediciness as per the national medicine list.
- 6.7.4.4 Pediatric intensive care unit (PICU) shall have the following functional equipments and supplies:
  - a) Cardiorespiratory monitor,
  - b) Continuous positive airway pressure apparatus,
  - c) ICU bed,
  - d) Pulse oximeter,
  - e) Ventilator,
  - f) Glucometer,
  - g) Perfuser,
  - h) Infusion pump,
  - i) Baby weighing scale,
  - j) Incubators,
  - k) X-ray viewer,
  - l) Diagnostics: Torch, Otoscope, ophthalmoscope, Stethoscopes, thermometer
  - m) Measuring board for measuring length, Measuring tape,
  - n) medicine trolley, Cup board
  - o) Suction machine,

- p) Tourniquets,
- q) IV stands,
- r) Radiant warmers,
- s) Refrigerator,
- t) Hand washing basin,
- u) Medicine cupboard,
- v) Oxygen cylinder, Flow-meters for oxygen, Nasal prongs catheters, Self inflating bags for respiratory support, Masks (infant size), endotracheal tubes (new born sizes), laryngoscope

# w)Consumables:

- Butterflies and/or cannulas of paediatric size
- NG-tubes-paediatric size, umbilical catheters
- x) Emergency medicines as per the national medicine list.
- 6.7.4.5 The neonatology unit shall have the following equipment:
  - (a) Neonatal bed/cradle,
  - (b) Incubator,
  - (c) Oxygen source,
  - (d) Baby weighing scale,
  - (e) Cardiorespiratory monitor,
  - (f) Pulse oximeter,
  - (g) Glucometer,
  - (h) Infusion pump,
  - (i) Phototherapy light with bed,
  - (j) X-ray viewer,
  - (k) Diagnostics: Torch, Otoscope, ophthalmoscope, Stethoscopes, thermometer
  - (l) Measuring board for measuring length, Measuring tape,
  - (m) Examination couch,
  - (n) Medicine trolley,
  - (o) Medicine Cup board,
  - (p) Lumbar puncture,
  - (q) Suction machine,
  - (r) Tourniquets,
  - (s) IV stands,

- (t) Exchange transfusion sets,
- (u) Radiant warmers,
- (v) Oxygen cylinder with flow-meters,
- (w) Nasal prong catheters,
- (x) Self inflating bags for respiratory support,
- (y) Masks (infant size),
- (z) endotracheal tubes (new born sizes),
- (aa) laryngoscope (new born size),
- (bb) Refrigerator,
- (cc) consumables:
  - Butterflies and/or cannulas of paediatric size,
  - NG-tubes-paediatric size,
  - Umbilical catheters
- (dd) Beds for mothers,
- (ee) Mobile X-ray machine,
- 6.7.4.6 Medicines and supplies shall be available in line with hospital's medicine list.

# 6.8 Surgical Care Services

### 6.8.1 Practices

- 6.8.1.1 Comprehensive emergency surgical service shall be available 24 hours a day, 365 days a year,
- 6.8.1.2 Services for non-emergency elective surgical cases shall be available only when all the necessary experts are available;
- 6.8.1.3 There shall be written protocols and procedures for admissions and discharges with follow up.
- 6.8.1.4 There shall be protocols for the management of the surgical conditions in the unit.
- 6.8.1.5 There shall be protocols for consultation and transfer of patients admitted to this unit and to other departments.
- 6.8.1.6 There shall be a clear policy for handling emergency surgical conditions. This service shall be available 24 hours a day throughout the year.

- 6.8.1.7 The hospital shall have emergency surgical services integrated with the general emergency service.
- 6.8.1.8 The admission process for emergency surgery shall be done by the emergency/ duty physician with consultation to the duty surgeon.
- 6.8.1.9 The admission process for elective surgery shall be done by the respective surgeon in consultation with the anesthesia department and with the other departments as needed.
- 6.8.1.10 For admitted patients the surgical service shall be organized in such a way that it covers all the shifts.
- 6.8.1.11 There shall be a mechanism of interdepartmental consultations with surgical unit for which the surgeon on duty shall be responsible.
- 6.8.1.12 Surgical records shall be kept for each patient and the patient's surgical record shall be integrated with the patient's over-all hospital record.
- 6.8.1.13 All 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.
- 6.8.1.14 The preoperative diagnosis shall be recorded in the medical record for all patients prior to surgery.
- 6.8.1.15 The surgeon shall explain the disease condition, possible surgical intervention and outcome possibilities in clear, simple and understandable terms to the patient and/or family.
- 6.8.1.16 Except in life-threatening emergencies, the 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 surgeon's clinical judgment.
- 6.8.1.17 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.
- 6.8.1.18 The nursing care of patients undergoing 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.
- 6.8.1.19 Operative reports shall be written in the patient's record and in the OR registration book immediately after surgery and include at least the following:
  - (a) Patient identification,
  - (b) Pre-operative diagnosis,
  - (c) Procedure performed,
  - (d) Findings during surgery,
  - (e) Post-operative diagnosis,
  - (f) Surgical specimens removed,
  - (g) Date and time operation started and ended,
  - (h) Name of surgeon, anesthesiologist/anesthetist, scrub nurse, and any assistants,
  - (i) Signature of the surgeon
  - (j) Immediate post-operative orders explicitly in the order sheet.
- 6.8.1.20 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 surgery.
- 6.8.1.21 There shall be processes and policies defining the appropriate safety before, during and immediately after surgery, including at least the following:
  - (a) Aseptic technique,
  - (b) Sterilization and disinfections,
  - (c) Selection of draping and gowning,
  - (d) Counting of sponges, instruments, and needles
- 6.8.1.22 The surgeon shall fill the pathology form and the specimen container shall be labeled properly. The container shall be leak proof with lid & filled with 10% formalin.
- 6.8.1.23 The specimen shall be sent to the pathology department by the OR staff.

- 6.8.1.24 There shall be a policy for preparing and availing appropriate and properly functioning supplies, equipment, and instruments available for all surgeries performed according to the country standard.
- 6.8.1.25 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 postanesthesia 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 professional in the following order: Anesthesiologist, Surgeon, Anesthetist or General Practitioner,
  - (e) The nurse in the recovery room shall inform the ward and the ward nurse shall transfer the patient with the signed transfer note.
- 6.8.1.26 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 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.
- 6.8.1.27 The hospital shall have clear protocol for surgical activities to be done at outpatients level, surgical referral clinics, follow up clinics, minor operations and orthopedic procedures

- 6.8.1.28 There shall be no time left without having general surgeon or physician attending the surgical unit.
- 6.8.1.29 There shall be a policy or procedure that clearly shows at least one surgeon shall be on call/ on duty to respond for emergency surgical requests.
- 6.8.1.30 There shall be a mechanism that the surgeon shall be available within 30 minutes upon call.
- 6.8.1.31 All patients in surgical unit shall be attended by registered nurse all the time with supervision by duty physician.
- 6.8.1.32 There shall be a mechanism by which the surgical unit provides board certificate in response to hospital medical board request. The board shall be composed of, at minimum, three specialist surgeons one of them being the treating one.
- 6.8.1.33 Emergency call access to each bed in the wards and recovery room shall be in place; at switches for emergency calls (nurse alarms) shall be placed accessible to beds

#### 6.8.2 Premises

- 6.8.2.1 A specialized hospital shall have a minimum of seven (7) operating theatres, one of which shall be dedicated for septic procedures.
- 6.8.2.2 Surgical service shall be composed of operation room, recovery room, the surgical inpatient wards and central sterilization room (CSR).
- 6.8.2.3 The operation room shall have operation theatres, changing rooms with lockers, nurse station, registration room, staff tea room, anesthesia store, consumable materials store, one general store, staff toilets, shower stands, offices, clean and soiled utility rooms, duty rooms and cleaners' room.
- 6.8.2.4 The operation room shall be readily accessible to the emergency service and inpatient wards.
- 6.8.2.5 Operation Room or Surgical Suite shall be access restricted where 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.
- 6.8.2.6 Operation Theatre:

- (a) 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.
- (b) The ceiling shall be monolithic, scrub-able and capable of withstanding chemicals. Cracks or perforation in these ceilings are not allowed.
- (c) Floors and walls penetrated by pipes, ducts and conduits' shall be tightly sealed.
- (d) 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.
- (e) There shall be drainage on the floor,
- (f) There shall be at least six fixed electric outlets in each theatre with cover,
- (g) The entrance and exit doors to the theatre shall be fitted with self-closing double doors.
- (h) There shall be at least one ceiling operation light and one mobile operation light for each operation table,
- (i) Glass cabinets and shelves shall be available,
- (j) The OR shall be cleansed and disinfected after each operation and thoroughly cleansed weekly. UV lights shall be installed in the OR.
- (k) Appropriate temperature shall be maintained in the operation theatre (considering the climatic conditions of the hospital location).

### 6.8.2.7 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 four theatres, it shall be wide enough to accommodate four staff scrubbing simultaneously.
- (b) Scrub area shall have direct access to the operating room,
- (c) Scrub area shall be provided with multiple sinks or with wide sink and taps for running (warm) water and mirror(s) above each sink. The taps for running water for scrubbing shall be hand free to be manipulated with elbow or knee joint. (e.g., long arm of valve gate to be manipulated with elbow or knee joint.)

### 6.8.2.8 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,

# 6.8.2.9 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) There shall be a space or corridor (Holding bay) to keep and observe preoperative patients until called to theatre.

# 6.8.2.10Staff Change Rooms

- (a) Suitable separate changing rooms shall be available and clearly labeled for male and female,
- (b) Each changing room 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) Each changing room shall be provided with hand wash basins.
- (g) For each changing room, there shall Toilets and shower stands.

### 6.8.2.11Set-up Area (optional):

(a) There shall be a set –up area where suture materials and other supplies and 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
- 6.8.2.120 perating 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 ready in case of power failure.
  - (b) Equipments shall always be stored at the same space/location and properly labeled.
  - (c) Shelves and cabinets.
- 6.8.2.13Operating 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.
- 6.8.2.14Clean Utility, Surgical Suite: There shall be a room allocated for storage of IV fluids, clean linen, medicines and other sundry items. The following requirements shall be fulfilled:
  - (a) Shall be situated where OR staff have easy access to the clean utility store.
  - (b) Washable metallic 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  $^{\circ}$ C.
  - (e) Sinks, cabinets and shelves.
- 6.8.2.15Soiled Utility/Sluice room shall be available with the following requirements:

- (a) This room shall be located at the rear side of the OR.
- (b) This room shall be for keeping contaminated materials until they are taken for disposal.
- (c) Sharp containers, leak proof containers with lids shall be available, for storing sharps/safety boxes temporarily,
- (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,
- 6.8.2.16Cleaner'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.
- 6.8.2.17Central sterilization room shall be available with following requirements:
  - (a) Direct access to OR,
  - (b) Needs following rooms:
    - Room for reception & sorting of equipments and clothes, and documentation process;
    - Room for inbuilt autoclaves:
    - Separate, properly ventilated room for storing and shelving sterile clothes and instruments,
    - · Room for staff and
    - Cleaners' room
  - (c) Shall have at least two inbuilt autoclaves, with small one as backup,
  - (d) Continuous water supply with extra reservoir,
  - (e) There shall be a closed drainage system for the autoclaves,
  - (f) Shelves shall be washable , corrosive free and metallic racks,
  - (g) The name of the set/instruments, date of sterilization, evidence of sterilization shall be written on the wrap of the set/instrument,
  - (h) Staff toilets,
- 6.8.2.18Recovery room shall be available with the following requirements:
  - (a) It shall be close to OR, and shall be within the semi-restricted area.

- (b) A minimum of four beds shall be available,
- (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) A trolley carrying functional emergency equipments shall be available in the recovery room,
- (g) A minimum of four bed pans
- (h) A minimum of four patient screens shall be available,
- (i) There shall be sufficient light for each bed, one head light per bed,
- (i) There shall be a heater,

## 6.8.2.19Minor operation theatre shall be available with the following requirements:

- (a) Located with low or no traffic area accessible to OPD,
- (b) There shall be one operation room with two theatres,
- (c) There shall be two glass cabinets for 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) Utility room,
- (g) Store with shelves and cabinets,
- (h) Nurse station with table and chairs,
- (i) Toilet rooms for male female,
- (j) Cleaners room,

### 6.8.2.20**Surgical ward** shall be available with the following requirements;

- (a) It shall be part of the inpatient service,
- (b) The beds shall be flexible and orthopedic beds,
- (c) In case of multiple beds, space between beds shall be at least 1.2m.
- (d) There shall be a minimum of one separate room, labeled "Septic Room" for septic patients,
- (e) The beds shall be equipped with fixtures for certain surgical patientsorthopedic cases,
- (f) Patient screens,

- (g) Patient toilets and showers with proximity to the ward, or covered walkways to the ablution facilities.
- 6.8.2.21 **Nurses' station** shall be available with the following requirements;
  - (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,
- 6.8.2.22**Surgical ward clean utility room (procedure room)** shall be available with the following;
  - (a) Dressing trolleys,
  - (b) Procedure beds
  - (c) POP equipments sets,
  - (d) Deep Sink,
  - (e) Hand washing basin,
  - (f) Worktable with laminated top,
  - (g) Cabinets and shelves,
- 6.8.2.23 Surgical ward clean linen room with shelves and cabinets shall be available
- 6.8.2.24**Surgical ward in patient store** with **s**helves, cabinets and fixed electrical plugs with protection shall be available
- 6.8.2.25**Surgical ward soiled utility room** with shelves and leak proof containers with leads shall be available
- 6.8.2.26**Surgical 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.

### 6.8.3 Professionals

- 6.8.3.1 Surgical services shall be directed by a licensed surgeon with a minimum of two (2) years experience.
- 6.8.3.2 The surgical service shall have a minimum of the following mix of professionals: general surgeons, orthopedic surgeons, sub specialist surgeon (at least one),

general practitioners, anesthesiologist and anesthetist, scrub nurses, circulating nurses, recovery nurses and ward nurses.

6.8.3.3	Minimum number of professionals for surgical service at <b>OR</b> for 24 hours services:					
	(a) Anesthesiologist	1				
	(b) Anesthetist	10				
	(c) Scrub nurses	10				
	(d) Circulating nurses	10				
	(e) Cleaners	4				
	(f) Technicians	2				
	(g) Porters	4				
6.8.3.4	onals for surgical service at <b>recovery</b> :					
	(a) Recovery nurses	8				
	(b) Porters	2				
6.8.3.5	Minimum number of professi	onals for surgical service at <b>CSR</b> :				
	(a) Nurse	6				
	(b) Technician	1				
	(c) Cleaner	10				
6.8.3.6	Minimum number of professi	onals for surgical service at <b>surgical ward</b> :				
	(a) General surgeons	3				
	(b) Sub specialist	1				
	(c) GP	6				
	(d) Nurses	(1 nurse per 6 beds)				
	(e) Cleaners	10				
	(f) Porters	5				
6.8.3.7	The surgical service shall pre	pare schedules for assignment of respective				
	professionals and suppor	t staff for the working hours and duty as per the				
	work load.					
6.8.3.8	The nursing services in the OR shall be coordinated by a licensed BSc nurse with a					
	minimum of 2 years expe	rience in surgical nursing.				
6.8.3.9	At least one sub specialist surgeon (Like Urologist, neurosurgeon, hand surgeon,					
plastic/reconstructive surgeon, cardio-thoraxic surgeon, facio-maxillary						
	surgeon, GI surgeon, pediatric surgeon) shall be available as full time					
	employee.					

- 6.8.3.10Number of general surgeons shall be determined by the 24 hour service availability. A minimum of one general surgeon in each shift is required.
- 6.8.3.11Number of scrub nurse shall suffice to the number of operation theatres.
- 6.8.3.12A surgeon or licensed general practitioner shall be responsible for the services provided to each patient; while the nurse coordinator shall be responsible for all nursing care provided to the patient.
- 6.8.3.13The duties and responsibilities of paramedical and porters shall be clearly outlined by the hospital.
- 6.8.3.14Orientation and continuous training shall be provided for cleaners for proper handling and disposal of sharp materials and surgical wastes by OR nurse coordinator or IP committee.

#### 6.8.4 Products

- 6.8.4.1 **Surgical ward** equipments and supplies:
  - (a) Bed and mattress
  - (c) Oxygen flow meter, 0-15
    - L/min

(b) Pillows

- (d) Chairs,
- (e) Feeding table/ Over bed table
- (f) Bed side cabinet
- (g) Bed screen, 3 sections

- (h) Waste paper basket
- (i) Safety boxes
- (j) Footstool
- (k) IV stands
- (l) Wheelchairs
- (m) Stretchers
- (n) Oxygen on trolleys
- (o) Hand washing basins
- 6.8.4.2 Equipment Clean Utility Room and procedure room
  - (a) Dressing trolley

(d) Walking rail,

(b) IV stand

(e) Crutches,

(c) Wheelchair

(f) Pop cutters

- 6.8.4.3 Equipment Nurses station
  - (a) Wall clock
  - (b) Desk
  - (c) Chair
  - (d) Trolley for vital sign monitoring

- (e) Refrigerator for medication with temperature control
- (f) Safety box
- (g) Waste paper basket
- (h) Adult sphygmomanometer

(i) Stethoscope, dual head	(k) Thermometer
(j) Stethoscope, adult head	
6.8.4.4 Equipment –ward/ in patient store:	
(a) General purpose trolleys, and	(g) Kidney basin, 475 ml
trays	(h) Wheelchair
(b) Patient chart holder	(i) General surgical dressing set
(c) Bed screen, three sections	(j) Tendon hammer
(d) Oxygen trolley, complete	(k) Mobile examination light
(e) Suction pump, portable	(l) Adult weight scales
(f) Bed pans	(i) Hadit Weight seales
(r) Dea pand	
6.8.4.5 Equipment – surgical ward soiled utility	y room:
(a) Soiled linen trolley	(e) General purpose trolley, trays
(b) Bin with lid	(f) Mobile trolley
(c) Worktable with laminated	(g) Bedpans
top	(h) Kidney basin, 475 ml
(d) Washing basins	
6.8.4.6 Equipment – surgical ward cleaner's ro	oom:
(a) Cleaning trolley	(e) Pail with handle
(b) Mop rack	(f) Brooms
(c) Worktable	(g) Mops
(d) Cabinets and shelves	(h) Cabinet for detergents
6.8.4.7 Equipment – reception/nurse station, o	operating theatre suite:
(a) Wall clock	(e) Chair, stackable, without
(b) Desk	armrests
(c) Desk chair	(f) Basket, waste-paper,
(d) Cabinet	
6.8.4.8 Equipment – entrance, patient transfer	area, operating theatre suite:
(a) Chairs	
(b) Patient stretchers	
6.8.4.9 Equipment –staff changing room, operations	ating theatre suite:
(a) Soiled linen trolley	(b) Clean linen cabinet

(c)	A big mirror	(f) Sh	(f) Shoe shelves	
(d)	Waste basket	(g) Ap	orons	
(e)	Lockers			
6.8.4.10E	quipment, operating theatre: Minimum equipm	nent lis	t for a single operating	
	theatre.			
(a)	Time clock	(u) M	obile operating lights	
(b)	Anesthesia trolley	(v) Op	perating table, 3 sections	
(c)	Oxygen cylinders ,different	(w)Su	iction machines	
	sizes.	(x) Bo	(x) Bone cutters	
(d)	Worktable with laminated	(y) IV	) IV fluid pressure bag	
	top	(z) X-	ray viewer	
(e)	Stools	(aa)	Anesthesia machine with	
(f)	IV stands	ve	ventilator, 2 vaporizers, and	
(g)	Kick buckets	ga	s cylinders	
(h)	Safety boxes	(bb)	Laryngoscope, set	
(i)	Swab rack with drip trays	(N	(Mackintosh)	
(j)	Swab count record boards	(cc)	Magill forceps (adult &	
(k)	Bowls and stands	pe	pediatrics)	
(l)	Instrument tables, Mayo type	(dd)	Laryngeal mask set	
(m)	Framed boards with pencil	(ee)	Mask holder	
	trays	(ff)	Mouth gauge	
(n)	Infusion pumps	(gg)	Patient monitor	
(o)	Chest tubes with bottles	(hh)	Dual head stethoscope	
(p)	Blankets, warming	(ii)	Tracheostomy tube,	
(q)	Tourniquets	(jj)	T-tube,	
(r)	Tongue depressors	(kk)	Colostomy bag,	
(s)	Coagulation unit, electro,	(ll)	Urinary bag,	
	mobile, 200 W			
(t)	Lights, operating, 1 large			
	copula, ceiling mounted			
6.8.4.11Equipment – scrub area:				
(a)	Soap dispenser	(c) Sin	nks	
(b)	Scrub-up brushes	(d) Mi	irror above each sink	

6.8.4.12Equipment: set up area	
(a) Worktable with laminated	(e) Blood warmer
top	(f) IV fluid warmer
(b) Cabinets and shelves	
(c) Dressing trolley	
(d) Instrument table, Mayo type	
6.8.4.13 Equipment – operating theatre store	
(a) Patient transfer, stretchers	(g) Positioner, bag, small
(b) General purpose trolleys	(h) Positioner, bag, medium
(c) IV stands	(i) Positioner, bag, large
(d) Hygrometer, humidity and	(j) Apron, protective, small
temperature	(k) Apron, protective, medium
(e) Pillows, abduction	(l) Apron, protective, large
(f) Support, head, operating	
table	
6.8.4.14Equipment – operating theatre sterile supply st	ore:
(a) General purpose trolleys,	(g) Gen.surg- Minor surgical
trays	set
(b) Gen.surg- Basic surgery	(h) Gen.surg-Suprapubic
set	puncture set
(c) Thyroidectomy set	(i) Cholecystectomy set
(d) Cholecystectomy set	(j) Billiary set
(e) Thoracotomy set ,etc	(k) Welicary set
(f) Gen.surg- Laparotomy set	
6.8.4.15Equipment – clean utility room, surgical suite:	
(a) General purpose trolley, trays	(d) Shelves
(b) Worktable, laminated top	(e) cabinets
(c) Refrigerator,	
6.8.4.16Equipment – operating theatre sluice room	
(a) Soiled linen trolley	(c) Bin with lid
(b) General purpose trolley, trays	

- (d) Worktable with laminated top
- (e) Wash basins
- (f) Bedpans
- 6.8.4.17Equipment cleaners' room, operating theatre:
  - (a) Cleaning trolley
  - (b) Mop rack
  - (c) Worktable
- 6.8.4.18Renewable/Consumables for surgical unit
  - (a) Guedel airways: size 0, 00, 3, 4 & 5
  - (b) Alcohol Swabs
  - (c) Disposable aprons
  - (d) Aqua-packs Oxygen humidifier
  - (e) Bags Refuse All Colors and Sizes
  - (f) Bags Urine
  - (g) Bandage Crepe
  - (h) Batteries Medical & General
  - (i) Bedpan Covers
  - (j) Blood Administration Sets
  - (k) 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
  - (l) Bottles Suction Glass/Plastic
  - (m)Braun Splints (Arm)
  - (n) Bubble tubing box
  - (o) Cannula Nasal-Oxygen
  - (p) Cannula, IV short, ster, disp, 18G, 20 G, 22 G, 24 G
  - (q) Caps Mop/Bonnet Type
  - (r) Catheter Jacques
  - (s) Central Venous Pressure Sets
  - (t) Chest, Electrode, Monitor
  - (u) Cleansing Swabs Sterile
  - (v) Cleansing Swabs Non-Sterile

- (g) Kidney basin, 475 ml
- (d) Pail with handle
- (e) Brooms
- (f) Mops
- (w) Cold/Hot Packs
- (x) Combur Tests
- (y) Connector,
  - Biconical Autoclavable
  - Connector, T/Y
  - Connectors Plastic Tapered
- (z) Container, Sample, urine, plastic, non-sterile, 60 ml
- (aa) Cotton
  - Cotton Buds
  - Cotton Wool Balls -Sterile/Non-Sterile
  - Cotton Wool Rolls
- (bb) POP
- (cc) Covers PVC Mattress/Bed Wedge
- (dd) CVP Cannulae
- (ee) Cytological Fixative Spray
- (ff) Drawsheet, plastic, 90x180cm
- (gg) Face Mask Water Repellent
- (hh) Foley Catheters Latex/Silicone Size 10, 12 and 14
- (ii) Gauze Absorbent Ribbon
- (jj) Gloves:
  - Household Large & Medium
  - Surgical Size 6, 6 ½, 7, 7 ½, 8
  - Exam, latex, disp, large, medium, small
- (kk) Hand wash Antiseptic Liquid (Hibiscrub)
- (ll) Hand wash Povidone (Betadine)
- (mm) Hot Packs

## (nn) I.V. Sets:

- I.V. Administration Sets 15 Drop
- I.V. Administration Sets 60 Drop
- I.V. Set, Infusion "Y", Luer lock, air inlet
- (oo) Incontinence Sheets
- (pp) Intubation stylet, adult, 15 Ch
- (qq) IV Infusion set Buretrol
- (rr) K.Y. Jelly
- (ss)IV stands
- (tt) Drums
- (uu) Latex Tubing
- (vv) Linen Savers
- (ww) Masks Nebulizer/Oxygen
- (xx) Masks Oxygen 40 %
- (yy) Nail Brushes -

Autoclavable/Disposable

- (zz) Needles:
  - Spinal disp, (0.9x90mm),sterile, 20G, 22G, 24G
  - Disp,15G, 18G, 21G, 22G, 23G, 25G
  - Butterfly 23G
- (aaa) Oxygen T Pieces
- (bbb) Oxygen Tubing
- (ccc) Face Masks
- (ddd) Razor Medical Disposable -Single Edge
- (eee) Rubber Bath Mat Non-Slip
- (fff) S.G. Meter (Urine Meters)
- (ggg) Safety Pins Large & Medium
- (hhh) Sharps Containers (Safety Box/used syringes and needles)
- (iii)Shrouds
- (jjj) Soap,toilet,bar,approx.110g,wrap ped
- (kkk) Spatulas Tongue
- (lll) Spigots Large, Medium and Small
- 6.8.4.190 perating Suite Renewable/Consumables:
  - (a) Airway Guedel, pediatric & adult size
  - (b) Plastic, reusable aprons

(mmm) Spray Bottles - Plunger Operated

(nnn) Surgical Splints

(000) Suture absorbable (Chromic) for episiotomy and perinea tears

# (ppp) Syringes:

- Volume: 2ml, 5ml, 10ml, 20ml
- Syringes 50 ml Conical Tip
- Syringes 50 ml Luer Lock
- Syringes Insulin

### (qqq) Tape:

- Elastic Adhesive Plaster - White 5cm and 10 cm
- Micropore tape
- Surgical Adhesive Hypo-Allergenic
- Adhesive, zinc oxide, perforated,10cmx5m
- Adhesive, zinc oxide, 2.5cmx5m
- (rrr)Clinical thermometer
- (sss) Fridge thermometer
- (ttt) Tourniquet, latex rubber,75cm
- (uuu) Tubes:
  - Endo-tracheal, disp. + connector, neonate mm, w.o balloon
  - Endo-tracheal, disp. + connector, balloon, 6.5mm, 7mm, 7.5mm, 8mm
  - Suction, L125cm,ster,disp, CH10, CH12, CH16
  - (c) Urine bags, collecting, 2000 ml
  - (d) 012 Band, Esmarch, 6 cm x 5

m

- (e) Survival blanketl,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) Bubble Tubing
- (i) Cannula, IV short, ster, disp, 18G, 20G, 22G, 24G
- (j) Catheters:
  - Sup-Pubic, CH 10, 1.65 cm, ster, disp adult with trocar
  - Ureteral, CH5, ster, disp
  - Urethral, CH6, ster, disp
  - Urethral, CH7, ster, disp
  - Foley, ster, disp, CH10, CH12, CH14
  - Three way foley catheter
- (k) 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
- (l) Connector, biconical, OD 7-11-7mm
- (m)Cotton wool,500g,roll,nonster
- (n) CVP Set
- (o) Diathermy pencil/ball/blade
- (p) Disposable, dispersive, electrode(Diathermy pad)
- (q) Drain, corrugated sheet, 3 cm x 25 cm
- (r) 063 Drain, wound, CH 12, ster, disp, CH12, CH16, CH6
- (s) Drawsheet, plastic, 90x180cm
- (t) Elastoplasts, 10 cm x 3 m
- (u) Electrode, Chest, Monitor
- (v) Extractor,mucus,20ml,ster,dis p
- (w) File for ampoules
- (x) Gauze:
  - Ball, Large (sterile)
  - Ball, Large (un-sterile)
  - Ball, Peanut (sterile)
  - Swabs RAYTEX® 10 X 10 cm
  - Swabs, Un-sterile (Green)
  - Roll,90cmx100m,nonster

- Vaseline gauze
- (y) Gloves,exam,latex,disp, large, medium & small
- (z) Gloves, surg, disp, 6.0, 6.5, 7.0, 7.5, 8, 8.5
- (aa) Gum elastic bougie, CH 15, 60 cm
- (bb) Intubation stylet, adult, 15 Ch
- (cc) Lancet,blood,ster,disp/PA C-200
- (dd) Mask, Clinical, Disposable (non-woven)
- (ee) Mask, Protection, High Filtration
- (ff) Needle, spinal, 0.9x90mm), ster, disp, 20G, 22G, 24G
- (gg) Oxygen mask, adult
- (hh) Oxygen, nasal cannula
- (ii) Reusable, Diathermy, Cable
- (jj) Safety box for .used syrgs/ndls
- (kk) Set, Infusion "Y", Luer lock, air inlet
- (ll) Scalpel blade,ster,disp,no.10, no. 11, no. 15, no. 22, no. 23
- (mm) Shoe cover, disposable
- (nn) Silicone Rubber Tubing
- (oo) Surgeon's Cap, Easy-Tie

- (pp) Suturing materials:abs,non abs,various types with and with out needles
  - Abs,DEC1,need1/2,18mm,round/BOX-36
  - Abs,DEC2,need 3/8 18mm,round/
  - Abs,DEC2,need 3/8,26mm,tri
  - Abs,DEC3,need 1/2 30mm,round
  - Abs,DEC3,need 3/850mm,round
  - Abs,DEC3,spool
  - Abs,DEC4,need 3/8 36mm,tri
  - Nonabs,DEC2,need 3/8 13mm,tri
  - Nonabs,DEC3,need 3/8 30mm,tri
- (qq) Syringe, dispos, 2ml, 5ml, 10ml, 20ml
- (rr) Tape,adhesive,Z.O,perforat ed,10cmx5m
- (ss) Tape,adhesive,Z.O.,2.5cmx 5m
- (tt) Telfa, dressing (Various Sizes)
- (uu) Tourniquet,latex rubber,75cm
- (vv) 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
- Trachea, balloon, int.can, ster, size 6
- Trachea, balloon, int.can, ster, size 8
- Suction,CH08,L50cm,st er,disp, CH08, CH10, CH14, CH16
- Double lumen endotracheal tubes
- N.G Tubes 12, 14, 16

# 6.8.4.20Operating Room Linen:

- (a) Apron Surgical, rubber
- (b) Trousers, Surgical, woven, Small, Medium & Large
- (c) Top(shirts), Surgical, woven, Small, Medium & Large
- (d) Gown, Surgical, woven(Plain)
- (e) Cap, Surgical, woven

- (f) Masks, surgical, woven
- (g) Drape:
  - Surgical, woven(1 x 1 m)
  - Surgical, woven(1 x 1.5 m)
  - Surgical, woven(1.5 x 1.5 m)(fenestrated

- Surgical, woven(45 cm x 70 cm)(fenestrated)
- Surgical woven (2 x 1.5 m)
- (h) Pillow case
- (i) Pillows
- (j) Sheet, Bed
- 6.8.4.21 Equipment recovery area:
  - (a) Vacuum aspirator
  - (b) Oxygen Flow meter, 0 15 l/min
  - (c) Oxygen (one cylinder per bed)
  - (d) Oxygen concentrater
  - (e) Patient transfer, (stretchers)
  - (f) Dressing trolley, trays
  - (g) Bed with mattress
  - (h) Stools
- 6.8.4.22 Equipment-Central sterilization room
  - (a) Auto claves; big
  - (b) Autoclaves; small
  - (c) Drums
  - (d) Metallic shelves

- (k) Sheet, draw, white
- (l) Cellular Blanket
- (m) Mayo cover
- (n) Towel Bath
- (o) Towel Hand
- (i) IV stands
- (j) Bed screen, 3 sections, mobile
- (k) Pedal bin
- (l) Oxygen trolley, complete
- (m)Pulse oximeter
- (n) Resuscitator, hand operated
- (o) Suction machines
- (p) Mobile examination light
- (q) Dual head stethoscope
- (e) Cabinets
- (f) Tables
- (g) Chairs

# 6.9 Orthopedics Services

#### 6.9.1 Practices

- 6.9.1.1 Comprehensive emergency orthopedic surgical service shall be available 24 hours a day 365 days a year,
- 6.9.1.2 Services for non-emergency elective orthopedic surgical cases shall be available only when all the necessary experts are available;
- 6.9.1.3 There shall be written protocols and procedures for admissions and discharges with follow up.
- 6.9.1.4 There shall be protocols for the management of the orthopedic surgical conditions in the unit.
- 6.9.1.5 There shall be protocols for consultation and transfer of patients admitted to this unit and to other departments.
- 6.9.1.6 There shall be a clear policy for handling emergency orthopedic surgical conditions. This service shall be available 24 hours a day throughout the year.
- 6.9.1.7 The hospital shall have emergency orthopedic surgical services integrated with the general emergency service.
- 6.9.1.8 The admission process for emergency orthopedic surgery shall be done by the emergency/ duty physician with consultation to the duty orthopedic surgeon.
- 6.9.1.9 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.
- 6.9.1.10For admitted patients the orthopedic surgical service shall be organized in such a way that it covers all the shifts.
- 6.9.1.11There shall be a mechanism of interdepartmental consultations with orthopedic surgical unit for which the orthopedic surgeon on duty shall be responsible.
- 6.9.1.12Adequate orthopedic surgical records shall be kept for each patient and the patient's orthopedic surgical record shall be integrated with the patient's over-all hospital record.
- 6.9.1.13All 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.
- 6.9.1.14The preoperative diagnosis shall be recorded in the medical record for all patients prior to orthopedic surgery.
- 6.9.1.15The 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.
- 6.9.1.16Except 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.
- 6.9.1.17If 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.
- 6.9.1.18The 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.
- 6.9.1.19Operative 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:
  - (k) Patient identification,
  - (l) Pre-operative diagnosis,
  - (m) The procedure performed,
  - (n) Findings during orthopedic surgery,
  - (o) Post-operative diagnosis,
  - (p) Orthopedic surgical specimens removed,
  - (q) Date and time operation started and ended,

- (r) Name of orthopedic surgeon, anesthesiologist/anesthetist, scrub nurse, and any assistants,
- (s) Signature of the orthopedic surgeon, and the scrub nurse
- (t) Immediate post-operative orders explicitly in the order sheet.
- 6.9.1.20There 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.
- 6.9.1.21There 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 labeled properly. The container shall be leak proof with lid & filled with 10% formalin.
  - (b) The specimen shall be sent to the pathology department by the OR staff.
    - Aseptic technique,
    - Sterilization and disinfections,
    - Selection of draping and gowning,
    - Counting of sponges, instruments, and needles,
- 6.9.1.22There shall be a policy for preparing and availing appropriate and properly functioning supplies, equipment, and instruments available for all surgeries performed according to the country standard.
- 6.9.1.23There 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.
- 6.9.1.24Post- 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.
- 6.9.1.25The hospital 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
- 6.9.1.26There shall be no time left without having general orthopedic surgeon or physician attending the orthopedic surgical unit.
- 6.9.1.27There 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.
- 6.9.1.28There shall be a mechanism that the orthopedic surgeon shall be available within 30 minutes upon call.
- 6.9.1.29All patients in orthopedic unit shall be attended by registered nurse all the time with supervision by duty physician.
- 6.9.1.30There shall be a mechanism by which the orthopedic unit provides board certificate in response to hospital medical board request. The board shall be composed of, at minimum, three specialist orthopedic surgeons one of them being the treating one.
- 6.9.1.31Emergency call access to each bed in the wards and recovery room shall be in place; at switches for emergency calls (nurse alarms) shall be placed accessible to beds

## 6.9.2 Premises

The orthopedics services may have separate orthopedic surgical Unit. If the orthopedic service does not have its own separate surgical facility, it shall use the general surgical unit. If the hospital has a separate orthopedic surgical unit, the following requirements shall be fulfilled.

## 6.9.2.1 Orthopedics Surgical Unit:

- (a) The orthopedic unit shall include orthopedic wards, operation room, recovery room, the central sterilization room (CSR), toilet rooms, showers and changing rooms with lockers, staff offices, store rooms, clean and soiled utility rooms, duty rooms and cleaners room.
- (b) The operation room shall be readily accessible to the orthopedic wards. 6.9.2.2 Orthopedics Operation Room / Suite :
  - (a) The operation room shall have three operation theatres of which one is for septic procedures, one nurse station, four staff toilets, six shower stands, four changing rooms with lockers, one rest room, anesthesia store, nurse store, one general store.
  - (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.

## 6.9.2.3 Operation Theatre:

- (a) At least three standard size operation theatres 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,

### 6.9.2.4 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 four 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. (e.g., long arm of valve gate to be manipulated with elbow or knee joint.)

## 6.9.2.5 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,

## 6.9.2.6 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 preoperative patients until called to theatre.

## 6.9.2.7 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,

## 6.9.2.8 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

# 6.9.2.9 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
- 6.9.2.10Operating 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.
- 6.9.2.11Clean 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
- 6.9.2.12Soiled 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,
- 6.9.2.13 Cleaner's Room shall be available with the followings:
  - (a) A room provided with two sets of cleaning equipments and materials,

- (b) Hand washing Basin,
- (c) Washing sink,
- (d) Detergent proof shelves and cabinets.
- 6.9.2.14Central sterilization room shall be available with followings:
  - (a) Direct access to OR,
  - (b) Needs a minimum of needs 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,
    - One staff room and
    - One cleaners' room
  - (c) Shall have at least two inbuilt autoclaves, with small one as backup,
  - (d) Continuous water supply with extra reservoir,
  - (e) Shelves shall be washable ,corrosive free and metallic racks as per the guideline,
  - (f) The date of sterilization & the name of the instruments shall be written after sterilization.
  - (g) Staff toilets,
- 6.9.2.15 Recovery facilities shall be available with the followings:
  - (a) It shall be close to OR, and shall be within the semi-restricted area.
  - (b) A minimum of four beds shall be available,
  - (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) A trolley carrying functional emergency equipments shall be available in the recovery room,
  - (g) A minimum of four bed pans
  - (h) A minimum of four patient screens shall be available,
  - (i) There shall be sufficient light for each bed, one head light per bed,
  - (j) There shall be a heater,

- 6.9.2.16Minor 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 minor operation room with two OR tables,
  - (c) There shall be two glass cabinets for orthopedic 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) Staff 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,

# 6.9.2.17**Orthopedic ward** shall be available with the followings;

- (a) It shall be part of the inpatient service,
- (b) The beds shall be flexible and orthopedic beds,
- (c) In case of multiple bed room, space between beds shall be at least 1.2m.
- (d) There shall be a minimum of one separate room, labeled "Septic Room" for septic patients,
- (e) The beds shall be equipped with fixtures for certain orthopedic surgical patients- orthopedic cases
- (f) Patient screens,
- (g) Patient toilets and showers with proximity to the ward, or covered walkways to the ablution facilities.

## 6.9.2.18**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,

- 6.9.2.19**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,
- 6.9.2.20**Orthopedic ward clean linen room** with shelves and cabinets shall be available
- 6.9.2.21**Orthopedic ward in patient store** with **s**helves, cabinets and fixed electrical plugs with protection shall be available
- 6.9.2.22**Orthopedic ward soiled utility room** with shelves and leak proof containers with leads shall be available
- 6.9.2.23 **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.

### 6.9.3 Professionals

- 6.9.3.1 Orthopedic services shall be directed by a licensed orthopedic surgeon with a minimum of two years of work experience.
- 6.9.3.2 If the hospital has a separate orthopedic surgical service, it shall have a minimum of the following mix of professionals: general orthopedic surgeons, sub specialist orthopedic surgeon (at least one), general practitioners, anesthesiologist and anesthetist, scrub nurses, circulating nurses and nurses for recovery and orthopedics ward.
- 6.9.3.3 If a separate orthopedic surgical service is not available, except the general and/or sub specialist orthopedic surgeon and orthopedic ward nurses, the other professionals mentioned in article 6.9.3.2 shall be shared with general surgical service.
  - 6.9.3.4 If the hospital has separate orthopedics surgical unit, it shall have the following minimum number of professionals

(a) Orthopedics OR:				
<ul> <li>Anesthesiologist</li> </ul>	2			
<ul> <li>Anesthetist</li> </ul>	10			
• Scrub nurses	20			
<ul> <li>Circulating nurses</li> </ul>	20			
• Cleaners	4			
<ul> <li>Technicians</li> </ul>	1			
<ul> <li>Porters</li> </ul>	4			
(b) Orthopedic surgical recovery:				
<ul> <li>Recovery nurses</li> </ul>	8			
<ul> <li>Porters</li> </ul>	2			
(c) Orthopedic surgical CSR (shared with surgical unit):				
• CSR nurse	6			
<ul> <li>Technician</li> </ul>	1			
• Cleaner	10			
(d) Orthopedic ward:				
<ul> <li>General orthopedic surgeons</li> </ul>		3		
• Pediatric orthopedic surgeon		2 (optional)		
<ul> <li>Hand surgeon</li> </ul>		2 (optional)		
• GP	6			
<ul> <li>Nurses</li> </ul>		30		
<ul> <li>Cleaners</li> </ul>		20		

6.9.3.5 The orthopedics service shall prepare schedules for assignment of respective professionals and support staff for the working hours and duty as per the work load

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Porters

- 6.9.3.6 The nursing services in the OR shall be coordinated by a licensed BSc nurse with two years of experience in orthopedic surgical services.
- 6.9.3.7 For specialized hospital where sub- specialty orthopedic surgical service rendered, at least one sub specialized orthopedic surgeon from each specialty or from one specialty shall be available: (hand surgeon, reconstructive orthopedic surgeon, pediatric orthopedic surgeon, etc)

- 6.9.3.8 Number of general orthopedic surgeons shall be determined by the 24 hour service availability. A minimum of one general orthopedic surgeon in each shift is required.
- 6.9.3.9 Number of scrub nurse shall suffice to the number of operation theatres.
- 6.9.3.10A orthopedic surgeon or licensed general practitioner shall be responsible for the services provided to each patient; while the nurse coordinator shall be responsible for all nursing care provided to the patient
- 6.9.3.11The duties and responsibilities of para-medicals and porters shall be clearly outlined by the hospital.
- 6.9.3.12Orientation and continuous training shall be provided for cleaners for proper handling and disposal of sharp materials and orthopedic surgical wastes by OR nurse coordinator or via IP committee.

## 6.9.4 Products

- 6.9.4.1 Medical equipment and supplies for orthopedics ward, clean and soiled utility rooms, procedure room, nurse station and cleaners room shall be in accordance with the inpatient service section of this standard
- 6.9.4.2 The hospital shall have the following orthopedics equipment for operating theatre:

(a)	Basic Orthopedic set	(p)	Forearm set with plate and screw
(b)	Amputation set	(q)	Spine fixation- plate
(c)	Drill- electrical,	(4)	with joint sets
	pneumatic, manual	(r)	External fixatures,
(d)	Wire cutter		different types
(e)	Kritchner wire	(s)	Hand surgery sets
(f)	Rush pin		with microsurgery
(g)	Kuncher nail		instruments
(h)	Sign nail	(t)	Skin graft sets,
(i)	Dynamic hip screw		manual, electrical
(j)	Cindylar screw	(u)	Hip replacement set
(k)	Patellar wire		with implants
(l)	Patellar clamp	(v)	Shoulder
(m)	Bone cutters		replacement set
(n)	Different	(w)	Elbow replacement
	osteotomes:		set
	manual, electrical,	(x)	Plates (angle: 95°
	compressed air		and 135°)
(o)	Knee replacement	(y)	Fluoroscope, C-
	set with implants		arm

(z)	Arthroscopic	(rr)	Swab rack with
	machine with sets		drip trays
(aa)	POP tray with POP	(ss)	Swab count record
(bb)	POP cutter,		boards
	electrical, manual	(tt)	Bowls and stands
(cc)	POP spreader	(uu)	Instrument tables,
(dd)	Tourniquet, upper		Mayo type
. ,	limb, lower limb,	(vv)	Framed boards
	(pneumatic,	, ,	with pencil trays
	manual)	(ww)	Blankets, warming
(ee)	Central compressed	(xx)	Coagulation unit,
	air system	, ,	electro-cauthery,
(ff)	Anesthesia		mobile, 200 W
. ,	machine	(yy)	Lights, operating, 1
(gg)	Anesthesia trolley		large copula, ceiling
(hh)	Stools		mounted
(ii)	Walking rail,	(zz)	Mobile operating
(jj)	Crutches,		lights
(kk)	Thomas splints,	(aaa)	Operating table, 3
(ll)	Brown's frame,		sections
(mm)	Oxygen cylinders,	(bbb)	Suction machines
	different size	(ccc)	Hip spica tables
(nn)	Tendon hammer	(ddd)	Anesthesia machine
(00)	IV stands		with ventilator, 2
(pp)	Kick buckets		vaporizers, and gas
(qq)	Safety boxes		cylinders
-		(eee)	Apron, protective,
urgory Fo	winmont OP storilo supply storo		

- 6.9.4.3 Surgery Equipment OR sterile supply store:
  - (a) General purpose trolleys, trays
  - (b) General surgical Suture set
  - (c) Minor surgical set
- 6.9.4.4 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 Administration 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, 18G, 20 G, 22 G, 24 G
- (p) Caps Mop/Bonnet Type
- (q) Catheter Jacques
- (r) Chest, Electrode, Monitor
- (s) Cleansing Swabs Sterile
- (t) Cleansing Swabs Non-Sterile
- (u) Cold/Hot Packs
- (v) Connector,
  - Biconical Autoclavable
  - Connector, T/Y
  - Connectors Plastic Tapered
- (w) Container, Sample, urine, plastic, non-sterile, 60 ml
- (x) Cotton
  - Cotton Buds
  - Cotton Wool Balls -Sterile/Non-Sterile
  - Cotton Wool Rolls
- (y) POP
- (z) Covers PVC Mattress/Bed Wedge
- (aa) CVP Cannulae
- (bb) Drawsheet,plastic,90x180 cm

- (cc) Foley Catheters –

  Latex/Silicone Size 10, 12 and
  14
- (dd) Gauze Absorbent Ribbon
- (ee) Gloves:
  - Household Large & Medium
  - Orthopedic surgical Size 6, 6 ½, 7, 7 ½, 8
  - Exam, latex, disp, large, medium, small
- (ff) Hand wash Antiseptic Liquid (Hibiscrub)
- (gg) Hand wash Povidone (Betadine)
- (hh) Hot Packs
- (ii) I.V. Sets:
  - I.V. Administration Sets –
     15 Drop
  - I.V. Administration Sets 60 Drop
  - I.V. Set, Infusion "Y", Luer lock, air inlet
- (jj) Intubation stylet, adult, 15 Ch
- (kk) IV Infusion set Buretrol
- (ll) K.Y. Jelly
- (mm) IV stands
- (nn) Drums
- (oo) Latex Tubing
- (pp) Linen Savers
- (qq) Nail Brushes Autoclavable/Disposable
  (rr)Needles:

- Spinal disp, (0.9x90mm),sterile, 20G, 22G, 24G
- Disp,15G, 18G, 21G, 22G, 23G, 25G
- Butterfly 23G
- (ss)Oxygen T Pieces
- (tt) Oxygen Tubing
- (uu) Face Masks
- (vv) Razor Medical -Disposable - Single Edge
- (ww) Safety Pins Large & Medium
- (xx) Sharps Containers (Safety Box/used syringes and needles)
- (yy) Shrouds
- (zz) Soap,toilet,bar,approx.110 g,wrapped
- (aaa) Spigots Large, Medium and Small
- (bbb) Spray Bottles Plunger Operated
- (ccc) Orthopedic surgical Splints
- (ddd) Syringes:
  - Volume: 2ml, 5ml, 10ml, 20ml
  - Syringes 50 ml Conical
     Tip
- 6.9.4.5 Operating Suite Renewable/Consumables:
  - (a) Airway Guedel, pediatric & adult size

- Syringes 50 ml Luer Lock
- Syringes Insulin
- (eee) Tape:
  - Elastic Adhesive
     Plaster White 5cm
     and 10 cm
  - Micropore tape
  - Orthopedic surgical Adhesive Hypo-Allergenic
  - Adhesive, zinc oxide, perforated,10cmx5m
  - Adhesive, zinc oxide,2.5cmx5m
- (fff) Tourniquet, latex rubber,75cm
- (ggg) Tourniquet, pneumatic
- (hhh) Tubes:
  - Endo-tracheal, disp. + connector, neonate mm, w.o balloon
  - Endo-tracheal, disp. + connector, balloon,
     6.5mm, 7mm, 7.5mm,
     8mm
  - Suction,
     L125cm,ster,disp, CH10,
     CH12, CH16
- (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
- (k) Connector, biconical, OD 7-11-7mm
- (l) Cotton wool,500g,roll,nonster
- (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,nonster

- 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) Suturing materials:

- Abs,DEC1,need
   1/2,18mm,round/BOX 36
- Abs,DEC2,need 3/8 18mm,round/
- Abs,DEC2,need 3/8,26mm,tri
- Abs,DEC3,need 1/2 30mm,round
- Abs,DEC3,need 3/850mm,round
- · Abs,DEC3,spool
- Abs,DEC4,need 3/8 36mm,tri
- Nonabs, DEC2,need 3/8 13mm,tri
- Nonabs, DEC3,need 3/8 30mm,tri
- Wires, different size/thickness
- Plates and screws, different size and shape
- Implants, different types and size
- (ll) Tape,adhesive,Z.O,perforated, 10cmx5m
- (mm) Tape,adhesive,Z.O.,2.5cmx 5m
- (nn) 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,st er,disp, CH08, CH10, CH14, CH16
- N.G Tubes 12, 14, 16

# 6.9.4.6 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, Orthopedic 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
- 6.9.4.7 Equipment recovery area:
  - (a) Vacuum aspirator
  - (b) Oxygen Flow meter, 0 15 l/min
  - (c) Oxygen (one cylinder per bed)
  - (d) Oxygen concentrater
  - (e) Patient transfer, (stretchers)
  - (f) Dressing trolley, trays
  - (g) Bed with mattress
  - (h) Stools
- 6.9.4.8 Equipment-Central sterilization room
  - (a) Auto claves; big
  - (b) Autoclaves; small
  - (c) Drums, metallic shelves, cabinets, tables and chairs

- (k) Sheet, draw, white
- (l) Cellular Blanket
- (m) Mayo cover
- (n) Towel Bath
- (o) Towel Hand

- (i) IV stands
- (j) Bed screen, 3 sections, mobile
- (k) Pedal bin
- (l) Oxygen trolley, complete
- (m)Pulse oximeter
- (n) Resuscitator, hand operated
- (o) Suction machines
- (p) Mobile examination light
- (q) Dual head stethoscope

## 6.10 Gynecology and Obstetrics Care Services

## 6.10.1 Practices

- 6.10.1.1The gynecological and obstetrics services shall have written protocols and procedures including
  - a) Antenatal care
  - b) Follow up of labour
  - c) New born care
  - d) Postnatal care
  - e) Immunization
  - f) Pre and post operative care
  - g) Administration of antibiotics, oxytocics and anticonvulsants

- h) Manual removal of the placenta
- i) Assisted delivery
- j) Infertility
- k) Admission and discharge
- l) Transfer and referal
- m) Infection prevention
- 6.10.1.2 Normal delivery and comprehensive emergency obstetric care shall be available 24 hours a day, 365 days a year. This includes:
  - a) Administration of antibiotics, oxytocics and anticonvulsants
  - b) Manual removal of the placenta
  - c) Removal of retained products following miscarriage or abortion
  - d) Assisted vaginal delivery, preferably with vacuum extractor
  - e) Blood transfusion
  - f) Caesarean section
- 6.10.1.3Essential newborn care and newborn resuscitation care shall be available 24 hours a day and 365 days a year. This service shall have written policies and procedures to transfer or refer neonates to neonatal unit that require further care.
- 6.10.1.4Routine examination for detection of congenital hip dysplasia and other congenital anomalies shall be done.
- 6.10.1.5Emergency gynecological services shall be available 24 hours a day, 365 days a year. This includes, but is not limited to, services for the medical and/or surgical management of:
  - a) Bleeding in early pregnancy
  - b) Ectopic pregnancy

- c) Acute pelvic inflammatory disease
- d) Ruptured or torsion of ovarian cyst
- 6.10.1.6Management of minor and major gynecological conditions shall be available including but not limited to:
  - a) Vaginal bleeding
  - b) Pelvic infection or abscess
  - c) Uterine pathology (fibroids, polyps etc)
  - d) Endometriosis
  - e) Ovarian pathology (cyst, torsion)
  - f) Gynecological cancers
  - g) Cervical cytology
  - h) treatment of cervical intraepithelial neoplasia
- 6.10.1.7Non emergency maternal health services shall be available during regular working hours.

### This includes:

- a) Antenatal care
- b) Post natal care

6.10.1.8

- c) Family planning services including counseling and the provision of:
  - Barrier contraceptives
  - Oral contraceptives
  - Injectable contraceptives
  - Implant contraceptives
  - d) Tetanus immunization
    - There shall be a mechanism of interdepartmental consultations with internal
- 6.10.1.9 Gynecology and obstetrics records shall be kept for each patient and the patient's record shall be integrated with the patient's over-all hospital record.

medicine, pediatrics, surgery and other relevant services.

6.10.1.10 All gynecologic and obstetrics 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.

- Intra-uterine contraceptive devices
  - Sterilization

- 6.10.1.11 The preoperative diagnosis shall be recorded in the medical record for all patients prior to surgery.
- 6.10.1.12 The gynecologist/obstetrician shall explain the disease condition, possible surgical intervention and outcome possibilities in clear, simple and understandable terms to the patient and/or family.
- 6.10.1.13 Except in life-threatening emergencies, the gynecologist/obstetrician 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 surgeon's clinical judgment. 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 on patient's medical record.
- 6.10.1.14 The nursing care of patients undergoing gynecologic/obstetrics 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.
- 6.10.1.15 The gynecological and obstetrics services shall strictly follow the infection prevention section of this standard.
- 6.10.1.16 The gynecological and obstetrics related surgical services shall follow practices standards stated under the surgery section of this standard

### 6.10.2 Premises

- 6.10.2.1The gynecology and obstetrics services shall have inpatient, outpatient, maternity and surgical facilities
- 6.10.2.2The Maternity Unit is comprised of the maternity ward, delivery suite, nursery and operation theatre
- 6.10.2.3The delivery suite shall be able to accommodate four first stage patients and two deliveries simultaneously. In case of 100% occupancy of the delivery rooms,

- the labour bays shall be equipped in such a way that patients can be accommodated there to deliver.
- 6.10.2.4The maternity ward and delivery suite shall be located close to each other to make the transfer of obstetric cases to and from the delivery suite as uncomplicated as possible.
- 6.10.2.5The obstetric gynecology services shall a separate operating theater for obstetric cases. The delivery room shall have easy access to this operation theatre.
- 6.10.2.6The maternity unit shall have the following facilities:
  - a) Maternity Ward:
    - Facilities shall be provided for antenatal and postnatal care including high dependency care and rooming in facilities for mother and newborn. These can be organized into patient bays +/- separate one or two bedded rooms for high risk patients.
    - Curtain tracks shall be installed around each bed, or in their absence bed screens shall be provided.
    - Sinks shall be provided in each patient bay or room. Patient toilets and showers shall be provided, in or adjacent to the ward. If this is not possible then covered walkways should lead from the ward to the ablution facilities.
    - A nurses' station shall be set up to enable nursing staff to monitor all visitors entering or leaving the unit.
  - b) Maternity Ward clean utility room: This is used for:
    - The storage of supplies, both clean and sterile
    - Preparing and storing dressing trolleys used on the ward
    - The storage, preparation and assembly of items of equipment for diagnostic and therapeutic procedures
    - IV fluid preparation
    - Injection preparation
  - c) Maternity Ward clean linen room: This is used for the storage of linen including bed sheets, mackintosh and draw sheets for use in the maternity unit. It requires cabinets and shelves

- d) Maternity Ward inpatient store: This is used for the storage of equipment required on the maternity ward that requires shelves, cabinets and sufficient electrical plugs should be available to keep the electrical equipment plugged in and keep batteries charged.
- e) Maternity Ward soiled utility room: This is used for:
  - Temporary storage point for urine and stool specimens to be sent to laboratory for analysis
  - Dipstick urinalysis
  - Temporary storage point for soiled linen
  - Temporary storage point for contaminated items for destruction at a later stage
  - Temporary storage point for used safety boxes prior to incineration
- f) Maternity Ward cleaner's room
- g) Maternity Ward kitchen: This is used to temporarily store and prepare food from the main kitchen and to prepare patient beverages. It requires stainless steel sink, drainer and cabinets
- h) Staff toilet, shower and changing facilities: These shall be separate from patient ablution facilities. Staff lockers shall be included. Facilities shall be sufficient for staff working on the maternity ward, delivery suite and obstetric operating theatre.
- i) Nursery: The nursery is used for the management of post caesarean section babies until the mother returns to the ward and for other sick or high risk babies. It requires:
  - The nursery unit shall have a room for milk preparation
  - The nursery shall have a single entrance to control access.
  - Work surface for washing, drying and changing babies
  - Sink, cabinets and shelves
- j) Baby isolation room: This room is used for the management of babies with high risk symptoms and infectious conditions that need isolation. It requires:
  - This room shall be located close to the nurses' station.

- A clinical basin and separate bathing facility are required.
- There shall be a work surface for basic hygiene and nappy changing.
- An extraction ventilation system with air conditioning control to maintain and regulate room temperature shall be available, or the room shall be designed to avoid air-borne cross infections
- k) Delivery Suite shall have the following
  - Labour Bay (6 beds) for the management of women in labour including induction of labour and fetal monitoring;
  - Sink, cabinets and toilet facilities;
  - Delivery Room (s) (two beds): Delivery rooms are used for all stages
    of labour including recovery following birth. Transfer to obstetric
    theatre shall be easy;
  - Obstetrics operation theatre;
  - Delivery room store: This shall be located within the delivery suite, with easy access from the labour and delivery rooms. It requires shelves and cabinets;
  - Soiled Utility delivery room.
- 6.10.2.7The hospital shall preferably have a separate operating theatre for gynecological cases. If the hospital has a separate operating theater (OR) for gynecologic cases, it shall comply with the following requirements.
  - a) Reception/Nurse station: A duty room or duty station 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, 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) Entrance/Patient transfer area
    - This area shall be large enough to allow for the transfer of patients from a bed to a trolley.
    - A line shall be clearly marked in red on the floor, beyond which no person from outside the operating department should be permitted to

- set foot without obtaining authority and putting on protective clothing.
- Holding bay: space shall be located to allow for the supervision of waiting patients to go into theatre.

## c) Changing room

- Suitable separate changing room facilities shall be provided for male and female staff.
- The changing room shall have one door that opens into the restricted access area, and must have a separate entrance from outside the restricted access area.
- Storage facilities for the personnel's personal clothing and effects.
- Storage of clean theatre attire and inside shoes and operation theatre gum boots.
- Provision must also be made for soiled theatre apparel.
- Wash hand basins: Toilets, showers, shelves, lockers
- d) Operating theatre shall have the following:
  - Patient entrance into theatre and exit out of theatre shall be through double self-closing doors situated in the centre of the operating room entrance.
  - General anaesthesia administration could be given in an anaesthetic room and patient then transferred to the operating room.
     Alternatively, the patient can be induced and anaesthesia will be maintained in the operating room.
  - Cabinets and shelves
  - Scrub area
    - A scrubbing-up area outside but adjacent to the operating room shall be provided. If the scrub area serves only one operating theatre there should be sufficient sinks for two staff to scrub at the same time. If it serves two theatres then the space should be sufficient for four staff to scrub up simultaneously.
    - o This area shall have direct access to the operating room

- Sterile gowns and gloves shall be available on a trolley in the scrub area or at the entrance of the operating room.
- o Sink with running water shall be available
- Set-up area (optional): Store area for suture material that could be stored on a trolley that could be wheeled into theatre. Requirements:
  - Doors into the operating room should 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.
  - Shelves for the days sets and pack to be stored during theatre list.
  - If there is no set up area then instruments can be set up within the operating theatre
  - Mayo table, dressing trolley, and runners to set up for the next case are kept in this area.
- Operating theatre equipment and sterile supply store
  - The equipment store area in the operating room shall be supplied with a sufficient number of electrical plugs to keep the electrical equipment plugged in, and in case of power failure to work on back up electrical supply / or emergency electrical supply.
  - Equipment is always stored at the same space/location so that if needed in an emergency all staff know where the equipment is kept.
  - Shelves and cabinets
- Operating theatre sterile supply store: This room is used for the storage of all sterile instrument sets, swabs and sterile renewable, consumables and it requires shelves.
- Clean Utility, Surgical Suite: This room is used for storage of IV fluids, clean linen, medicines and other sundry items, flash autoclaving of equipment in case of emergencies.

- This room shall be so situated that operating room staff have easy access to the clean utility store where medicines and medication are stored.
- Storage space/room shall be provided for sterile packs. No wood or porous shelving may be used in this area.
- $\circ$  Refrigerator shall be available for storing medications that needs to be stored at a temperature of 4  $^{\rm o}$  C
- Sink, cabinets and shelves shall be available
- 3-Bed Recovery: This area shall be used to stabilize the patient postsurgery, and to prepare for transfer if transfer is needed.
  - o The recovery area shall be within the restricted area.
  - A recovery area shall have room for two beds (one per operating room) and one over-flow bed space to accommodate patients from the two operating rooms.
  - o A clinical basin shall be provided.
  - Electrical switch socket outlets for every recovery bed or trolley shall be available.
  - Facilities for screening off to ensure patient privacy: bed screens or curtain track with curtain between the bays.
  - An emergency call system shall be installed and adherence to policy and protocol regarding emergency management followed.
  - Sufficient lighting to enable adequate observation shall be installed.
  - A work surface to do administrative tasks during recovery of patients, and shelving to store necessary equipment are required.
- Soiled Utility/Sluice room: This acts as a store area for contaminated materials until they can be disposed of. Used sharps/safety boxes are to be stored here before being sent for incineration
  - The flow of the operating rooms shall run from clean to dirty.
     This area shall be fitted with a deep bowl sink and/or slop

hopper, a wash hand basin with hot and cold water and cabinets and shelves

 Cleaner's Room: The janitor/cleaner's room is the base from which domestic services staff provide a cleaning service to the theatre suite.
 It requires shelves, cabinets and sinks with hot and cold water.

#### 6.10.3 Professionals

- 6.10.3.1The gynecology and obstetrics services shall be directed by a licensed obstetrician and gynecologist with a minimum of two years work experience.
- 6.10.3.2There shall be adequate qualified medical and nursing professionals in the gynecology and obstetrics unit available at all times to meet the service needs
- 6.10.3.3The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis)
- 6.10.3.4A physician or licensed independent practitioner shall be available (physically present) at all times in the gynecology and obstetrics unit
- 6.10.3.5A licensed obstetrician and gynecologist shall be available at all times. The obstetrician and gynecologist shall be also available on call after working hours in a period not to exceed thirty (30) minutes.
- 6.10.3.6The nursing care in obstetric shall be administered by a licensed professional nurse with at least two years of work experience in gynecology and obstetrics services
- 6.10.3.7There shall be adequate support staff available as per the service need

### 6.10.4 Products

- 6.10.4.1Equipment Clean Utility Room
  - a) Trolley for vital sign monitoring with thermometer and sphygmomanometer
  - b) Dressing trolley (s)
  - c) Refrigerator for medication with temperature control
  - d) IV stand
  - e) Wheelchair
- 6.10.4.2Equipment Clean linen room
  - a) Trolley to be used for bed linen changes during patient hygiene
  - b) Cabinet (s)
- 6.10.4.3 Equipment maternity ward:

- a) Bed and mattress e) Baby cot b) Vacuum aspirator, 0 f) Bed side cabinet 250mm/Hg with bottle g) Over bed table h) Bed screen, 3 sections and tubing c) Oxygen flow meter, 0-15 i) Footstool L/min j) IV stands d) Oxygen source k) Wheelchairs 6.10.4.4Equipment – Nurses station a) Crash cart, with sufficient equipment and medicines for the resuscitation of mother and neonate, including defibrillator, intubation sets and oxygen b) Diagnostic set with ophthalmoscope and Otoscope c) Adult sphygmomanometer d) Paediatric sphygmomanometer e) Stethoscope, foetal f) Stethoscope, dual head g) Stethoscope, paediatric head h) Thermometer 6.10.4.5 Equipment – maternity ward store: a) Patient transfer, roller h) Suction pump, portable system b) General purpose trolley, two trays, stainless steel c) Patient chart holder
  - i) Bed pan j) Kidney basin, 475 ml k) Wheelchair l) General surgical dressing set
  - m) Tendon hammer
  - n) Mobile examination light
  - o) Adult weight scales
- 6.10.4.6Equipment maternity ward soiled utility room:
  - a) Soiled linen trolley
  - b) Bin with lid

e) IV stand

c) Worktable with laminated top

d) Bed screen, three sections

f) Mobile bedpan trolley

g) Oxygen trolley, complete

d) Wash tub (65L)

- e) General purpose trolley, two travs
- f) Mobile trolley and bedpans
- g) Bedpan
- h) Kidney basin, 475 ml
- 6.10.4.7Equipment maternity ward cleaner's room:

- a) Cleaning trolley
- b) Mop rack
- c) Worktable
- d) Cabinets and shelves
- 6.10.4.8Equipment maternity ward kitchen:
  - a) Pedal bin
  - b) Worktable with laminated top
  - c) Stove or kettle to prepare beverages for patients
- 6.10.4.9Equipment milk formula room:
  - a) Worktable with laminated top
  - b) Refrigerator
  - c) Kitchen scale
  - d) Sterilizing equipment or solutions
- 6.10.4.10 Equipment nursery
  - a) Vacuum aspirator, 0 250 mm/Hg, w bottle and tubing
  - b) Flow meter, 0 15 l/min
  - c) Oxygen source
  - d) Baby cot
  - e) Chair
  - f) Stool
  - g) IV stand
- 6.10.4.11 Equipment baby isolation room
  - a) Vacuum aspirator, 0-250mmHg, with bottle and tubing
  - b) Oxygen
  - c) Flow meter, 0 15 l/min
  - d) Oxygen hood
  - e) Oxygen saturation monitor
  - f) Baby warmer or overhead heater
- 6.10.4.12 Equipment labour bay:
  - a) CTG monitor on trolley
  - b) Foetal Doppler
  - c) Vacuum aspirator, 0-250mm/Hg with bottle and tubing
  - d) Flow meter, 0-15l/min
  - e) Oxygen source
  - f) Wall clock
- 6.10.4.13 Equipment delivery room store:

- e) Pail with handle
- f) Broom
- g) Mop

- e) Stove or kettle to heat water for warming feeds
- f) Baby bottles, teats and bottle brushes
- g) Pedal bin
- h) Stool
- h) Infusion pump, drop controlled
- i) Pedal bin
- j) Baby warmer or overhead heater
- k) Incubator, automatic
- l) Breast pump
- m) Neonatal resuscitation kit
- n) Infant scale
- g) Patient monitor
- h) Baby bassinet with mattress
- i) Waste container, with lid
- j) Bedside cabinet
- k) Baby dressing table, with padded top
- l) Pedal bin
- m) Chairs
- g) Worktable with laminated top
- h) Bed
- i) Bedside cabinet
- j) IV stand
- k) Bed screen, three sections
- l) Waste paper basket
- m) Stethoscope, dual head

a) Patient transfer, roller e) Vacuum extractor, Bird, system manual, complete set b) Patient stretcher f) Newborn circumcision set c) IV stand g) Delivery set d) Portable suction pump h) Obstetric forceps 6.10.4.14 Equipment –delivery room (s) j) Kick bucket, stainless steel a) Vacuum aspirator, 0 - 250 mm/Hg, w bottle and k) Bowl and stand l) Instrument table, Mayo tubing b) Trolley, oxygen, complete type, mobile c) Flow meter, 0 - 15 l/min m) Infusion pump, volumetric d) Wall clock n) Newborn care table e) Dressing trolley, two trays o) Operating light, ceiling f) Soiled line trolley, 2 rings mounted or mobile g) Baby cot p) Neonatal resuscitation kit h) Delivery bed g) CTC monitor on trolley i) IV stand r) Foetal Doppler 6.10.4.15 Equipment – soiled utility room, delivery suite: a) Soiled linen trolley e) General purpose trolley, b) Bin with lid two travs c) Worktable with laminated f) Mobile trolley and bedpans top d) Wash tub (65L) g) Bedpan h) Kidney basin, 475 ml 6.10.4.16 Equipment – reception/nurse station, operating theatre suite: a) Wall clock e) Chair, stackable, without b) Desk armrests c) Desk chair f) Basket, waste-paper, d) Cabinet metal 6.10.4.17 Equipment – entrance, patient transfer area, operating theatre suite: a) Patient transfer, roller system b) Patient stretcher 6.10.4.18 Equipment –staff changing room, operating theatre suite: a) Soiled linen trolley b) Waste basket 6.10.4.19 Equipment, one operating theatre: a) Elapsed time clock h) Swab count record board b) Anaesthesia trolley and i) Bowl and stand Oxygen cylinders j) Instrument table, Mayo c) Worktable with laminated k) Framed board with pencil top d) Stool e) IV stand l) Infusion pump and

Suction pump

m) Blanket, warming

f) Kick bucket

g) Swab rack with drip tray

- n) Tourniquet and Tongue depressor
- o) Coagulation unit, electro, mobile, 200 W
- p) Light, operating, large copula, ceiling mounted
- q) Three operating tables,
- r) IV fluid pressure bag
- 6.10.4.20 Equipment scrub area
  - a) Soap dispenser
  - b) Scrub-up brushes
- 6.10.4.21 Equipment: set up area
  - a) Worktable with laminated top
  - b) Cabinets and shelves
  - c) Dressing trolley
- 6.10.4.22 Equipment operating theatre store
  - a) Patient transfer, roller system
  - b) General purpose trolley
  - c) IV stand
  - d) Hygrometer, humidity and temperature
  - e) Newborn general care table
  - f) Pillow, abduction
  - g) Support, head, operating table
- 6.10.4.23 Equipment operating theatre sterile supply store:
  - a) General purpose trolley, 2 trays
  - b) Gen.surg-Suture set
  - c) Gen.surg- Abdominal set
  - d) Gen.surg- Basic surgery set
  - e) Gen.surg-Laparotomy set
  - f) Gen.surg- Small dissection set

- s) Anaesthesia machine with ventilator, vaporizers, and gas cylinders
- t) Laryngoscope set
- u) Magill forceps (adult)
- v) Laryngeal mask set and Mask holder
- w) Mouth gauge
- x) Patient monitor
- y) Dual head stethoscope
- d) Instrument table, Mayo type
- e) Blood warmer
- f) IV fluid warmer
- h) Positioner, bag, patient, small
- i) Positioner, bag, patient, medium
- j) Positioner, bag, patient, large
- k) Apron, protective, small
- l) Apron, protective, medium
- m) Apron, protective, large

- g) Gen.surg- Minor surgical set
- h) Gen.surg-Suprapubic puncture set
- i) Gen.surg-Circumcision set, newborns
- j) Gyn/Obs-IUD set
- k) Gyn/Obs- Cranioplasty/craniotomy set
- l) Gyn/Obs- Dilation & curettage (D&C) set
- m) Gyn/Obs- Manual vacuum aspiration set
- n) Gyn/Obs- Obstetric forceps
- o) Gyn/Obs- Caesarean section set
- p) Gyn/Obs- Abdominal hysterectomy set
- q) Gyn/Obs- Vaginal hysterectomy set, extras
- r) Gyn/Obs- Gynaecology examination set (EUA)
- s) Gyn/Obs- Cervical biopsy set

# 6.10.4.24 Equipment – clean utility room, surgical suite:

- a) General purpose trolley, two trays
- b) Worktable, laminated top
- c) Refrigerator, 140 l + 20 l
- d) Steam sterilizer

# 6.10.4.25 Equipment recovery area:

- a) Vacuum aspirator
- b) Oxygen Flow meter, 0 15 l/min
- c) Oxygen (one cylinder per bed)
- d) Patient transfer, roller system
- e) Dressing trolley, two trays
- f) Bed with mattress
- g) Bed screen, 3 sections, mobile
- h) Pedal bin
- i) Oxygen trolle, complete
- j) Ventilator
- k) Resuscitator, hand operated
- l) Mobile examination light
- m) Dual head stethoscope

### 6.10.4.26 Equipment – operating theatre sluice room

- a) Soiled linen trolley
- b) General purpose trolley, two trays
- c) Bin with lid
- d) Worktable with laminated top
- e) Wash tub, 65 L
- f) Mobile bedpan trolley
- g) Bedpan
- h) Kidney basin, 475 ml
- 6.10.4.27 Equipment cleaners' room, operating theatre:
  - a) Cleaning trolley
  - b) Mop rack
  - c) Worktable
  - d) Pail with handle
  - e) Broom
  - f) Mop
- 6.10.4.28 Renewable/Consumables for maternity unit
  - Guedel airways: size 0, 00, 3, 4 & 5
  - Alcohol Swabs
  - Disposable aprons
  - Aqua-packs Oxygen humidifier
  - Bag urine baby
  - Bags Refuse All Colours and Sizes
  - Bags Urine
  - Bandage Crepe
  - Batteries Medical & General
  - Bedpan Covers
  - Blood Administration Sets
  - Blood Sampling Needles, disposable, sterile, 20 G, 21 G, 23 G
  - Blood Sampling Tubes:
  - Vacuum 5ml (Vacutainer)
  - Vacuum EDTA 5ml (Vacutainer)
  - Vacuum Heparinised 5ml (Vacutainer)
  - Blood Sampling Vacutainer Holder

- Bottles Suction Glass/Plastic
- Braun Splints (Arm)
- Bubble tubing box
- Cannula Nasal-Oxygen
- Cannula, IV short, ster, disp, 18G, 20 G, 22 G, 24 G
- Caps Mop/Bonnet Type
- Catheter Jacques
- Central Venous Pressure Sets
- Chest, Electrode, Monitor
- Cleansing Swabs Sterile
- Cleansing Swabs Non-Sterile
- Cold/Hot Packs
- Combur Tests
- Connectors:
- Biconical Autoclavable
- Connector, T/Y
- Connectors Plastic Tapered
- Container, Sample, urine, plastic, non-sterile, 60 ml
- Cotton:
- Buds
- Wool Balls Sterile/Non-Sterile
- Wool Rolls
- Covers PVC Mattress/Bed Wedge
- CVP Cannulae
- Cytological Fixative Spray
- Drawsheet,plastic,90x180cm
- Face Mask Water Repellent
- Foley Catheters Latex/Silicone Size 10, 12 and 14
- Gauze Absorbent Ribbon
- Gloves:
  - Household Large & Medium
  - o Surgical Size 6, 6 ½, 7, 7 ½, 8

- o Exam, latex, disp, large, medium, small
- Hand wash Antiseptic Liquid (Hibiscrub)
- Hand wash Povidone (Betadine)
- Hot Packs
- I.V set:
  - o Administration Sets 15 Drop
  - o Administration Sets 60 Drop
  - o Set, Infusion "Y", Luer lock, air inlet
  - Infusion set Buretrol
- Incontinence Sheets
- Intubation stylet, adult, 15 Ch
- K.Y. Jelly
- Latex Tubing
- Linen Savers
- Masks Nebulizer/Oxygen
- Masks Oxygen 40 %
- N.G Tubes 12, 14, 16
- Nail Brushes Autoclavable/Disposable
- Needles:
  - o Spinal disp, (0.9x90mm), sterile, 20G, 22G, 24G
  - o Disp,15G, 18G, 21G, 22G, 23G, 25G
  - o Butterfly 23G
- Oxygen T Pieces and Oxygen Tubing
- Pads Sanitary Maternity
- Paper CTG
- Face Masks
- Razor Medical Disposable Single Edge
- Rubber Bath Mat Non-Slip
- S.G. Meter (Urine Meters)
- Safety Pins Large & Medium
- Sharps Containers (Safety Box/used syringes and needles)
- Shrouds
- Soap,toilet,bar,approx.110g,wrapped

- Spatulas Tongue
- Spigots Large, Medium and Small
- Spray Bottles Plunger Operated
- Surgical Spirits
- Suture absorbable (Chromic) for episiotomy and perinea tears
- Syringes:
  - o 2ml, 5ml, 10ml, 20ml
  - o Syringes 50 ml Conical Tip
  - o Syringes 50 ml Luer Lock
  - Syringes Insulin
- Tapes
  - Elastic Adhesive Plaster White 5cm and 10 cm
  - Micropore tape
  - o Tape Surgical Adhesive Hypo-Allergenic
  - o Tape,adhesive,Z.O,perforated,10cmx5m
- o Tape,adhesive,Z.O.,2.5cmx5m
- Clinical thermometer
- Fridge thermometer
- Tourniquet, latex rubber,75cm
- Tube:
  - o Endo-tracheal, disp. + connector, neonate mm, w.o balloon
  - Endo-tracheal, disp. + connector, balloon, 6.5mm, 7mm, 7.5mm, 8mm
  - o Suction, L125cm, ster, disp, CH10, CH12, CH16
- Umbilical clamp
- Umbilical cord tape

## 6.10.4.29 Operating Suite Renewable/Consumables:

- Airway Guedel, 00 (neonatal), 3, 4 & 5
- Plastic, reusable aprons
- Urine bags, collecting, 2000 ml
- 012 Band, Esmarch, 6 cm x 5 m
- Survival blanketl,220x140cm
- First Referral Hospitals

- Blood Sampling:
- Needle, disposable, sterile, 20G, 21G
- Tube, Vacuum 5ml (Vacutainer)
- Tube, Vacuum EDTA 5ml (Vacutainer)
- Tube, Vacuum Heparinised 5ml (Vacutainer)
- Vacutainer Holder
- Bouffant Nurse Cap
- Bubble Tubing
- Cannula,IV short,ster,disp, 18G, 20G, 22G, 24G
- Catheters:
  - o 036 Catheter Sup-Pubic, CH 10, 1.65 cm, ster, disp., adult
  - o 037 Catheter, ureteral, CH5, ster, disp
  - o 038 Catheter, urethral, CH6, ster, disp
  - o 039 Catheter, urethral, CH7, ster, disp
  - o Catheter, Foley, ster, disp, CH10, CH12, CH14
- Compresses:
  - o Abdominal compress, 40 x 40 cm
  - o Compress, Swab, 20x 20 cm
  - o Compress,gauze,10x10cm,n/ster/PAC-100
  - o Compress,gauze,10x10cm,ster/PAC-5
  - o Compress,paraffin,10x10cm,ster/BOX-10
- Connector, biconical, OD 7-11-7mm
- Cotton wool,500g,roll,non-ster
- CVP Set
- Diathermy pencil/ball/blade
- Disposable, dispersive, electrode(Diathermy pad)
- Drain, corrugated sheet, 3 cm x 25 cm
- Drain, wound, CH 12, ster, disp, 450 ml (Redon + Needle), CH12, CH16,
   CH6
- Drawsheet,plastic,90x180cm
- Elastoplasts, 10 cm x 3 m
- Electrode, Chest, Monitor
- Extractor,mucus,20ml,ster,disp

- File for ampoules
- Gauze:
  - o Gauze Ball, Large (sterile)
  - o Gauze Ball, Large (un-sterile)
  - Gauze Ball, Peanut (sterile)
  - o Gauze Swabs RAYTEX® 10 X 10 cm
  - o Gauze Swabs, Un-sterile (Green)
  - o Gauze,roll,90cmx100m,non-ster
- Gloves:
  - o Gloves, exam, latex, disp, large, medium & small
  - o Gloves, gynaeco, ster, disp, 6.5, 7,5 & 8.5
  - o Gloves, surg, disp, 6.0, 6.5, 7.0, 7.5, 8, 8.5
- Gum elastic bougie, CH 15, 60 cm
- I.U.D., copper, T
- Intubation stylet, adult, 15 Ch
- Lancet,blood,ster,disp/PAC-200
- Mask, Clinical, Disposable (non-woven)
- Mask, Protection, High Filtration
- Needle, spinal, 0.9x90mm), ster, disp, 20G, 22G, 24G
- Obstetrical Pads
- Opsite Flexi-grid (Various Sizes)
- Oxygen mask, adult
- Oxygen, nasal cannula
- Reusable, Diathermy, Cable
- Safety box for .used syrgs/ndls 5lt/BOX-25
- Set, Infusion "Y", Luer lock, air inlet
- Scalpel blades:
  - o Scalpel blade, ster, disp, no. 10, no. 11, no. 15, no. 22, no. 23
  - Scalpel blade,ster,disp,no.11
- Shoe cover, disposable
- Silicone Rubber Tubing
- Surgeon's Cap, Easy-Tie
- Sut, abs, non-absorbable, various

- Syringe, dispos, 2ml, 5ml, 10ml, 20ml
- Tape,adhesive,Z.O,perforated,10cmx5m
- Tape,adhesive,Z.O.,2.5cmx5m
- Telfa, dressing (Various Sizes)
- Tourniquet,latex rubber,75cm
- Tubes different type and size
- Umbilical Cord Clamp
- Operating Room Linen:
- Apron Surgical, rubber
- Trousers, Surgical, woven, Small, Medium & Large
- Top, Surgical, woven, Small, Medium & Large
- Gown, Surgical, woven(Plain)
- Cap, Surgical, woven
- Drapes:
  - o Drape, Surgical, woven(1 X 1 m)
  - o Drape, Surgical, woven(1 X 1,5 m)
  - o Drape, Surgical, woven(1.5 x 1,5 m)(fenestrated
  - o Drape, Surgical, woven(45 cm X 70 cm)(fenestrated)
- Bed
- Sheet, draw, white
- Cellular Blanket (Recovery and outside blankets)
- Mayo cover
- Towel Bath
- Towel Hand

### 6.11 Anesthesia Services

#### 6.11.1 Practices

- 6.11.1.1The general anesthesia service shall be provided only in the operation theatre (OR) facility.
- 6.11.1.2There shall be a written policy about administration and monitoring of regional and general anesthesia in the hospital,
- 6.11.1.3The hospital shall have written policy to administer and monitor minor regional blocks
- 6.11.1.4Anesthesia services shall be administered in accordance with written policies and procedures. The policy 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) Pre anesthetic /sedation assessment shall be done by anesthesiologist or anesthetist before admission and prior to induction.
  - (c) Each patient's physiologic status shall be continuously monitored and documented every 10 minutes during general anesthesia, regional anesthesia and sedation
  - (d) 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.
  - (e) Prior to administration of any pre-anesthesia medication, a written informed consent for the use of anesthesia must be obtained and documented in the medical record.
  - (f) 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.
- (g) As part of the anesthesia administration policy, the anesthesia record shall include:
  - 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.
- (h) 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.
- (i) The time of arrival and discharge from anesthesia recovery room shall be recorded.
- (j) The observation recovery room shall be done by qualified licensed nurses with training of basic advanced cardio-pulmonary support
- (k) 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.
- (l) The discharge order from the recovery shall be documented on patients chart and signed by anesthesiologist or anesthetist or other qualified physician before transfer.
- 6.11.1.5 Provision shall be made for remote monitoring of the patient if radiation or another direct hazard necessitates the removal of personnel from anesthetized person.
- 6.11.1.6 An anesthesiologist shall be available during working hours and on-call after working hours within 30 minutes.
- 6.11.1.7 The anesthesiologist or 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.

- 6.11.1.8 The anesthesiologist or anesthetist shall discuss possible plans of management with the patient and explains any options available, to enable the patient to make an informed choice.
- 6.11.1.9 Information on any medicines or treatments such as blood transfusion shall be discussed with the patient.
- 6.11.1.10 The anesthesiologist or anesthetist shall ensure that all the necessary equipment and medicines are present and checked before starting anesthesia.
- 6.11.1.11 The anesthesiologist or anesthetist shall confirm the identity of the patient before inducing anesthesia.
- 6.11.1.12 The anesthesiologist or anesthetist shall be present in the operating theatre throughout the operation and shall be present on-site until the patient has been discharged from the recovery room.
- 6.11.1.13 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,
  - c) The inspired oxygen concentration; and
  - d) A written record of the anesthetic shall be kept as a permanent record in the case notes.
- 6.11.1.14 Pain shall be assessed in discussion with surgeon and/or the patient and pain control shall be provided.
- 6.11.1.15 Patients shall be managed in a recovery room, except patients requiring transfer for intensive care in ICU, until overcome effect of anesthetic.
- 6.11.1.16 There shall be one person on duty in the operating theatre at all times with certified training in advanced cardiac life support.
- 6.11.1.17 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 anesthetist or any qualified physician.
- 6.11.1.18 The policies and procedures used for anesthesia service shall be available and well understood by the surgical team.

- 6.11.1.19 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.
- 6.11.1.20 There shall be a written protocol to assure that surgery does not proceed when there are disabled alarms, depleted batteries and inactive sensors in oxygen monitors or carbon dioxide monitors, improperly positioned breathing-circuit sensors, or other insufficiencies.
- 6.11.1.21 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.
- 6.11.1.22 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 may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness.
- 6.11.1.23 End-tidal carbon dioxide monitoring shall be performed continuously during administration of all general anaesthesia, unless such monitoring is not clinically feasible for the patient (optional).
- 6.11.1.24 An electrocardiogram (ECG) monitor shall be used continuously on all patients receiving general anesthesia, regional anesthesia, or conscious sedation at any anesthetizing location.
- 6.11.1.25 Blood pressure, pulse rate, and respirations, 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.
- 6.11.1.26 Monitoring of regional labour analgesia shall include: documented temperature, pulse, respiration, blood pressure, and oxygen saturation until the patient is deemed stable. The patient shall be monitored subsequently in accordance with hospital protocol.

#### 6.11.2 Premises

- 6.11.2.1**Operation theatre:** in addition to the standards prescribed under the Surgical service:
  - (a) There shall be a mechanism for taking exhaust air from anesthesia machine to outside of OR; important when performing open system for pediatric anesthesia,
  - (b) There shall be central oxygen system or a system where there is continuous supply of Oxygen cylinders,
- 6.11.2.2**Anesthesia store:** in addition to the standards prescribed under the Surgical service :
  - (a) 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,
  - (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,
- 6.11.2.3**Staff office room** with chairs, table, cabinet; in addition to the standards prescribed under the Surgical service:
- 6.11.2.4**Recovery Room**: in addition to the standards prescribed under the Surgical service and shall be sited within the operating suit and has a minimum of:
  - Two beds with side protection,
  - Monitoring equipment, including ECG;
  - Resuscitation equipment including a defibrillator on trolley,
  - Oxygen source,
  - Ensures ease of communication and access for anesthesia department staff for close follow up.

### 6.11.3 Professionals

6.11.3.1Anesthesia service shall be directed by a licensed anesthesiologist.

- 6.11.3.2All 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.
- 6.11.3.3General or major regional anesthesia shall be administered and monitored only by the following:
  - a) An anesthesiologist;
  - b) BSc in anesthesiology;
  - c) nurse anesthetist; or
  - d) A physician resident (anesthesiology), a student nurse anesthetist, a student anesthetist under the supervision of a licensed anesthesiologist, BSc in anesthesiology and/or nurse anesthetist.
- 6.11.3.4The supervision of general or major regional anesthesia shall be provided by anesthesiologist who is immediately available. The supervising physician may concurrently be responsible for patient care, with the exception of performing major surgery, administering general anesthesia, or major regional anesthesia.
- 6.11.3.5Minor regional blocks shall be administered by the following licensed professionals:
  - a) An Anesthesiologist, or
  - b) An anesthetist,
  - c) A physician, podiatrist (foot doctor) or dentist;
  - d) A medical intern, physician resident, dental resident, or a student nurse anesthetist, or student anesthetist, licensed health officer, a licensed nurse midwife or clinical nurse under the supervision of a physician

### 6.11.4 Products

- 6.11.4.1Anaesthesia supplies and equipment and safety systems shall include the following:
  - a) Diameter index safety systems or equivalent shall be used on all large cylinders of medical gases and wall and ceiling outlets of medical gases.
  - b) Pin index safety systems with a single washer shall be used on all small cylinders to prevent interchangeability of medical gas cylinders.
  - c) All medical gas hoses and adapters shall be colour-coded and labeled according to current national standards.

- d) An oxygen failure-protection device ("fail-safe" system) shall be used on all anaesthesia 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.
- e) Vaporizer exclusion ("interlock") system shall be used to assure that only one vaporizer, and therefore only a single agent, can be actuated on any anaesthesia machine at one time.
- f) To prevent delivery of excess anaesthesia during an oxygen flush, no vaporizer shall be placed in the circuit downstream of the oxygen flush valve.
- g) All anaesthesia vaporizers shall be pressure-compensated in order to administer a constant non-pulsatile output.
- h) 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.
- Alarm systems shall be in place for high (disconnect), low (sub atmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anaesthesia.

## 6.11.4.2Anaesthesia supplies and equipment and patient monitoring shall include:

- a) An in-circuit oxygen analyzer shall monitor the oxygen concentration within the breathing circuit, displaying the percent oxygen of the total mixture, for all patients receiving general anaesthesia.
- b) A respirometer (volumeter) measuring exhaled tidal volume shall be used whenever the breathing circuit of a patient under general anesthesia allows.
- c) The capacity for invasive monitoring of arterial pressure shall exist within the operating suite/ theatre.
- d) A difficult airway container or trolley shall be immediately available in each anesthesia department for handling emergencies. The following items are required for inclusion in the difficult airway container or trolley:
  - Resuscitation equipment like ambu bag, laryngoscope, defibrillator, laryngeal mask and endotracheal tube stylet,
  - Emergency medicines,

- Laryngeal mask airway, and/or other items of similar technical capability.
- e) 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.
- f) A peripheral nerve stimulator shall be available in any anesthetizing location in which patients receive general or regional anesthesia to monitor the patient's extent of muscle paralysis from muscle relaxants. Another peripheral nerve stimulator shall be available within the post anaesthesia care unit.
- g) 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.

#### 6.11.4.3 Equipments:

- a) Anesthesia machine with ventilator, 2 vaporizers, and gas cylinders
- b) Adult and pediatric anesthesia circuits with filters
- c) Mechanical ventilators
- d) Oxygen cylinders, oxygen trolley and oxygen regulator
- e) Worktable with laminated top
- f) Resuscitation equipments; Ambu bag, adult pediatric neonates, with inflatable bag,
- g) Refrigerator,
- h) Time clock
- i) Stools
- j) Clips
- k) Bathroom Weight scale; adult & pediatric
- l) Resuscitation trolley
- m) Syringe pump
- n) Defibrillator
- o) Blood gas analyzer (optional)
- p) Dust bin
- q) Blankets, warming
- r) Framed boards with pencil trays

- s) IV stands, infusion pumps, IV fluid pressure bags, blood warmer and IV fluid warmer
- t) Tourniquets, tongue depressors, disposable
- u) Operation table and accessories:
  - Pillows, abduction
  - Support, head, operating table
  - Positioner bag, small, medium, large
  - Adjustable Head screen
  - Patient transferring Stretchers
  - Suction machines

## v) Patient monitor

- ECG monitor
- 12 leads Electrode, Monitor
- Pulse oximeter
- Temperature monitor
- Nerve stimulator
- Dual head stethoscope
- BP apparatus with different size cuffs

## w) Intubation gadgets:

- Airway Guedel, pediatric & adult size: 0, 00, 3, 4 & 5
- Laryngeal mask set
- · Mask holder
- Cannula Nasal-Oxygen,
- Face mask- 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
- Tube, Endo-tracheal, different size with connectors:
- Tube, Trachea, balloon, different size

- Tube, Suction, CH08, L50 cm, ster, disp, CH08, CH10, CH14, CH16
- Extractor, mucus, 20ml, ster, disp
- Safety Pins Large & Medium
- Connector, Biconical, Autoclavable
- Connector, T/Y
- Connectors Plastic Tapered
- Masks Nebulizer/Oxygen
- Other accessories/ supplies:
- Braun Splints (Arm)
- Draw sheet, plastic, 90x180cm
- Clinical thermometer
- Fridge thermometer
- Tourniquet, latex rubber,75cm
- 6.11.4.4All anesthetic medicines and supplies shall be available as per the national medicine list of Ethiopia.
- 6.11.4.50 perating Room Linen:
  - a) Apron Surgical, rubber
  - b) Trousers, Surgical, woven; Small, Medium & Large
  - c) Top(shirts), Surgical, woven; Small, Medium & Large
  - d) Gown, Surgical, woven(Plain)
  - e) Caps, Surgical, woven
  - f) Masks, surgical, woven
  - g) Pillow case
  - h) Pillows
  - i) Sheet, Bed
  - j) Sheet, draw, white
  - k) Cellular Blanket
  - l) Organ protections,
  - m) Shelves
  - n) cabinets

## 6.12 Intensive Care unit (ICU) Services

#### 6.12.1 Practices

- 6.12.1.1 The hospital shall have at least one intensive care unit comprising of medicalsurgical intensive care services
- 6.12.1.2 In addition, the hospital shall have one neonatal intensive care unit
- 6.12.1.3 This intensive care unit may have the following additional intensive care subunits:
  - (a) Psychiatric Intensive Care Unit (PICU)
  - (b) Coronary Care Unit (CCU)
  - (c) Burn Wounds Intensive Care Unit (BWICU)
  - (d) Trauma Intensive care Unit (TICU)
  - (e) Respiratory Intensive Care Unit (RICU)
  - (f) Neuro-Intensive Care Unit (NICU)
- 6.12.1.4 The ICU is open 24 hours and 7 days a week, with available medical personnel with CPR training available round the clock with shift.
- 6.12.1.5 The ICU shall have written policies and procedures that are reviewed at least once every 5 years and implemented. They shall include at least:
  - (a) Criteria for admission to ICU,
  - (b) Criteria for discharge and transfer from the service to other patient care units in the hospital;
  - (c) Criteria for transfer / discharge from the service to other health care facilities;
  - (d) A list of procedures that licensed physicians, who are certified/ accredited in intensive care, may or may not perform;
  - (e) Protocols for transfer and transport of patients within the hospital or from the hospital to another facility including who shall accompany the patient being transferred or transported;
  - Infection control procedures and/or protocols as indicated under infection prevention standards;

- (g) A visitors policy that specifies visiting hours and number which subject to the discretion of the patient's physician or primary care nurse;
- (h) A policy on the removal of a patient's life support system;
- (i) 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;
- (j) Standing orders for patient emergencies;
- (k) Policies and procedures which ensure that priority laboratory services will be available to critical care patients at all times if medically indicated;
- (l) Side laboratory with specific service to ICU shall be available 24 hours a day throughout the year,
- 6.12.1.6 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 intensivist or trained internist or independent practitioner who is exclusively responsible for patients.
- 6.12.1.7 Nursing care shall be the responsibility of a licensed nurse.
- 6.12.1.8 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 hospital record,
- 6.12.1.9 A ratio of two patients to one nurse shall be available at a general ICU.
- 6.12.1.10 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?".

- 6.12.1.11 There shall be portable life-support equipment for use in patient transport, both within the hospital 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.
- 6.12.1.12 There shall be a policy or protocol available that state availability of 24 hours access for the services of advanced diagnostic facilities.
- 6.12.1.13 There shall be a system in the hospital of assuring the functionality of the ICU gadgets/ equipments and evidence with labeling of the service.
- 6.12.1.14 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.
- 6.12.1.15 There shall be a program of continuous quality improvement for the ICU service that is integrated into the hospital 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.

#### 6.12.2 Premises

- 6.12.2.1 The ICU shall be located in access restricted area of the hospital and well identified.
- 6.12.2.2 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 4 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).

#### 6.12.2.3 Nurse station in the ICU:

- a) Isolated with glass, full visual access to monitor admitted patients on monitors,
- 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,
- 6.12.2.4 The ICU shall have easily accessible hand wash basin around the entrance-exit door.
- 6.12.2.5 In addition to the main ICU for critical care, the unit shall have the following spaces (rooms): nurse room, utility room, store, duty room, cleaner's room, staff tea room, toilets with shower and spacious corridor for stretchers and wheelchairs.
- 6.12.2.6 The ICU shall have 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.
- 6.12.2.7 The ICU shall have at least 2 electric outlets per bed.
- 6.12.2.8 Changing room and/ or 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.
- 6.12.2.9 ICU Utility/ Sluice room: There shall be soiled utility/sluice room which acts as a storage area for contaminated materials until they are taken for disposal 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.
- 6.12.2.10 Store room: There shall be an ICU supply room (store) 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.

- 6.12.2.11 Cleaner's room: There shall be an ICU cleaner'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.
- 6.12.2.12 Staff tea room: There shall be a staff tea room in close proximity to the ICU.

#### 6.12.3 Professionals

- 6.12.3.1 The hospital ICU shall be directed by a licensed anesthesiologist or intensivist or ICU trained internist who has clinical responsibility for the standard of care rendered in each critical care unit or combination of critical care units.
- 6.12.3.2 The specialist in each discipline shall be responsible for the management of patients in specialized ICU (Example: thoracic surgeon for surgical ICU, neonatologist for neonatology ICU and the likes).
- 6.12.3.3 Each specialized ICU shall be lead by the sub-specialists.
- 6.12.3.4 The physicians working in the ICU shall be certified in internal medicine, anesthesia, surgery, neonatology or general practice and/or have completed a formal training program in critical care approved by Authority. In the case of an ICU that provides one specialty area of critical care, such as coronary care, neonatal care, the director of the unit shall be certified in that particular specialty or subspecialty (e.g., cardiologist, pediatrician, neonatologist, obstetrician).
- 6.12.3.5 There shall be a licensed 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.
- 6.12.3.6 The nursing staff of each unit within the ICU service shall have special training in critical care nursing and certified by the Authority.
- 6.12.3.7 All practicing nurses in the ICU shall be trained and certified in basic cardiac life support.
- 6.12.3.8 Nurse staffing shall be determined by the number and acuity of illness of the patients (workload analysis) on the critical care unit.
- 6.12.3.9 Assistants assigned in ICU shall be oriented and trained on basic cardiac life support and critical care.
- 6.12.3.10 There shall be at least one licensed ICU nurse in the ICU for 24 hours a day and 365 days a year.

- 6.12.3.11 At least the following professionals are required:
  - a) One anesthesiologist or intensivist
  - b) At least one ICU trained nurse for two beds
  - c) Clinical nurse
  - d) Cleaners
  - e) Porters

#### 6.12.4 Products

- 6.12.4.1 Medicines selected for ICU services by the hospital shall be available at all times.
- 6.12.4.2 The hospital 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,
  - h) defibrillators; at least 2,
  - i) Reliable Oxygen delivery systems: Oxygen cylinder or oxygen concentrator,
  - j) Oxygen regulator,
  - k) pulse oximeter,
  - l) end-tidal carbon dioxide monitoring,
  - m) Titrated therapeutic interventions with infusion pumps,
  - a web of intravenous lines for medicine infusions fluids or total parenteral nutrition,
  - o) Suction pumps,
  - p) Infusion pumps,
  - 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) Stethoscopes: pediatric and adult,
- cc) Electrical suction machine (at least 1 as a backup),
- dd) Pedal suction machine,
- ee) Acid base analyzer, minimum two ventilators and a mobile x-ray
- ff) Nasal CPAP,
- gg) Bed pan, plenty in number, different size,
- hh) Pacing boxes (at least 2)
- ii) X-ray viewer per bed, at least 4
- jj) Wall clock (at least 2)
- kk) Soiled cloth hampers,
- ll) Telemetry monitoring with transmitters,
- mm) Telephone end,
- nn) Medication boards,
- oo) Calculators,
- pp) Weight scale,
- qq) Ready to use CPR equipments and defibrillator on trolley,
- rr) Patient labeling for diet, allergy, etc.,
- ss) Patient screen per bed and
- tt) IV stands, at least two per bed,

## 6.13 Dentistry Services

#### 6.13.1 Practices

- 6.13.1.1The dental service shall be available during working hours.
- 6.13.1.2There shall be written protocols and procedures for the management of dental conditions as well as consultation, referral and transfer of inpatients /outpatients to other services inside/outside the hospital.
- 6.13.1.3The dental unit shall be functional for dental emergency cases on on-call basis after working hours.
- 6.13.1.4Emergency care with a qualified staff shall be available 24 hours a day.
- 6.13.1.5Emergency oral and maxillofacial surgery services shall be available 24 hours a day and 365 days a year. This includes:
  - a) Facial and dent alveolar infections (cellulitis)
  - b) Treatment for facial injuries and associated injuries
  - c) Lower or upper jaw fractures
  - d) Evaluation and treatment of nerve injury
  - e) Dental trauma
- 6.13.1.6Non emergency oral and maxillofacial surgery services should be available during the regular working hours. This includes:
  - a) Treatment for craniofacial and jaw deformities
  - b) Implants and preprosthetic surgery
  - c) Temporomandibular joint therapy
  - d) Facial cosmetic surgery
  - e) Surgery for oral pathological lesions, including oral cancer
  - f) Physical therapy for orofacial pain
  - g) Removal of malpositioned or impacted teeth
  - h) Surgery for cleft lip and palate (team work)
  - i) Apicectomia & Cystectomia etc.
- 6.13.1.7Non emergency dental services shall be available during the regular working hours. This includes:
  - a) Restorative
  - b) Prosthetic
  - c) Endodontic therapy

- d) Periodontal therapy
- e) Exodontias
- f) Oral Community (Oral Health Education)
- 6.13.1.8The dental service shall be provided in accordance with infection prevention standards.
- 6.13.1.9For admitted patients the dental service shall be organized in such a way that it covers all the shifts.
- 6.13.1.10 Adequate dental records shall be kept for each patient and the patient's dental service record shall be integrated with the patient's over-all hospital record
- 6.13.1.11 Information contained in the dental record shall be complete and sufficiently detailed with respect to the patient's history, physical examination, oral (Intra & Extra) examination, diagnosis, diagnostic procedures, medication administration, and treatment to facilitate continuity of care.
- 6.13.1.12 Informed Consent (written/verbal) shall be complete for every dental procedure in addition to minor & major surgeries.

#### 6.13.2 Premises

- 6.13.2.1The dental service shall be located in the outpatient service of the hospital.
- 6.13.2.2There shall be inpatient rooms for admission of surgical cases.
- 6.13.2.3 There shall be a minimum of one room with two dental units or set ups.
- 6.13.2.4The number and size of the rooms shall be adequate depending on the volume and nature of the activity in the service unit.
- 6.13.2.5There shall be a reception area which will serve as oral health education.
- 6.13.2.6There shall be X-Ray mounted dental unit with leaded door and lead apron. The design of rooms for dental X-ray equipment should be in accordance with the guidelines of Ethiopian Radiation Protection Authority.
- 6.13.2.7The dental service shall have a dental laboratory room for orthodontics and prosthodontics.
- 6.13.2.8The premises for dental service shall have the following rooms:
  - a) Examination Room with dental units,
  - b) Room for dental laboratory,
  - c) Dental Sterilization area/ Store room /shelves
  - d) Staff Office

- e) Store
- f) Room for mini pharmacy
- g) Staff toilets, showers and changing room
- h) Patient toilet and shower
- i) Places for air compressor and equipment for evacuation,
- j) Places for electric generator, back up
- 6.13.2.9The dental service shall use the hospital operation theatre (OR), ICU & anaesthesia services.

## 6.13.3 Professionals

- 6.13.3.1The dental service shall be directed by licensed Dental Specialist or dental surgeon.
- 6.13.3.2There shall be adequate qualified dental and auxiliary personnel in the dental service unit available at all times to meet the service needs.
- 6.13.3.3The number and type of technical staff shall be determined by the volume and type of work carried out (Work load Analysis).
- 6.13.3.4A Dental surgeon/doctor or licensed independent practitioner shall be available (Physically present) at all times in the dental unit.
- 6.13.3.5A senior Dental Specialist shall be on duty or on call at all times. The specialist shall be able to present at the service unit within thirty (30) minutes upon call.
- 6.13.3.6Licensed dental professionals (BDSc, Dental Therapist, Dental Technician, and Dental & Hygienist) shall be available at all times to assess, evaluate, and follow the dental care provided.
- 6.13.3.7The Dental nurse with administrative responsibility for dental care shall be a licensed dental professional with at least two years of experience in dentistry.
- 6.13.3.8There shall be adequate support staff available as per the service need
- 6.13.3.9There shall be a mechanism for exchange of scientific knowledge, skills and services in line with upgrading standard of dental services
- 6.13.3.10 Professionals in dental service unit shall have good clinical and/or dental laboratory practice.

#### 6.13.4 Products

- 6.13.4.1The dental services shall have the following equipment and instruments
  - a) The dental units
    - Air-water syringes

Operating light

- Saliva ejector (oral evacuator system)
- Cuspidor
- Adjustable work surface
- Individual hand-piece holder
- Halogen cure light
- Dental Chair
- Operator's stool
- Assistant stool
- Matrix band (metallic & celluloid, different size for molar & bicuspid)
- Aticulating paper
- Wooden wedge
- Paper pad
- Glass slab
- Dental floss
- Dappen dishes
- Finishing disc (various sizes and grits)

- Abrasive stones and dics (green, white)
- Brushes (prophylaxix type)
- Rubber disc with abrasives
- Polishing pastes
- Sand paper disc
- Mortar and pestle
- Kit for friction lock retention pin
- Spatula (various sizes and shapes metallic, plastic)
- Rubber bowl
- Sets of preformed temporary stainless steel crown
- Sets or preformed anatomical plastic crown of polycarbonate resin

## b) Instruments for examining

- Dental mirror
- Explorers (different types, no. 521,22,17 & 23)
- Cotton pliers

- Spoon excavator (different size)
- Periodontal pocket probe

#### c) Instruments for filling treatment

- Condenser (serrated & plain, Medium, and big size)
- Beaver tail
- Burnisher (ball type, football type, interproximal type)
- Carve (Hollenback, tanner, ward, discoid-cleoid)
- Trimmers
- Knife (interproximal, finishing gold foil)
- Amalgam carriers (doubled ended, guntype)
- Proximal trimmer
- Matrix retainer (different types tofflemire, ziqueland)

#### d) Plastic Instruments for filling treatment

• Carriers for restorative materials

- Carvers
- Condenser Beaver tail

# e) Materials & instruments to keep the area free from moistures & to improve visibility

- Rubber dam equipment
- Clamps (different type, posterior & anterior, mandibular & maxillar)

- Universal rubber-Dam clamps forceps
- Rubber- dam punch
- Holder young frame
- Automation

## f) Dental hand pieces

- Low speed hand pieces
- Straight hand pieces
- Contra angle hand pieces

- High speed hand pieces
- Polishing hand pieces unit
- Ultrasonic Scaler

## g) Scissors:

- Hemostats (curved, straight, mosquito, Kelly needle holder)
- Crow scissors
- Ligature scissors
- Surgical scissors

## h) Instruments for root canal treatment

- Endodontic probe
- Straight and curved gutta percha pluggers
- Broach (smooth and barber type)
- Files ( Hedstrom files, K types files, Rat-Tail files
- Disposable syringe
- Gates Glidden drills

- Spreaders
- Lebtyki sourak
- Millimeter ruler
- Vitalometer (electrical pulp tester)
- Glass bead sterilizer
- Endodontic measureing Gauge

## i) Materials for root canal treatment

Paper points

 Gutta percha points (From 1 to 6 and from 7 to 12)

- Endodontic kits
- j) Rotating instruments & hand cutting instruments
  - Burs (carbide, diamonds, plain steel, carborundum for slow hand piece& high hand piece types)
  - Round burs (Number ½-11)
  - Pear- shape burs (230-232)
  - Inverted cone burs (31 ½-44)
  - Taper fissure burs (169-171 plain, 699-703)
  - Round- end
  - Fissure burs
  - Flat-end fissure burs (957-959)
  - Cylinder burs
  - Wheel burs (11 ½ -16)
  - End-cutting burs
  - Drills for pin retention

- Flames burs (242-246)
- Straight fissure (55 ½-62 plain,556-563 dentate)
- Composites burs
- Bud Burs (44 ½-51)
- Oval burs (218-221)
- Cone burs (22 ½ -33)
- Mandrel (straight and latch type)
- Carborundum, Silica, Crocus, discs and stones
- Enamel Hatches
- Enamel chisel
- Discoid-cleoid
- Dental Hoe
- Gingival margin
   Trimmer
- Angle former

- k) Instrument for Oral Surgery
  - Periosteoteme (Periosteal elevator)
  - Surgical Kit (MFS)
  - elevators
- l) Forceps for Dental Extractions (Deciduous teeth)
  - Maxillary forceps for anterior teeth:
    - o Forceps 99 A (Canine forceps)
    - o Forceps 99 C (incisor forceps)
    - o Forceps 150 (Universal forceps)
    - o Forceps 213 (incisor forceps)
  - Maxillary forceps for back teeth
    - o Forceps 18 right and left
    - o Forceps 210 (wisdom forceps)
    - o Forceps 24 (universal forceps for molar)
- m) Mandibular forceps for anterior & posterior teeth extraction
  - Mandibular forceps for anterior teeth
    - o Forceps 103-(incisors forceps)
    - o Forceps 203 (incisor forceps)

- Forceps 1519 universal forceps)
- Mandibular forceps for posterior teeth:
  - o Forceps 16 (1st molar forceps)
  - o Forceps 23 (1st molar forceps)
  - Forceps 297 (2nd molar forceps)
  - Forceps 222 (Wisdom forceps)
- n) Right-angled forceps for mandibular Extraction
  - Mead 3 forceps
  - Mead 4 forceps
- o) Maxillar Forceps for anterior & posterior teeth extraction

## p) Forceps for maxillary Root Extractions

- Upper frontal milk forceps (forceps 1)
- Upper molar milk forceps (forceps 8)
- Lower frontal milk forceps (forceps 4)
- Lower molar molk forceps (Forceps 5)
- Root forceps (Bayonet)-(forceps 2)
- q) Forceps for Maxillary and mandibular root extraction
  - Forceps for Maxillary Root Extraction:
    - Forceps 286 (Bayonet forceps)
  - Forceps for mandibular root Extractions:
    - Forceps 44

## r) Orthodontics instrument

- Band removing pliers
- Band pusher
- Band adapter
- How pliers (straight and curved)
- Bird-beak pliers
- Ligature cutter
- Distal end cutler
- Band removing pliers
- Wire bending pliers-
- s) **Periodontal instruments** 
  - Scalers- different types, sickle, Jaquete, Chisel, Hoe, file scaler
  - Curettes (Universal, Gracey)
  - Periodontal knives:
  - a) Kirkland
  - b) Interdentally

- Lingual arch forming pliers
- Loop pliers
- Clasp bending pliers
- TP pliers (110,130)
- Assorted orthodontics band
- Preformed edgewise arch wires/
- c) Surgical Hoe
- Periodontal pocket marker
- Electro surgery apparatus with different netting tips
- Arkansas flat stones,
- Electrical sharpener,

- Mounted
- stones

#### t) Prosthodontics Instruments:

- Crown remover
- Trays-(perforated, rim lock, acrylic, metallic, different sizes, for the upper & lower jaws)
- Wax carvers
- Porcelain carvers

## u) Basic Dental Laboratory Equipments:

- Model trimmer Vibrator
- Bench lathe
- Vacuum Spatulator
- Bench motor with Hand piece
- Casting unit
- Arch articulator

- Wax spatula
- Acrylic stones
- Stones for gold alloy
- Bunsen burner
- Sep up & units for heating & processing dentures materials
- Laboratory spatula
- Coping saw
- Laboratory Knife
- Simulation laboratory
- Typodont

## v) Equipment for Radiology Department:

- Dental X-ray unit
- Panoramic radiography
- Cephalometric radiolgrapy (Optional)
- Intraoral X-rays system
- Extraoral X-rays ststem
- View box for radiography (Negatoscope)
- Automatic film processing
- Lead aprone

## w) Equipments for sterilization

- Super heated steam under pressure (Autoclave)
- Dry heat sterilization (Oven)
- · Chemical autoclave-
- Ultrasonic cleaner system
- Different pans use for disinfections & sterilization of instruments
- Cotton roll sterilizer

## x) Equipment used for amalgam restoration:

- Amalgam mixing machine (Amalgamatory)
- Electric spot welder

## y) Different operatory cabinets:

- Mobile cabinets
- Fixed cabinet

## z) Central Air compressor

## aa) Other surgical instruments

- Curettes (Angled, Straight, different Sizes)
- Rongeurs (Bonecutting forceps)
- Bone-file
- Scalped and Handle for scalped
- Cheek and Tongue retractors
- a) Farabeut
- b) 3rd molar retractors
- Mouth props
- 6.13.4.2 The dental service shall have the following materials
  - a) Dental materials: Temporary & permanent fillings
  - b) Dental films (Periapical, occlusal & panoramic view)
  - c) Light curing unit with composite materials
  - d) Local anesthesia (Spray, Cartridge with & without adrenalin)
  - e) Other consumables (analgesics, disposable syringe & gloves etc)

- Bone chisels
- Mallets
- Suture needles
- Irrigation syringe
- Aspirating tip
- Local anesthetic equipment (metal anesthesia syringe
- Pliers flat nose and serrated
- Contouring pliers (Number 112,114,118,800,41
   7

## 6.14 Otorhinolaryngology (ORL) Service

#### 6.14.1 Practices

- 6.14.1.1The ORL service shall have written policies and procedures
- 6.14.1.2There shall be written protocols and procedures for the management of the medical conditions in the unit as well as consultation and transfer of patients admitted to this unit or other departments
- 6.14.1.3Every medical records shall be kept for each patient as specified in the medical records section of this standard
- 6.14.1.4Integrated emergency ORL service shall be available 24 hours a day and 365 days a year
- 6.14.1.5Outpatient and elective interventions for ORL service shall be available during working hours
- 6.14.1.6The hospital may have ORL services at subspecialty level.
- 6.14.1.7The .ORL service shall include the following.
  - a) Daily outpatient services.
  - b) Minor and major surgical services.
  - c) Inpatient services
  - d) ORL diagnostic tests and procedures.
  - e) Pre operative investigations and Postoperative follow ups.
  - f) Outpatient and inpatient consultations from other departments.
  - g) ORL emergency services management.
  - h) Post graduate training and research, optional
- 6.14.1.8Infection prevention standards shall be implemented in the ORL service as per the IP section of this standard.
- 6.14.1.9The service shall have access to laboratory, digital X-ray, CT or MRI, blood transfusion, pharmacy, medical record and registry and other services.

## 6.14.2 Premises

- 6.14.2.1The ORL service shall have the following units.
  - a) The outpatient service unit which shall be located adjacent to the general
     OPD, or in a separate area. It shall include the following rooms
    - Three examination rooms
    - Staff office

- Waiting room
- Nurses station
- Staff room and teaching hall, optional
- Toilets for staff (female and male)
- Toilet for patients (Female and male)
- b) There shall be in patient service unit for ORL services including;
  - ORL ward
  - Nurses station
  - Reception area and mini store
  - room for duty doctors
  - Private and common toilet rooms
- c) Minor operation room
- d) Diagnostic unit shall have the following rooms
  - Room for neurotology tests and procedures
  - Room for endoscopy
- 6.14.2.2The hospital ORL service shall have changing room, the staff room, recovery room, major operating theatre and ICU shared with other services of the hospital.

## 6.14.3 Professionals

- 6.14.3.1The ORL service shall be directed by an licensed ENT specialist
- 6.14.3.2The ORL service shall have and maintain job descriptions, including qualifications to perform specific jobs.
- 6.14.3.3The ORL service management shall provide adequate training, continuing education or access to training for technical staff, and assess staff competency at regular intervals. All these documents shall be filed.
- 6.14.3.4 Students and other staff on attachment shall work under the direct supervision of licensed ENT specialist
- 6.14.3.5The Otorhinolaryngology services shall have the following professionals and staffs.
  - a) A minimum of two licensed ORL specialists
  - b) One neurottologist or audiometrist (Optional).
  - c) Two GPs
  - d) Five OPD nurses

- e) Three in-patient nurses.
- f) Two OR nurses.
- g) Three cleaners
- h) Porter
- i) Runner.

#### 6.14.4 Products

#### 6.14.4.1 The ORL OPD shall have

- a) Three ORL diagnostic unites each integrated with:
  - Suction machine
  - Compressed air system
  - Warm water irrigation
  - Cold light source, for endoscopes
  - Instrument cabin
  - Container for used instruments.
  - One wall mounted OPD microscope
- b) Flexible patient chairs.
- c) mobile doctors chairs
- d) Sterilizer.
- e) X-ray viewers.
- f) head lights
- g) Tongue depressors
- h) Rhinoscopes(nasal specula)
- i) Otoscopes( ear specula)
- j) Laryngeal mirrors
- k) Tuning forks(250,500,1000,2000,4000,8000hzs)
- l) Metallic suction tips
- m) Aural forceps
- n) Packing forceps
- o) Minor surgical sets
- p) Ear hooks
- q) Nasal packing forceps
- r) Biopsy forceps(Laryngeal, Nasopharyngeal)

- 6.14.4.2 The in-patient unit shall have,
  - a) Adult and pediatric beds.
  - b) One cupboard to store medicines and materials.
- 6.14.4.3The OR shall have the following:
  - a) Major OR
    - OR table for general anesthesia
  - Ceiling lights as for General Surgery.
  - Operating microscope ceiling mounted or mobile
  - OR Table flexible in all sides, up Down with Head Rest.
  - Medicines and instrument cup Boards
  - Central oxygen and suction system if possible
  - Separate suction
  - Cautery machine
  - Cold light source and head lights
  - ENT OR Chairs (mobile)
  - Anesthesia machines as desired by the anesthesia service.
  - One Co2 laser machine.
  - b) Minor OR
  - OR Table for local anesthesia
  - ENT OR Table with head rest.
  - Light Source & head lights
  - Cupboards for instruments and medicines
  - Suction machine
  - Cautery machine
  - One Mobile chair
  - Easy access to general anesthesia when needed.
  - c) Other ORL Surgical Instrument Sets that includes:
  - Myryngoplasty sets
  - Typanoplasty sets
  - Mastoidectomy sets
  - Surgical drill and tips
  - Otoplasty sets
  - FESS sets

- Rhinoplasty sets
- Septoplasty sets
- Cald -wel- luc sets
- Nasal polyp sets
- Total laryngectomy

sets

- Neck dissection sets
- Laryngoscopy sets(adult)
- Laryngoscopy set(pediatric)
- Laser laryngoscopy adult set
- Laser laryngoscopy pediatric set
- Tracheostomy sets
- Tracheostomy tubes metallic (weith inner canula)

- Tracheostomy tubes plastic( with inner canmula)
- Parotidecomy set
- Adeno-tonsillectomy sets
- Suture materials
- Esophagoscopy set
- Bronchoscopy set

## 6.14.4.4 The diagnostic unit shall have the followings:

- a) Endoscopic room with video, video camera, 21 inch TV set, Stroboscope etc.
- b) Neurotology room with audiometry, tympanometry, brain evoked response audiometry, (BERA), Sound proof box, computer and printer.

## 6.15 Ophthalmology Services

#### 6.15.1 Practices

- 6.15.1.1The Ophthalmology service shall have written policies and procedures including:
  - (a) Admission and discharge criteria specific to the service;
  - (b) Visitors policy
  - (c) Transfer and referral of patients
  - (d) Monitoring and follow-up of patients
  - (e) Infection prevention and control as per the IP section of this standard
- 6.15.1.2The Ophthalmology service shall provide at least the following services
  - (a) Visual acuity testing
  - (b) Slit lamp examination
  - (c) Keratometry and ultrasound examinations
  - (d) Laser therapy
  - (e) Visual field examination
  - (f) Minor and major ophthalmologic surgical procedures (Tarsoraphy, cataract, enoculation etc)
  - (g) Medical management of glaucoma
  - (h) Optometry service
- 6.15.1.3 The ophthalmology service shall have protocols and procedure at least for the following:
  - (a) Penetrating eye injury
  - (b) Glaucoma management
  - (c) Red eye
  - (d) Corneal laceration
  - (e) Surgical interventions
- 6.15.1.4The Ophthalmology service shall be available during the regular working hours.
- 6.15.1.5Integrate emergency Ophthalmology service shall be rendered within the general emergency service at all times
- 6.15.1.6Information contained in the medical record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis,

- diagnostic procedures, medication administration, and treatment as per the medical record section of this standard.
- 6.15.1.7For admitted patients the medical service shall be organized in a way that it covers all the shifts.
- 6.15.1.8The hospital may have ophthalmology services at subspecialty level.

#### 6.15.2 Premises

- 6.15.2.1The ophthalmology service shall have the following premises for outpatient service.
  - (a) Waiting room with TV news paper and magazines and brochures about eye disease
  - (b) Nurse station
  - (c) Examination rooms
    - Visual acuity: 2 rooms each having 6 m length or 3 m with mirror and washing basin facilities
    - Visual field room
    - Keratometery and Ultrasound room
    - Two rooms having Slit lamp biomicroscopy with washing basin
  - (d) Physicians room
  - (e) Minor OR room with washing basin
  - (f) Administration staff rooms
  - (g) Sterilization room
  - (h) Toilet room for staffs separate for male and female
  - (i) Toilet rooms for patients separate for male and female
- 6.15.2.2The ward shall have the following service areas:
  - (a) The number of admission rooms and beds shall be determined depending on the nature of the work to be performed.
  - (b) Staff room
  - (c) Nurse station
  - (d) Examination room for visual acuity testing with Slit lamp and Tonometry shall have washing basin
  - (e) Shower and toilet.
  - (f) Laser room

- (g) Staff toilet and shower separate for female and male
- 6.15.2.3 The hospital ophthalmology service shall have changing room, the staff room, recovery room, major operating theatre and ICU shared with other services of the hospital
- 6.15.2.4The ophthalmology service shall have a minor operation theater including.
  - (a) Patient's preparation room
  - (b) Changing room with lockers separate for male and female
  - (c) Scrubbing room with washing basins
  - (d) Minor operation theater with swinging doors
  - (e) Toilet for male and female
- 6.15.2.5In addition, the ophthalmology service shall have following rooms:
  - a) Meeting room; as appropriate
  - b) Utility rooms;
  - c) Store;
  - d) Pharmacy as appropriate

#### 6.15.3 Professionals

- 6.15.3.1The ophthalmology service shall be directed by a licensed ophthalmologist
- 6.15.3.2 There shall be qualified medical and nursing personnel for ophthalmology services at all times
- 6.15.3.3 An ophthalmologist shall be available at all working hours and he/she shall be also available on call at duty hours.
- 6.15.3.4 Nursing service shall be administered by licensed BSC ophthalmic nurse and shall be supervised by licensed ophthalmologist.
- 6.15.3.5 A licensed nurse shall be available at all times to assess, evaluate, and follow up the nursing care provided.
  - 6.15.3.60ptometrist/refractionist shall be available on working hours
- 6.15.3.7 Anesthesiologist or nurse anesthetist or anesthetist or BSc in anesthesiology shall be available, as appropriate.
- 6.15.3.8 Ophthalmic nurse or OR trained nurse shall be available during working hours and on call at duty hours
  - 6.15.3.9The service shall have supporting staff such as cleaners.

## 6.15.4 Products

# 6.15.4.1The ophthalmology service shall have the following medicines, supplies and functional equipment

- a) Diagnostic Equipment
  - Slit lamp
  - Trial set with trial frame (children and adult),
     Cross cylinder
  - Slit lamp biomicroscopy with applanation tonometery
  - Snellen test chart (Distance chart)
  - Near point Acuity test card
  - Color test (Ishara)
  - Fundus camera, optional
  - Lang stereo test
  - PD meter
  - Retinoscopy
  - Autorefractometer
  - Lensometer
  - Prisma set /Prisma Bar (horizontal + vertical)
- b) Diagnostic Medicines
  - Phenynephrine
  - Tropicamide eye drops
  - Atropin drops
  - Fluorescein strips /drops
- c) Therapeutic Equipment/Instrument
  - Laser (Diode /Argon,
     Nd YAG Laser-

- Torch (light)
- Ophthalmoscope (direct and indirect)
- Aspheric funds lenses volk: 78
  /90 dpt.
- Gonioscopy lens
- Three mirror Lens
- Lacrimal dilator and probe
- Probung set
- BP apparat
- Glucometer
- Ex Ophthalmometer (Hertel)
- Aplanation tonometer /Schiotz
- A-scan ultrasound
- B-scan ultrasound
- Autoclave
- Consumable materials

- · Cyclopentlate drops
- Tetracaine drops

Neodymium: Yttruium-Aluminium-garnet)

- OR microscope
- Cataract set
- Glaucoma OP set
- Tarsotomy set
- Chalazion set
- Enuclation set
- Strabismus set
- Keratome set,
- Crescent set
- Bucking set
- DCR set
- IOL (both Posterior chamber and anterior

- chamber lenses of different diopters)
- Suture different size (3.0, 4.0, 9.0, 10.0)
- Viscoelastic
- Eye pad
- Ringer, saline
- Ambu bag and oxygen cylinder
- Patient cardiorespiratory monitor
- 6.15.4.2The inpatient service shall have the following supplies and facilities
  - a) Beds with toilet
  - b) Ambu bag and oxygen cylinder
- 6.15.4.3The service shall have at least a general follow-up clinic that shall have the following supplies and functional equipments:
  - a) One examination bed
  - b) Slit lamp biomicroscopy
  - c) Tonometer
- 6.15.4.4 Medicines and supplies shall be available in line with national medicines list.

## 6.16 Mental Healthcare Services

#### 6.16.1 Practices

- 6.16.1.1 Psychiatry service shall have written policies and procedures that shall include
  - (a) Admission and discharge criteria specific to the service;
  - (b) Visitors policy that allows for 24 hour visitation by designated visitors specifying the number of visitors permitted for each patient at any time
  - (c) Infection control specified under this standard and National and or Hospital IP guideline
  - (d) Transfer and referral of patients
  - (e) Monitoring and follow-up of patients
- 6.16.1.2 Psychiatric patients shall receive all medical, surgical, diagnostic and treatment services as ordered by a physician.
- 6.16.1.3 There shall be written protocols and procedures for the management of the psychiatric conditions in the hospital
- 6.16.1.4 There shall be written SOPs regarding the admission, consultation, discharge, transfer and follow-up of psychiatric patients
- 6.16.1.5 There shall be an integrated psychiatry emergency service for 24 hours a day and 365 days a year in the hospital.
- 6.16.1.6 There shall be psychiatry follow-up service during working hours
- 6.16.1.7 There shall be pharmacotherapy and Electro Convulsive Therapy (ECT) services in the hospital.
- 6.16.1.8 There shall be a dedicated outpatient and inpatient service for mental healthcare services
- 6.16.1.9 The psychiatry team shall be responsible wherever the psychiatric patient is referred and treated for other medical illnesses within the hospital.
- 6.16.1.10 The following services shall be available as part of the program of the psychiatry care unit;
  - (a) Individual, group and family therapy;
  - (b) Rehabilitative services;

- (c) Psychological services and
- (d) Recreational therapy
- (e) Electro Convulsive Therapy (ECT)
- 6.16.1.11 A social worker shall complete a psychosocial assessment for each patient which includes at least the following:
  - (a) Identified problems;
  - (b) Social and family history;
  - (c) Educational and employment history;
  - (d) Financial status; and
  - (e) Present living arrangements.
- 6.16.1.12 Psychiatric evaluation shall be documented in the medical record and shall include at least:
  - (a) The chief complaint;
  - (b) History of present illness;
  - (c) Family history;
  - (d) Pertinent medical history including previous reactions to psychotropic medications:
  - (e) Mental status and;
  - (f) Diagnostic impression
- 6.16.1.13 An individual, comprehensive, multidisciplinary care plan shall be developed for each patient based on an assessment of the patients' strength and limitations which includes the followings:
  - (a) A psychiatric diagnosis specifying undercurrent diseases.
  - (b) Observable treatment goals
  - (c) The specific treatment methods to be used and;
  - (d) The responsibilities of each member of the interdisciplinary care team.
- 6.16.1.14 Nursing services shall be the responsibility of licensed psychiatry nurses and other mental health workers and shall be directed by an experienced professional psychiatry nurse.
- 6.16.1.15 The multidisciplinary care plan shall be discussed with the patient and/or the patient's next of kin and implemented accordingly.

- 6.16.1.16 Written discharge plan shall be developed for each patient by the multidisciplinary team, who either meet or make notes individually in the patient's record.
- 6.16.1.17 There shall be Infection control practices for the day/dining room, equipment and rooms used by more than one patient based on the hospital wide infection control policies and procedures manual.
- 6.16.1.18 There shall be Safety and security precautions for the prevention of suicide, assault, elopement and patient injury.
- 6.16.1.19 There shall be mechanisms for providing immediate security assistance to staff and patients.
- 6.16.1.20 Patients shall be advised of the reasons for, and expected effects of, medications prescribed for them.
- 6.16.1.21 There shall be a milieu program that includes patient community meetings and daily activities.
- 6.16.1.22 Every medical record relevant to psychiatric illness shall be kept for each patient stated under the medical records section of this standard
- 6.16.1.23 An accurate schedule of activities shall be posted conspicuously in the unit.
- 6.16.1.24 Authorized security personnel shall have immediate access to locked units.
- 6.16.1.25 There shall be a system for summoning help from other areas of the unit in an emergency.
- 6.16.1.26 Disturbed Children and Adolescents shall have access to clinical or general psychological, and clinical or general social works service in addition to psychiatric service every day including emergency service that takes consideration age specific psychiatric conditions among this age group and psychosocial crisis.
- 6.16.1.27 The hospital shall have addictive substances' detoxification, treatment, rehabilitation services specific to the problem and shall have access to psychiatric, clinical or general psychological, and clinical or general social works service every day
- 6.16.1.28 There shall be substance abuse care and follow up service
- 6.16.1.29 There shall be a pediatric and adolescent psychiatry care and service

6.16.1.30 There shall be a system for clinical staff to refer patients directly to the social works unit.

#### 6.16.2 Premises

- 6.16.2.1A private setting shall be available for interviewing patients.
- 6.16.2.2There shall be a separate psychiatry emergency room (s). The psychiatry emergency room(s) shall have additional doors through which escape is possible for mental health professional working there in the case of imminent assault by acutely disturbed violent patient. Restraint of such patients shall be carried out by trained paramedical staff so that emergency medication shall be possible
- 6.16.2.3The unit shall have access to at least one acute care/seclusion room.
- 6.16.2.4Acute care/seclusion rooms shall be at least 9 square meters and shall be large enough to provide access to the patient from all sides of the bed or mattress and have room for emergency life-sustaining equipment.
- 6.16.2.5 Patients in acute care/seclusion rooms shall be either under direct observation in a room near the nurses' station.
- 6.16.2.6There shall be psychiatric ward dedicated for psychiatry services
- 6.16.2.7There shall be an Electro Convulsive Therapy procedure room with instruments and materials needed together with documentation forms and documentation book and a cupboard for bed sheets and mattresses with pillows the equipment
- 6.16.2.8The psychiatric emergency room(s) shall have additional doors through which escape is possible for mental health professional working there in the case of imminent assault by acutely disturbed violent patient. Restraint of such patients shall be carried out by trained paramedical staff so that emergency medication shall be possible.
- 6.16.2.9The psychiatry unit shall have a day room/dining room that allows for social interaction, dining, and therapy.
- 6.16.2.10 Space for structured physical exercise programs shall be available to patients.

- 6.16.2.11 There shall be space in each patient room for storage of patient's personal belongings. There shall be a system for securing patient's valuable belongings.
- 6.16.2.12 The outpatient layout shall include the following:
  - a) Waiting area of the psychiatric wing: room /lobby with public telephone, TV area, drinking tap water, and gender specific toilets
  - b) Reception and Recording area/desk
  - c) Dedicated patient examination rooms
  - d) Room for providing injections
  - e) Storage place for sterile supplies
  - f) Utility room for cleaning and holding used equipments and disposing patients specimen
  - g) Staff room (for changing cloth)
  - h) Janitors closet
- 6.16.2.13 The psychiatric service unit shall have a isolation room for treatment of conditions that require isolation for inpatients (e. g., active open TB)
- 6.16.2.14 Patients in acute care shall be under direct observation in a room near the nurses' station.

#### 6.16.3 Professionals

- 6.16.3.1 The Psychiatric service shall be directed by a licensed psychiatrist.
- 6.16.3.2 A psychiatrist or licensed independent practitioner shall be on duty or on call at all times
- 6.16.3.3 A psychiatrist or licensed independent practitioner shall be responsible for the follow-up clinics.
- 6.16.3.4The number, type and skills of clinicians and support staff shall ensure that patients are appropriately treated and cared for at all times.
- 6.16.3.5 Nursing care on the psychiatrist care unit shall be directed by a licensed psychiatry professional nurse with at least two years of experience in clinical psychiatric service

- 6.16.3.6 A licensed psychiatric nurse shall be available at all times to assess, evaluate, and follow the nursing care.
- 6.16.3.7 In addition;
  - a) Clinical psychologist or General psychologist with exposure to clinical medicine in hospital for one year should be available
  - b) Professional nurse with clinical psychiatry experience.
  - c) Nurses with clinical psychiatric experience
  - d) A social worker with experience in social work or mental health.

#### 6.16.4 Products

- 6.16.4.1 The restraint equipment needed by the unit shall be immediately available on the unit and accessible to unit staff.
  - 6.16.4.2All medicines to this level of hospital shall be available at all times
- 6.16.4.3 Recreational and therapy equipment and supplies needed for psychiatry care shall be available on the unit and stored in locked storage.
  - 6.16.4.4The psychiatric OPD shall have the following supplies and functional equipment in addition to office furniture's
    - a) Torch,
    - b) Weighing scales for adults and/or children
    - c) thermometer
    - d) Stethoscopes
    - e) Sphygmomanometer
    - f) Examination couch
    - g) Vaccutainer needles with stand for blood drawing for laboratory investigation
    - h) Hand washing basin
    - i) Emergency ECT access when inpatient treatment is not possible
    - j) Spatula, disposable gloves, cotton, gauze
    - k) Prescription, certificate, and appropriate referral forms, request forms for laboratory, X-ray and other imaging investigations
  - 6.16.3.11. The inpatient service shall have the following supplies and functional equipments
    - a) ECT machine, gags, electrode application rubbers, electrodes, gel for electrode placement

- b) Torch,
- c) Weighing scales
- d) Tape meter, thermometer, patella hammer
- e) Stethoscopes and Sphygmomanometer
- f) Examination couch, medicine trolley, Cup board
- g) EKG machine,
- h) Computerized EEG mach with at least 18 channels
- i) Suction machine
- j) Drip counters/Infusion pump, Tourniquets and IV stands
- k) Oxygen cylinder, Flow-meters for oxygen, Nasal prongs catheters
- l) Self inflating bags for respiratory support, Masks, endotracheal tubes,
- m) Cannulas, Nasogastric tube
- n) Beds for patients and hand washing basin
- o) Glucometer
- 6.16.4.5 The service shall have at least a general follow-up clinic that shall have the following supplies and functional equipments:
  - a) Weighing scales
  - b) Tape meter (optional), thermometer, patella hammer
  - c) Stethoscopes and Sphygmomanometer
  - d) Examination couch
  - e) Gauzes, Vaccutainer needles with appropriate stands for blood drawing
  - f) Disposable rubber gloves
  - g) partitioned spaces for Injection
  - h) hand Washing basin
- 6.16.4.6 Locked storage areas shall be available for supplies and the safekeeping of the individual, ongoing projects of patients.
- 6.16.4.7 Psychotropic medications and other medicines shall be available in line with the national medicine list.

# 6.17 Dermatology Services

#### 6.17.1 Practices

- 6.17.1.1 Dermatological services shall be available for 24 hours a day and 365 days a year.
- 6.17.1.2 There shall be written policies, procedures and protocols for admission, ward rounds, management, appointment, discharge, and referral of patients.
- 6.17.1.3 There shall be an agreed definition of a day case and recognition of the time required to perform the various surgical procedures.
- 6.17.1.4 Patient discharge shall under direct supervision of available GPIS (GPs with special interest in dermatology and get special training in dermatology for minimum of 3 month). Advice on further management, including follow-up shall be documented on patient card
- 6.17.1.5 There shall be regular training of the non-dermatology nursing staff on a good nursing care of patients with severe skin diseases.
- 6.17.1.6 The dermatologist who is responsible to direct/coordinate the service shall ensure that there is full medical cover for inpatients at all times.
- 6.17.1.7 There shall be a system for the handover of clinical problems when other dermatologists take over the care of patients.
- 6.17.1.8 Dermatologists shall ensure that protocols are in place to ensure the safe and appropriate delivery of outpatient therapy, which is usually delivered by other members of the multi-professional team.
- 6.17.1.9 There shall be a system in place to ensure that the dermatologist is consulted when there is any problem that needs his/her expertise.
- 6.17.1.10 Thorough, contemporaneous records shall be kept and a system shall be in place to ensure continuity of care when patients are transferred between assessment and admission units or from other wards and hospitals.
- 6.17.1.11 Dermatologists shall give patients information in a way they can understand and ensure that patients give informed consent to their clinical care.
- 6.17.1.12 There shall be a protocol or a policy that states the report of critical conditions which need urgent response/intervention like suspected melanoma or squamous cell carcinoma in the hospital.

- 6.17.1.13 There shall be a teamwork involving other disciplines when necessary.
- 6.17.1.14 The dermatology outpatient services shall provide the following services:
  - (a) Occupational skin disease clinic
  - (b) Photo dermatology clinic
  - (c) Specialized skin cancer/pigmented lesion (dermato- oncology clinic)
  - (d) Allergy clinic with side laboratory
  - (e) Venerology/STI clinic
  - (f) Paediatric dermatology clinic(eg. atopic eczema)
  - (g) Electrocautery
  - (h) Cryotherapy
- 6.17.1.15 The dermatology outpatient services may have:
  - (a) Photodynamic therapy
  - (b) Specialist clinics in psoriasis, eczema, Vitiligo, Fungal infections, leprosy, cutaneous leishmaniasis, leg ulcers, connective tissue disease, lymphoedema, psychosomatic disorders and others - depending upon available expertise and population.
  - (c) Teledermatology support for a managed clinical network
  - (d) Iontophoresis
  - (e) Botulinum toxin (example: palmar, plantar and axillary hyperhydrosis)
  - (f) Dermatoscopy
  - (g) Dermojet (for intralesional administration of medicines)
- 6.17.1.16 The dermatology inpatient services shall have:
  - a) A 24 hours admission services
  - b) Admission and treatment of patients requiring such facilities which at least include:
    - generalized skin failure (e.g., erythroderma of different causes),
    - severe drug eruptions (e.g., Stevens-Johnson syndrome and TEN)
    - severe blistering disorders (e.g., immunobullous diseases),
    - Leprosy reactions and diffuse cutaneous leishmaniasis,
    - Acute neutrophilic dermatoses (e.g., pyoderma gangrenosum, sweet syndrome amongst others.

- 6.17.1.17 Dermatologic interventions shall be rendered by licensed dermatologists or trainee physician or medical student under the direct supervision of the dermatologist.
- 6.17.1.18 Students and other staff on attachment shall work under the direct supervision of the dermatologist. Dermatologists shall ensure that these personnels are adequately trained to carry out surgical or other therapeutic procedures.
- 6.17.1.19 There shall be a mechanism that ensures 24 hours access to specialized services provided by dermatologists on call basis.
- 6.17.1.20 There shall be cooperation with the pharmacy services to have access for the preparation of topical medicaments and allergens for contact allergy testing.
- 6.17.1.21 The phototherapy units may:
  - (a) Deliver narrow band UVB (TL 01), BBUVB, UVA1 and PUVA (Psoralen plus UVA) light treatment,
  - (b) Be supervised by a experienced dermatologist ensuring safety, accuracy of dosimetry, proper record keeping and monitoring of training.
  - (c) Have a yearly evaluations and calibrations of the output of each unit by medical physicist.

# 6.17.1.22 The LASER unit may:

- (a) Be supervised by an experienced dermatologist ensuring safety and accuracy of Laser irradiance dose and time for specific disorder.
- (b) Be calibrated and evaluated by medical physicist annually.

## 6.17.2 Premises

- 6.17.2.1 The hospital shall have patient friendly premises maintaining privacy, illumination and friendly for person with disability.
- 6.17.2.2 The hospital shall have adequate rooms and facilities needed for inpatient, outpatient and emergency services- skin cancers, day treatment, wound care including leg ulcer management, dermatological surgery, contact allergy testing, phototherapy, cryosurgery, electrocautery treatment and patient education.
- 6.17.2.3 There shall be well shaded patient waiting area.

- 6.17.2.4 Specialized service facilities shall be installed with physical proximity to inpatient and outpatient facilities.
- 6.17.2.5 The hospital may have access to inpatient service within a paediatric inpatient ward for paediatric dermatology clinics.
- 6.17.2.6 The dermatological services shall have the following units:
  - (a) Outpatient units (as per the outpatient section of this standard)
  - (b) Surgical units
  - (c) Inpatient units (as per the inpatient section of this standard)
  - (d) Dermato-histopathology and immuno-pathology unit, optional
  - (e) Phototherapy units, optional
  - (f) LASER unit, optional
  - (g) Laboratory unit (eg. to perform dermatologic and STI diagnostic tests, culture and serologic test)
- 6.17.2.7Outpatient units shall have a dedicated outpatient service area with consultation and examination rooms with the following requirements:
  - a) Examination room:
    - Two adjacent communicating rooms per doctor,
    - Patient undressing room,
    - Hand wash basin,
    - · Adequate natural lighting and additional lighting
    - External wall fitted with laminated glass above 1.8 m high,
    - Space for Cautery machine,
    - Space for cryotherapy machine,
    - Phototherapy unit including UVB and UVA panel (phototest, photopatch test, etc), (optional)
    - Wound dressing area
    - Treatment rooms with facilities for adults and children
  - b) Waiting area (room or shaded area)
  - c) Side Laboratory with facilities for contact allergy testing (Patch testing, prick tests) including appropriate storage for allergens, optional
  - d) Separate room\_for Medical photography services, (optional)
  - e) Special room for Wood lamp.

- 6.17.2.8 The surgical units shall have the following requirements:
  - a) Well-lit and ventilated operating room with couches,
  - b) Access to latex free facilities,
  - c) Facilities for freezing biopsies and storing frozen samples (optional),
  - d) Laser-safe areas where required
  - e) Facilities for Moh's surgery, e.g., specialist micrographic surgery, cryostat and histopathology equipment in some specialist units (optional).
- 6.17.2.9 LASER units may be equipped and confer different wavelength laser for different skin disease conditions that are amenable to laser treatment.
- 6.17.2.10 The inpatient service unit shall have:
  - a) Dedicated inpatient room or integrated with other inpatient services with dedicated dermatology beds for adults in internal medicine ward and children in pediatric ward.
  - b) Adjacent bathing and showering facilities.
  - c) Proximity to the outpatient unit.
  - d) At least one bed in isolation room, with provision of photo-protection.
  - e) Treatment area.
- 6.17.2.11 Dermatology offices shall include:
  - a) Staff rooms,
  - b) Nurse station,

#### 6.17.3 Professionals

- 6.17.3.1 The dermatologic services shall be directed by licensed dermatovenerologist or dermatologist.
- 6.17.3.2 The phototherapy units may be staffed by nurse trained or experienced nurses in dermatology or physiotherapists trained in skin care.
- 6.17.3.3 LASER units may be staffed by cosmetology trained technicians
- 6.17.3.4 The following professionals shall be available:
  - a) Dermato-venereologist,
  - b) GPIS,
  - c) Nurse Experienced or trained in dermatology,
  - d) Physiotherapist,
  - e) Supportive staffs,

- 6.17.3.5 In addition to professional stated under article 6.17.3.4, the following professionals may be required:
  - a) Sub-Specialists in dermatopathology, photodermatology, dermatosurgery, tropical dermatology, etc
  - b) Medical physicist,
  - c) Cosmetology technician,
  - d) Pharmacist,
  - e) Medical immunologist,

### 6.17.4 Products

- 6.17.4.1The dermatology service shall have the following products:
  - a) Dermatology examination kit,
  - b) Examination lamp,
  - c) Cautery machine,
  - d) Cryotherapy machine,
  - e) Wood lamp,
  - f) Dermojet,
  - g) Dermatoscope,
  - h) Magnifying glass,
  - i) Laser machine,
  - i) Specula,
  - k) Punch biopsy set and minor set,
  - l) Phlebotomy set and others,
  - m) Examination couches,
  - n) Surgical packs of appropriate instruments,
  - o) Equipment for electrocautery (diathermy and hyfrecation),
  - p) Equipment for cryosurgery and storage for liquid nitrogen,
  - q) PUVA (1,3,5 Trimethoxy Psoralen, UV-A),
  - r) Radiation monitoring equipment,

## 6.18 Cardiac Services

### 6.18.1 Practices

- 6.18.1.1 Cardiac emergency services shall be available 24 hours a day and 365 days a year for at least the following conditions:
  - a) Resuscitation of patients with sudden cardiac events like cardiac arrest and malignant ventricular arrhythmia.
  - b) Treatment, including defibrillation or cardioversion for patients with sudden life threatening rhythm disturbances.
  - Resuscitation of patients with cardiogenic shock and severe hemodynamic instability.
  - d) Resuscitation of newborns with life threatening congenital heart disease.
  - e) Resuscitation and management of sudden cardiac arrest in children with congenital or acquired cardiac lesions.
- 6.18.1.2 The cardiac unit outpatient service shall be available during working hours which at least includes the following:
  - a) Acceptance and evaluation of patients with heart diseases,
  - b) Follow-up care for patients on whom cardiac surgery or interventional catheterization has been performed,
  - c) Follow-up of patients on whom medical or conservative management has been decided.
  - d) The cardiac unit shall provide Stress testing.
  - e) The cardiac unit shall provide Echocardiography.
- 6.18.1.3 The cardiac unit of the hospital shall have policies, protocols and procedures for cardiac conditions, interventions including, not limited with:
  - a) Patient admission, discharge and referral,
  - b) Advanced life support,
  - c) Common Cardiovascular accidents,
  - d) Catheterization,

- e) Emergency resuscitation,
- 6.18.1.4 The Cardiac unit inpatient services shall be available 24 hours a day and 365 days a year including the following:
  - (a) Admission of patients on emergency basis for care and management of cardiac related conditions.
  - (b) Admission of patients for cardiac surgery or interventional catheterization purposes.
  - (c) Transfer of patients from ICU after cardiac surgery or interventional procedure.
- 6.18.1.5 The cardiac unit shall have intensive care unit (ICU) available for 24 hours a day and 365 days a year which includes:
  - (a) Care of patients with acute life threatening cardiac conditions like myocardial infarction, malignant arrhythmias, acute heart failure, pulmonary thromboebolism and others.
  - (b) Care of patients after cardiac surgery or interventional procedures
  - (c) Care of critical cardiac patients before or long after cardiac surgery or interventional procedure
- 6.18.1.6 The cardiac unit at this level may provide cardiac surgery services. The hospital that provides cardiac surgery shall have a standard cardiac surgery operating theatre and shall render the following services:
  - (a) Open heart surgery for patients with acquired or congenital cardiac diseases,
  - (b) Closed heart operations for different types of heart diseases in a child or an adult,
  - (c) Insertion of chest tubes, drainage of pericardial effusions, insertion of permanent pacemakers etc.
- 6.18.1.7 The hospital may provide cardiac catheterization service.
- 6.18.1.8 Catheterization Laboratory shall be available to provide invasive coronary treatment. This shall include the following but not limited to:

- (a) Diagnostic cardiac catheterization for purpose of cardiac anatomy and function,
- (b) Interventional cardiac catheterization for coronary angiography and Percutaneous Coronary Intervention (PCI),
- (c) Interventional cardiac catheterization for different types of congenital and acquired heart diseases,
- (d) Cardiac catheterization for the purpose of electrophysiological studies and transcatheter radiofrequency ablation.

#### **6.18.2** Premises

- 6.18.2.1 The cardiac unit shall have premises for outpatient, inpatient, Emergency, catheterization laboratory, cardiac surgery, advanced cardiac imaging and examinations,
- 6.18.2.2 The outpatient service shall have the following space and specified requirements:
  - (a) Examination rooms:
    - The room shall have adequate space (at least 20 square meters wide with good lighting and ventilation windows).
    - Hand maneuvered patient examination coach.
    - Hand washing sink in each examination room.
    - Patient waiting area equipped with chairs to accommodate at least 10 patients at a time.
  - (b) The emergency resuscitation room:
    - The emergency resuscitation room shall at least be 50 sq. m. wide with a good lighting and ventilation windows.
    - There shall at least be two resuscitation couches, cupboards and shelves, a wheelchair and patient transporter.
  - (c) Stress testing room:
    - With good lighting and ventilation.
    - There shall be a Treadmill or a bicycle ergo meter, the stress test recording panel and at least a chair.

- There shall be a resuscitation trolley and a defibrillator available for immediate use.
- Provided with at least three (3) electric outlets.

## 6.18.2.3 The cardiac inpatient ward shall fulfill the followings:

- (a) The cardiac unit shall have at least 10 beds. The inpatient premises for cardiac unit shall be as per the inpatient service section of this standard.
- (b) Nursing stations with telephone and telephone terminals, computer and computer points, chairs and working laminated top tables.
- (c) Patient toilet and shower facilities.
- (d) There shall be separate staff toilet, shower and changing facilities.
- (e) Clean utility room used for storage of supplies both clean and sterile consumables and linen, preparing and storing dressing trolleys, the storage, preparation and assembly of items or equipment for diagnostic and therapeutic procedures.

# 6.18.2.4 Cardiac Intensive Care Unit (CICU):

- (a) The cardiac ICU shall accommodate at least 4 electrically operated patient beds fitted with full range of monitors, better with a central monitor.
- (b) There shall be a distance of at least one and half meters 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 shall be a hand washing basin by the entrance/ exit of the ICU room.
- (e) There shall be patient toilet and shower facilities.
- (f) There shall be an ICU staff locker room in proximity with the ICU.
- (g) The ICU area is generally regarded as a sterile zone and there shall be shoe and cloth change point for families and staff.
- (h) There shall be soiled utility/sluice room which acts as a storage area for contaminated materials until they are disposed off as well as disinfecting and cleaning of contaminated equipments.

- (i) There shall be an ICU supply room for storage of consumables and spare equipments and shall be equipped with cabinets and shelves.
- (j) There shall be an ICU cleaner's room for an easy access to cleaning equipments and materials or the ICU floor.
- 6.18.2.5 Cardiac Operating Theatre: The operating zone shall be sterile and demarcations shall be clear beyond which one cannot cross without scrub shoes on. The cardiac operating rooms shall consist of the operating theatre, scrub room, the heart lung machine supply room, the OR supply room, the staff locker room, and a soiled utility/sluice room with the following requirements:

# (a) The cardiac operation theatre:

- The operating theatre size shall at least be 9m x 7m wide and shall accommodate all the equipments mentioned under the section 'Cardiac OR equipments' below.
- There shall be enough space for safe and adequate movement of the surgical team (cardiac surgeon, assistant surgeon, anesthetist,
   Transesophageal echocardiographer, perfusionist, scrub nurse and circulating nurses).

# (b) The scrub room:

- The scrub room shall be in close proximity with the operation theatre and no more than one door shall be crossed after scrubbing.
- The scrub room shall accommodate at least two professionals scrubbing simultaneously.

# (c) The OR supply room:

• The OR supply room storage of consumable and small sized equipments shall be in continuity with the operation theatre.

### (d) Staff locker rooms:

- There shall be separate staff locker rooms for ladies and gentlemen used for staff changing facilities, placement of scrub suits and scrub shoes in proximity with the procedure room.
- There shall be separate staff toilets and shower facilities for ladies and gentlemen in proximity with the locker rooms.

- (e) Soiled utility / sluice rooms:
  - The room shall have the facility for storage of contaminated OR materials until wastes are disposed off and cleaning of contaminated equipments.
  - There shall be supply of hot and cold running water.
  - There shall be adequate supply of clean gloves and heavy duty gloves for those working in the soiled utility area.
- 6.18.2.6 CAT Lab (Cardiac Catheterization Laboratory): The diagnostic and interventional cardiac catheterization laboratory shall have the catheterization room, the control room, the scrub room and the catheterization lab supply room.
  - (a) Catheterization room / procedure room:
    - The procedure room shall be at least 36 sq. m and accommodate all the equipments mentioned in 'catheterization laboratory equipments'.
    - The catheterization room shall have enough space for free movement of the operator, assistant operator, scrub nurse, circulating nurse, anesthetist, sonographer and the X – ray technologist.
    - There shall be catheter hangers on the wall with in the procedure room.
    - The doors and wall of the procedure room shall be leaded or the wall
      thickness shall be appropriately thick to reduce radiation hazards to the
      surrounding area and the radiation safety shall be approved by the
      Ethiopian Radiation Protection Authority and this standard.
  - (b) The control room:
    - The size shall at least be 12 m<sup>2</sup> in size and accommodate the CATHCOR system, the HICOR system and the CD writer system and all other data management systems.
    - The control room shall be separated from the procedure room with a leaded door and there must be a leaded glass window of at least 2m x 1m size to enable visual communication between the staff in the procedure room and the control room.
  - (c) The Catheterization lab scrub room:

- The scrub room shall be in proximity with the procedure room and there shall be no more than one door separation between the two.
- The scrub room shall have adequate scrub facilities and allow at least two professionals scrubbing simultaneously.

## (d) Catheterization lab supply room:

- The supply room shall in close proximity to the Catheterization lab and is used for storage of a range of consumables used for the procedure.
- The room shall be furnished with shelves, cupboards and lockers.

# (e) Staff locker rooms:

- There shall be separate locker rooms for ladies and gentlemen located in proximity with the procedure room.
- There shall be toilet, shower facilities and hand wash sinks either in or in proximity with the locker rooms.

## 6.18.3 Professionals

- (a) The cardiac unit shall be directed by a licensed cardiologist.
- (b) If the hospital provides cardiac surgery, there shall be at least one licensed cardiac or cardiothoracic surgeon with experience in open and closed cardiac surgery for adult service and/or qualified pediatric cardiac surgeon if the unit is providing pediatric cardiac surgical service.
- (c) There shall be at least one licensed cardiologist with a minimum of nine months training on diagnostic and interventional cardiac catheterization during working time.
- (d) There shall be a cardiology fellow or pediatrician or internist with experience in cardiology at all times and a cardiologist and/or a cardiac surgeon shall be available on call.
- (e) There shall be at least one licensed anesthesiologist with a minimum of six months training in cardiovascular anesthesia.
- (f) There shall be at least one perfusionist with a minimum of two years of training.
- (g) There shall be one nurse to one patient ratio as long as the patient stays in the cardiac intensive care unit available 24 hrs a day and 365 days a year, if there is no central monitor. If the ICU is assisted with a central monitor the nurse to patient ratio can be reduced to at least one to two.

- (h) There shall be at least three qualified nurses with enough experience in the operating room.
- (i) There shall be at least three qualified nurses with enough experience in the diagnostic and interventional catheterization laboratory.
- (j) There shall be one nurse to three patient ratios while the operated patients stay in the step-down care and shall be available 24 hrs a day and 365 days a year.
- (k) There shall be at least two qualified nurses in the outpatient and emergency department available 24 hrs a day and 365 days a year.
- (l) There shall be an x-ray technologist with at least three months of training in the diagnostic and interventional catheterization laboratory.
- (m) There shall be one biomedical engineer responsible for fixing the equipments and ensuring continuous power supply within the unit (shared with the other medical services).

### 6.18.4 Products

- 6.18.4.1 The cardiac unit of the hospital shall have the following equipment for outpatient service unit:
  - a)sphygmomanometer
  - b) stethoscopes
  - c) Thermometers
  - d) A pulse oximeter
  - e) Weight and height scales
  - f) Standard 12 lead EKG machines
  - g)Holter monitors (24 hour ambulatory EKG) or event recorder
  - h) Resuscitation trolleys
  - i) Ultrasound machine with 2D, color Doppler, spectral Doppler and tissue Doppler

- j) Reliable oxygen source (preferably central oxygen supply)
- k) Exam coaches
- l) Syringe pumps
- m) Endotracheal tubes
- n) Laryngoscopes
- o) Defibrillators
- p) Wheel chair
- q) Patient transport stretcher
- 6.18.4.2 The cardiac unit of the hospital shall have the following equipment for inpatient service unit:
  - Patient beds fitted with non-invasive monitors and

mounting rails behind all beds

- b) Chairs (one per bed)
- c) Drip stands
- d) Medical gas ports
- e) Telephone terminals
- f) Working laminated top table
- g) Nurse trolleys
- h) Resuscitation trolleys
- i) Reliable oxygen source
- j) Syringe pump
- k) Endotracheal tubes of different sizes
- l) Laryngoscopes
- m) Defibrillators
- n) Dressing sets

- q) So
- p) Kidney dishes
- q) Scissors

o) Bed pans

- r) Surgical blade holders
- s) Lockers and cupboards
- t) shelves
- Telemetry monitoring for post operative patients with transmitters for step down care and selected patients in the ward.
- v) Nurse stations with chairs and computers plus computer points.

# 6.18.4.3 Consumables

- a) Disposable gloves
- b) Sterile surgical gloves
- c) Foley catheters of different sizes
- d) Sterile gauze
- e) Needles and syringes of different sizes

- f) Venous cannulae of different sizes
- g) Transfusion sets
- h) Surgical blades
- i) Patient cards/charts
- 6.18.4.4 Medicines as per the national list for such hospitals
- 6.18.4.5 The cardiac unit of the hospital shall have the following equipment for Operating theatre:
  - (a) Surgical instrument cabinet
  - (b) Endoscope cabinets
  - (c) Sterile instruments cabinet
  - (d) Electrically maneuvered operating tables
  - (e) Anesthesia machine designed and dedicated for cardiovascular anesthesia
  - (f) Laryngoscope
  - (g) Backup cylinder ports for oxygen/air

- (h) Heart lung machine with all its accessories
- (i) Standard OR lights
- (j) Surgeons head light
- (k) Headlight source
- (l) Cardiac monitors with screens (fitted with all invasive monitors)
- (m)Surgeon's goggles
- (n) Surgeon's sitting and standing stools
- (o) Scrub shoes

- (p) Tubing clump and Tubing scissors
- (q) Drip stands
- (r) Drums
- (s) kidney dishes
- (t) Vacuum/electrical suctions
- (u) Medical gas supply (ports for oxygen, atmospheric air and nitrous oxide)
- (v) Diathermy
- (w) Theatre trolleys
- (x) Anesthetic trolley
- (y) Perfusionist's trolley
- (z) Bowl trolley
- (aa) Sterilized device and cloth trolley
- (bb) Medication trolley
- (cc) Medical waste trolley
- (dd) Laundry collection trolley
- (ee) Mayo stand
- (ff) Sharp container's
- (gg) Digitally operated air conditioner
- (hh) Autoclaves (Tabletop)
- (ii) Wall sockets
- (jj) Open heart surgical set
- (kk) Closed heart surgical set
- (ll) Electric / pneumatic saw

- (mm) Defibrillator with internal paddles
- (nn) Echo machine with pediatric and adult Transesophageal facilities
- (oo) Heater/cooler
- (pp) Patient warmer with electric blanket
- (qq) Heating cabinet to warm patient fluid
- (rr)Balloon pump
- (ss)Pressure transducers
- (tt) Syringe pumps
- (uu) Pressure bags
- (vv) Stainless steel bowel
- (ww) Racks
- (xx) Blood gas analyzer
- (yy) Transport monitor
- (zz) Transport oxygen cylinder
- (aaa) Activated Clotting time Testing machine (ACT machine)
- (bbb) Temporary pacing boxes
- (ccc) Refrigerators
- (ddd) Sharp/blunt sterile scissors
- (eee) Oxygen saturation probes (newborn, infant pediatric)
- (fff) Patient transport stretcher
- 6.18.4.6 The cardiac unit of the hospital shall have the following Consumables for OR service unit:
  - (a) Scrub brushes with soap and iodine
  - (b) Antiseptics
  - (c) Angled perfusion cannullae of different sizes
  - (d) IV cannullae of different sizes
  - (e) Pressure domes
  - (f) Oxygenator and venous reservoir
  - (g) Cardioplegia set
  - (h) Cardiovascular set

- (i) Heart exchanger
- (j) Disposable connectors
- (k) Arterial for perfusion (range of sizes)
- (l) Left heart vent catheters
- (m)Blood transfusion filters for perfusion
- (n) Arterial Cannullae of different sizes

- (o) Coated, braided polyester sutures (1/0, 2/0, 3/0, 4/0, 5/0, 6/0)
- (p) ECG electrodes
- (q) Diathermy pencils
- (r) Gore-Tex stretch graft suture
- (s) Gore-Tex large diameter stretch graft
- (t) Gore-Tex stretch graft
- (u) Quadrilumen CVC sets
- (v) Triplelumen CVC sets
- (w) ACT cartridges
- (x) Pediatric multi-lumen Central Venous Catheterization sets of different sizes
- (y) Swan-Ganz pulmonary artery wedge catheters of different sizes
- (z) Uncuffed Endotracheal tubes of different sizes
- (aa) Cuffed Endotracheal tubes of different sizes
- (bb) I-STAT cartridges
- (cc) Temporary pacing wires
- (dd) Blood burettes
- (ee) Clear fluid burettes
- (ff) Chest tube set
- (gg) Urine bags with urinary catheters and urine meter
- (hh) Intraosseous infusion needle
- (ii) Nasal cannula
- (jj) Oxygen face mask (infant, pediatric, adult)
- (kk) Nebulisers
- (ll) Micropore tape
- (mm) IV site dressing
- (nn) Blood transfusion set
- (oo) Hypodermic needles (orange, blue, white, green)

- (pp) Connecting 3-way stopcocks
- (qq) Bladder syringes
- (rr)Luer-lock syringes
- (ss)Luer-Slip syringes
- (tt) Sterile suction tubing
- (uu) Non-sterile examination gloves
- (vv) Sterile surgical gloves of different sizes
- (ww) Tender tip suction catheter of different sizes
- (xx) Wound care packs
- (yy) Sterile oral hygiene packs
- (zz) Non-woven swabs
- (aaa) X-ray detectable gauze swabs
- (bbb) Pre-injection swabs
- (ccc) Nasogastric tubes of different sizes
- (ddd) Silk stitches
- (eee) Sterile drapes
- (fff) Scrub suits
- (ggg) Ambubag
- (hhh) Snapper plate
- (iii) Haemofilters
- (jjj) Balloon tipped silicon coronary artery ostial cannula of different sizes
- (kkk) Foley catheter of different sizes
- (Ill) Steel wires
- (mmm) Surgical gowns of different sizes
- (nnn) Chest drainage bottles
- (000) Powder free latex sterile gloves of different sizes
- (ppp) Surgical blades of different sizes
- (qqq) Thoracic catheter of different sizes
- (rrr) Medicines as per the national list for such hospitals

- 6.18.4.7 The cardiac unit of the hospital shall have the following equipment for Intensive Care Unit:
  - (a) Electrically maneuvered pediatric and adult beds fitted with monitors and screens
  - (b) Invasive pressure transducers (1 per bed)
  - (c) Ventilators with accompanying accessories
  - (d) Feeding tables (per bed)
  - (e) Ports for oxygen, atmospheric air and vacuum (1 of each per bed)
  - (f) Electrical suction machine (at least 1 as a backup)
  - (g) Drip stands (2 per bed)
  - (h) Infusion pumps (1per bed)
  - (i) Syringe pump (3 per bed)
  - (j) Incubators and radiant warmers
  - (k) Refrigerator (at least 1)
  - (l) Nasal CPAP
  - (m)Bed pan (1 per bed)
  - (n) Pacing boxes (at least 2)
  - (o) Device trolleys (1 per bed)
  - (p) Pharmacy trolley (at least 1)
  - (q) Resuscitation trolley (at least1) Refrigerator
  - (r) Defibrillator (at least 1)
  - (s) Electrical sockets on the nurse station desk (at least 12-16)
  - (t) 2 meter long mounting rails behind all beds
  - (u) 10 main sockets behind each bed

- (v) Portable x-ray machine with protective lead apron and lead curtain
- (w) X-ray viewer
- (x) Echocardiography machine with 2D, color, spectral Doppler and tissue Doppler.
- (y) Nurse stations equipped with chairs, tables, drawers and computers, shelves, lockers
- (z) Linen boards
- (aa) Screen and curtain (for privacy)
- (bb) Water supply and sink facility with soap
- (cc) Paper towel dispenser
- (dd) Telephone and telephone point
- (ee) Arterial pressure bags
- (ff) Blood gas analyzer
- (gg) A 12 lead standard ECG machine
- (hh) Medication boards
- (ii) Controlled drug locker
- (jj) Calculators
- (kk) Weight scale
- (ll) Wall clock (at least 2)
- (mm) Soiled cloth hampers
- (nn) Manual sphygmomanometers with infant, pediatric and adult cuffs.
- (oo) Thermometers
- (pp) Stethoscope
- (qq) Intubation set
- 6.18.4.8 The cardiac unit of the hospital shall have the following Consumables for intensive care unit:
  - (a) Non-sterile examination gloves

- (b) Sterile surgical gloves
- (c) Chest drainage bottles
- (d) Foley catheters with urine bags
- (e) Adhesive plasters
- (f) Cannullae of different sizes
- (g) Needles
- (h) A range of crystalloid and colloid IV fluids
- (i) Patient charts/cards (case summary, order sheet, nurses monitoring sheet etc.) and other stationeries.
- 6.18.4.9 The cardiac unit of the hospital shall have the following equipment for Diagnostic and interventional cardiac catheterization laboratory:
  - (a) At least a single C-arm angiography machine with a movable angiography table
  - (b) Angiography and RGB monitoring screens
  - (c) A well functioning CATHCOR system
  - (d) CD recorder
  - (e) Digitally operated air conditioner
  - (f) Standalone pressure injector system
  - (g) A pressure amplifier box
  - (h) Pressure transducer cables
  - (i) ECG monitor system
  - (i) Syringe pump
  - (k) Infusion pump
  - (l) An anesthesia machine
  - (m)Laryngoscope
  - (n) Gas ports for oxygen, medical air and nitrous oxide
  - (o) Echocardiogram with pediatric and adult
    Transesophageal facilities
  - (p) An Ambubag
  - (q) A control room with chairs
  - (r) Scrub room with scrub facilities
  - (s) Drip stands
  - (t) Light source

- (u) Lead aprons and thyroid shield for every member of staff working in the cath lab
- (v) A telephone and telephone point
- (w) Catheter and wire rinsing basins
- (x) Drums
- (y) Galipot
- (z) Kidney dishes
- (aa) Scissors
- (bb) Artery forceps
- (cc) Surgical blade holders
- (dd) Sponge forceps
- (ee) Blood gas analyzer
- (ff) Nurse trolleys
- (gg) Device trolley
- (hh) Resuscitation trolley
- (ii) Defibrillators
- (jj) Computer and computer network terminal
- (kk) Patient transport coaches
- (ll) Pulse oximeter
- (mm) Vital sign tray
- (nn) Waste baskets for soiled and dry linen
- (00) Sharp disposal containers
- (pp) Catheter hangers
- (qq) Apron hangers

- 6.18.4.10 The cardiac unit of the hospital shall have the following Consumables for Diagnostic and interventional cardiac catheterization laboratory:
  - (a) Local anesthetics (Lidocaine, Bupivacaine, Xylocaine, etc)
  - (b) Contrast injector syringes
  - (c) 3, 5 and 10ml syringes
  - (d) Puncture needles
  - (e) Surgical blades
  - (f) Disinfectants
  - (g) Sterile gauze
  - (h) Small guide wires (J-guide wires)
  - (i) Valved introducers with dilators (with a range of sizes)
  - (j) Multipurpose catheters (a range of sizes)
  - (k) NIH catheters (with a range of sizes)
  - (l) Pigtail catheters (a range of sizes)
  - (m)Balloon tipped flow guided catheters (a range of sizes)
  - (n) Left and right coronary catheters (a range of sizes)
  - (o) Soft tipped guide wires (a range of sizes)
  - (p) Exchange range guide wires(a range of sizes)
  - (q) Super stiff guide wires (a range of sizes)
  - (r) Contrast agents (Omnipac, Iopamiron)
  - (s) Balloon angiocatheters of different types ( with a range of sizes)
  - (t) Coronary stents with associated delivery systems (a range of sizes)

- (u) Vascular stents with associated delivery systems (a range of sizes)
- (v) Duct occluders with associated delivery systems (a range of sizes)
- (w) Septal occluders with associated delivery systems (a range of sizes)
- (x) Face mask
- (y) IV cannullae (a range of sizes)
- (z) Butterfly needles
- (aa) Patient drapes
- (bb) Scrub suits (single use or fabric)
- (cc) Pressure domes and connectors
- (dd) Injector connecting tubes
- (ee) Endotracheal tubes of different sizes
- (ff) Cidex solution for probe cleaning
- (gg) Probe covers
- (hh) Lubricant and transmission gel
- (ii) Adult and pediatric ECG electrodes
- (jj) Non sterile examination gloves
- (kk) Sterile surgical gloves of different sizes
- (ll) Suction tubes
- (mm) Medicines as per the national list of such hospitals

6.18.4.11 In addition the cardiac unit should have the following devices:

- (a) Stent graft thrombectomy device,
- (b) Distal protection device,
- (c) Intra aortic balloon counterpulation,
- (d) Medicines as per the national medicine list.

# 6.19 Neurology service

### 6.19.1 Practice

- 6.19.1.1 The Neurology service unit shall have a minimum of the following services:
  - (a) outpatient and follow-up clinic service
  - (b) neurologic consultations
  - (c) referral services to respective facilities
  - (d) Emergency and/ or stroke care
  - (e) Inpatient neurologic care
  - (f) Advanced Neurologic tests and procedures
  - (g) Headache and pain management (optional)
- 6.19.1.2 There shall be written protocols and procedures which shall be enforced that establish the management of the neurological conditions in the unit as well as consultation and transfer of patients admitted to this unit or other services
- 6.19.1.3 For emergency neurological condition the service shall be available 24 hours a day throughout the year.
- 6.19.1.4 For non-emergency condition the neurological service shall be available during the regular working hours.
- 6.19.1.5 For admitted patients the neurological service shall be organized in such a way that it covers all the shifts (24 hours of the day and seven days of the week)
- 6.19.1.6 Nursing care shall be the responsibility of a licensed nurse.
- 6.19.1.7 The neurology service shall have written policies and procedures that shall include
  - (a) Admission and discharge criteria specific to the service;
  - (b) A visitors policy that allows for 24 hour visitation by designated visitors and specifies the number of visitors permitted for each patient at any one time,
  - (c) Infection control as per the IP section of this standard and the National IP guideline
  - (d) Transfer and Referral of patients
  - (e) Stroke management and Coma care,
  - (f) Monitoring and follow-up of patients
- 6.19.1.8 The administrative functions shall be a responsibility of the hospital administration.
- 6.19.1.9 Every neurological records shall be kept for each patient
- 6.19.1.10 Information contained in the neurological record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis, diagnostic

- procedures, medication administration, and treatment as per the medical record section of this standard.
- 6.19.1.11 The neurological unit shall have a follow-up service for patients with chronic ailments.
- 6.19.1.12 Notifiable diseases shall be notified through the proper channel (to medical director, chief executive officer and hence to the FMOH)
- 6.19.1.13 The unit shall avail updated reference materials, treatment guidelines and manuals (e.g., National TB and leprosy, pain management, Malaria treatment, ART, meningitis etc)
- 6.19.1.14 The patients and/or caretakers shall be included in the development of the nursing patient plan of care.
- 6.19.1.15 There shall be a system for clinical staff to refer patients directly to the social works unit.

# 6.19.2 Premises

- 6.19.2.1 The neurology service premises shall have a maximum room capacity of not more than six (6) patients or beds per room.
- 6.19.2.2 The requirements for inpatient services, number of beds and rooms shall depend on the work load, as per the inpatient section of this standard.
- 6.19.2.3 The neurological service unit shall have an isolation room.
- 6.19.2.4 Patients in acute care shall be under direct observation in a room near the nurses' station.
- 6.19.2.5 The neurology service of the hospital shall have the following rooms:
  - (a) Examination room(s),
  - (b) Rooms for follow-up clinics,
  - (c) Electroencephalography (EEG) room,
  - (d) Nerve conduction test room,
  - (e) Inpatient rooms,
  - (f) Nurse station
  - (g) Utility rooms
  - (h) office for physician
  - (i) Duty room/Station,
  - (j) Staff/ changing room
  - (k) Meeting room
  - (l) Store

- (m) Staff Toilets, showers (male and female) and
- (n) Toilet and shower, Separate male, female or at least one per each room

#### 6.19.3 Professionals

- 6.19.3.1 The neurological service shall be directed by a licensed neurologist.
- 6.19.3.2 There shall be qualified neurological and nursing personnel in the neurological service unit available at all times.
- 6.19.3.3 The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis).
- 6.19.3.4 The neurologist or licensed physician shall:
  - (a) Be responsible for the services provided to each patient; while the licensed nurse shall be responsible for all nursing care,
  - (b) Control the nursing care, carryout and execution of the orders,
  - (c) Be available (physically present) during working hours,
  - (d) Be on duty or on call at all times. This physician or practitioner shall be able to present at the unit in a period of time not to exceed thirty (30) minutes.
  - (e) Be responsible for the follow-up clinics.
- 6.19.3.5 A licensed nurse shall be available at all times to assess, evaluate, and follow up the nursing care provided.
- 6.19.3.6 There shall be adequate support staff available as per the service need
- 6.19.3.7 The neurology unit shall have at least the following professionals:
  - (a) Licensed neurologist
  - (b) Licensed physician
  - (c) Licensed nurses
  - (d) EEG trained nurse or EEG technician
  - (e) Cleaners

### 6.19.4 Products

- 6.19.4.1 The neurology service unit shall have at least the following equipments:
  - (a) Stethoscope,
  - (b) reflex hammers,
  - (c) ophthalmoscope,
  - (d) thermometer,

- (e) sphygmomanometer,
- (f) Snellen's chart,
- (g) Tuning fork,
- (h) EEG machine,
- (i) Nerve conduction/electromyography,
- (j) Examination coach,
- (k) Doppler ultrasound (optional)
- (l) Lumbar puncture set with manometer,
- 6.19.4.2 The neurology service unit shall have all medicines in accordance with the national medicines list.

# 6.20 Gastroenterology

#### 6.20.1 Practices

- 6.20.1.1 The Gastroenterology unit shall have the following services:
  - (a) outpatient service,
  - (b) follow-up clinic,
  - (c) Emergency gastroenterology and/or care for GI bleedings,
  - (d) Inpatient care for different gastroenterology diseases,
  - (e) Investigation & interventions with endoscopies.
- 6.20.1.2 There shall be written policies, protocols and procedures for the consultation and management of cases that shall include:
  - (a) Identifying critical cases,
  - (b) Handling of Emergency & critically ill patients,
  - (c) Infection control specified as per the IP section of this standard and National IP guideline,
  - (d) Procedures, interventions and special investigations like Endoscopy, sigmoidoscopy, proctoscopy, etc.,
  - (e) Admission, discharge and referral of patients,
  - (f) Monitoring and follow-up of patients.
  - (g) Inpatient Gastroenterology Service.
- 6.20.1.3 The unit shall avail medical service for emergency conditions for 24 hours throughout the year.
- 6.20.1.4 Information contained in the medical record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis, diagnostic procedures, medication administration, and treatment as per the medical record section of this standard.
- 6.20.1.5 The Gastroenterology unit shall have a follow-up service for patients with chronic ailments.
- 6.20.1.6 Diseases under national surveillance shall be reported through the proper channel (CCO, CEO and to FMOH).
- 6.20.1.7 The Gastroenterology unit shall avail updated reference materials, treatment guidelines and manuals within its scope of practice (e.g. TB, pain management, etc)
- 6.20.1.8 The gastroenterology unit shall have a system for involving patients, family members &/ or caretakers in the process of care & treatment.
- 6.20.1.9 There shall be chronic care follow up service for certain prevalent GI conditions in the unit (e.g., cirrhosis).

6.20.1.10 There shall be written protocol for disinfection and processing of endoscopic instruments with high level disinfection.

#### 6.20.2 Premises

- 6.20.2.1 The gastroenterology unit shall have inpatient service. Admission rooms shall be with a maximum capacity of six beds per room.
- 6.20.2.2 The Gastroenterology unit shall have an isolation room for treatment of conditions that require such services.
- 6.20.2.3 The nurse station shall be situated in a central place where direct observation for patients in acute care.
- 6.20.2.4 In addition to the ward rooms the Gastroenterology unit shall have the following rooms & facilities:
  - (a) Examination rooms,
  - (b) Nurse station,
  - (c) Endoscopy room,
  - (d) Instrument processing room,
  - (e) Utility rooms
  - (f) Duty room/Station

# 6.20.3 Professionals

- 6.20.3.1 The Gastroenterology unit shall be directed by a gastroenterologist with a minimum of two years related experience.
- 6.20.3.2 At least one gastroenterologist shall be available to run the outpatient and inpatient service during working time.
- 6.20.3.3 The unit shall have an internist and general practitioner.
- 6.20.3.4 The nursing service in the unit shall be directed by licensed nurse trained on gastroenterology patient care.
- 6.20.3.5 There shall be adequate support staff available as per the service need
- 6.20.3.6 Additional number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis).
- 6.20.3.7 There shall be adequate support staff available as per the service need.

## 6.20.4 Products

6.20.4.1 The gastroenterology unit shall have the following supplies and functional equipments at OPD:

- a) Diagnostic Equipments:
  - Stethoscope,
  - Sphygmomanometer,
  - Weighing scales for adults,
  - Height Measurement,
- b) X-ray viewer,
- c) Examination couch,
- d) Examination light,
- e) Biopsy set,
- f) Cut down set,
- g) Endoscope,
- h) Proctoscope,
- i) Laryngoscope (optional),

- Tape meter,
- Thermometer,
- Reflex/patellar hammer,
- j) Resuscitation kits: Ambu bag, air ways,
- k) Oxygen cylinder, Flowmeters for oxygen, Nasal prongs/ catheters,
- l) Plastic bowels for chemical disinfection,
- 6.20.4.2 The inpatient service of Gastroenterology unit shall have the following supplies and functional equipments:
  - a) Examination couch,
  - b) Patient beds,
  - c) Bed side cabinet,
  - d) Diagnostic sets (like Torch, Otoscope, fundoscope, patella hammer)
  - e) Weighing scales,
  - f) Vital sign set like thermometer, BP apparatus, stethoscope,
  - g) Medicine trolley,
  - h) Suction machine,
  - i) IV stands,
  - j) Oxygen source/ Oxygen cylinder, Flow-meters for oxygen,
  - k) Oxygen face mask,

- l) Nasal prongs catheters,
- m) Self inflating bags for respiratory support, Masks, endotracheal tubes,
- n) Laryngoscope,
- o) Cannulas,
- p) Nasogastric tubes,
- q) Glucometer and glucostick,
- r) Pulse oximeter,
- s) Wheelchair,
- t) Kick buckets,
- u) Cup board,
- v) Over bed table (for feeding),
- w) Curtain fixed with the ceiling,
- 6.20.4.3 The gastroenterology unit shall have emergency medicines as per the national medicines list.

## 6.21 Renal Services

#### 6.21.1 Practice

- 6.21.1.1 The Renal unit shall provide both medical & surgical services (i.e., Nephrology & Urology) with the following modalities:
  - (a) Outpatient service,
  - (b) Follow-up clinic,
  - (c) Referral services to respective facilities,
  - (d) Emergency service for kidney & related problems,
  - (e) Inpatient care for related diseases,
  - (f) Surgical interventions,
  - (g) Hemodialysis,
- 6.21.1.2 There shall be written protocols and procedures for medical & surgical management of common genito- urinary & kidney conditions.
- 6.21.1.3 The unit shall avail both nephrology & urology services for emergency renal conditions for 24 hours a day throughout the year,
- 6.21.1.4 The unit shall have access to Intensive Care Unit (ICU) with all requirements stipulated under ICU standards,
- 6.21.1.5 The unit shall provide anaesthesia services as per the anaesthesia section of these standards.
- 6.21.1.6 For non-emergency condition the nephrology & urology services shall be available during the regular working hours.
- 6.21.1.7 The nephrology & urology services shall be organized to cover all the shifts for admitted patients (24 hours of the day and seven days of the week),
- 6.21.1.8 Nursing care shall be carried out by licensed nurse responsible,
- 6.21.1.9 The service shall have written policies and procedures that shall include:
  - (a) Admission and discharge criteria specific to the service;
  - (b) A visitors policy,
  - (c) Infection control as per the National IP guideline and this standard,
  - (d) Transfer and Referral of patients,
  - (e) Monitoring and follow-up of patients,
  - (f) Criteria for interventions like haemodialysis and surgical interventions,
- 6.21.1.10 The renal unit shall have the following urology services:
  - (a) Urethroscopy,
  - (b) Extracorporal Shock Wave Lithotripsy,
  - (c) Percutaneous lithotripsy,
  - (d) Insertion of stents,

- (e) Transurethral diagnostic procedures &/ or lithotripsy
- (f) And other related services
- 6.21.1.11 The renal unit shall have the following nephrology services:
  - (a) Medical treatment,
  - (b) Dialysis,
- 6.21.1.12 The unit shall develop & implement operational policies addressing at least the following concerns:

# (a) Policies & protocols related with Lithotripsy:

- o Pre-admission testing requirements,
- o Maximum number of shocks &/ or voltage allowable,
- o Post ESWL follow-up,
- o Contraindicated medication,
- o Pediatric cases,
- o Criteria for: treatment; cancelation; retreatment;
- General safety protocols,
- Inspection of lithotripter by qualified person; with documentation of all preventive maintenances,

# (b) Policies & protocols related with Hemodialysis:

- Admission criteria that includes acceptance of patients who have communicable or transmittable diseases,
- Orientation of new patients to the unit,
- Contraindications.
- Pre-admission testing requirements,
- Criteria for: treatment; cancelation; retreatment;
- General safety protocols,
- Infection control protocol & dialysis waste management,
- Specific facility response to medical & non-medical emergencies including, for e.g., equipment failure & water supply problems,
- Regular inspection of hemodialysis machine by qualified person; with documentation of all preventive maintenances,
- There shall be proper written and verbal instruction for patients about dialysis process and the machine used.
- 6.21.1.13 There shall be a red alarm light and an audible beep on the dialysis machine.
- 6.21.1.14 There shall be a written protocol or procedure for application of haemodialysis machine on:
  - (a) infection control,
  - (b) management of waste from the machine, and
  - (c) set up & rinsing the machine before the patient is connected.
- 6.21.1.15 All medical records & laboratory investigations with plan shall be documented on each patient's record.

- 6.21.1.16 Dialysis treatment shall be approved by licensed nephrologists or trained and certified physicians. The duration and frequency of dialysis treatment shall be stated by ordering physician.
- 6.21.1.17 Information contained in the medical record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis, diagnostic procedures, medication administration, and treatment.
- 6.21.1.18 The unit shall have a system for involving patients, family members &/ or caretakers in the process of care & treatment.
- 6.21.1.19 There shall be chronic care follow up service for certain prevalent renal conditions in the unit.

#### 6.21.2 Premises

- 6.21.2.1 The renal unit shall have the following premises: examination rooms at outpatient, inpatient ward with isolation room & nurse station, rooms for surgical procedures and haemodialysis rooms.
- 6.21.2.2 Admission rooms shall be with a maximum capacity of six beds per room.
- 6.21.2.3 The number of rooms and beds shall be as per the load, volume and nature of work performed.
- 6.21.2.4 The haemodialysis unit shall have the following premises and requirements:
  - (a) located in a purpose built room with traffic restricted area of the hospital,
  - (b) set up of the unit shall be to the level of intensive care.
  - (c) The size of the room depends on the number of dialysis machines available.
  - (d) The header of beds or dialysis chairs shall be 0.9m away from the wall. There shall be a 1.2 m wide free traffic area by side of beds and between any of two beds.
  - (e) nurse station:
    - Isolated with glass, Full visual access to monitor admitted patient on machine,
    - Equipped with chairs, working laminated top tables, drawers and computers,
    - Linen boards, shelves, lockers,
    - Telephone end,
    - Medication boards,
    - Weight scale,
    - Patient screen per bed and
    - Dust bins, separate leak proof containers on trolley for used dialysis sets and waste products.
  - (f) staff locker room with shoe and cloth change point,
  - (g) soiled utility room with sink with hot and cold water,

- (h) store room,
- (i) hand washing basin,
- (j) toilets,
- 6.21.2.5 The renal unit shall have the following premises for surgical procedure:
  - (a) Urethroscopy room,
  - (b) Lithotripsy (ESWL) rooms,
  - (c) Operation theatre, shared with the general OR,
  - (d) Staff rooms with lockers,
  - (e) Store room,
  - (f) Toilets with shower for patients and staff,

### 6.21.3 Professionals

- 6.21.3.1 The renal unit shall be directed by a licensed nephrologist or urologist/urosurgeon
- 6.21.3.2 At least one nephrologist and urologist shall be available to run the outpatient and inpatient service during working time.
- 6.21.3.3 The nephrologist shall be responsible for:
  - (a) Medical services provided to each patient; while the licensed nurse shall be responsible for all nursing care provided to the patient, nursing visits, care, carry out and execution of the orders,
  - (b) Control of the hemodialysis service.
  - (c) Being available (physically present) during working time, and on call basis during after hours,
  - (d) While on duty or on call, the specialist shall be able to present at the unit in a period of time not to exceed thirty (30) minutes.
- 6.21.3.4 The urologist shall be responsible for:
  - (a) Surgical services provided to patients; all-tripsies, all-scopies,
  - (b) Being available (physically present) during working time, and on call basis during after working hours,
  - (c) While on duty or on call, the specialist shall be able to present at the unit in a period of time not to exceed thirty (30) minutes.
- 6.21.3.5 The renal unit shall have an internist and general practitioner at all times.
- 6.21.3.6 The nursing service in the unit shall be directed by licensed nurse trained on renal patient care.
- 6.21.3.7 There shall be one nurse to two dialysis machines at all times.
- 6.21.3.8 The dialysis machine shall be attended & checked all the time by appropriate technician or engineer.
- 6.21.3.9 There shall be adequate support staff available.

- 6.21.3.10 Additional number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis),
- 6.21.3.11 In summary the renal unit shall have the following staff
  - (a) Nephrologist

(e) Technician/Engineer (pulled)

(b) Urologist/Urosurgeon

(f) Nurses

(c) Internist

(g) Cleaners

(d) General Practitioner

(h) Porters

#### 6.21.4 Products

- 6.21.4.1 The outpatient service of the renal unit shall have the following equipment & supplies:
  - (a) Examination couches,
  - (b) Examination light,
  - (c) X-Ray viewer,
  - (d) Diagnostic sets:
    - reflex hammers
    - ophthalmoscope
    - thermometer

- sphygmomanometer
- Tuning fork
- (e) Weighing scale,
- (f) Height measurement,
- (g) Doppler ultrasound (shared),
- (h) Cystoscope,
- 6.21.4.2 The inpatient service for renal unit shall have the following equipments & supplies:
  - (a) Patient beds,
  - (b) Diagnostic sets like torch, Otoscope, funduscope, patella hammer
  - (c) Weighing scales,
  - (d) Vital sign set like thermometer, BP apparatus, stethoscope
  - (e) Examination couch,
  - (f) Medicine trolley,
  - (g) Cystoscope,
  - (h) Suction machine,
  - (i) Drip counters/Infusion pump,
  - (j) IV stands,
  - (k) Oxygen source with flowmeters,
  - (l) Oxygen face mask/ nasal prongs catheters,

- (m)Self inflating bags for respiratory support, Masks, endotracheal tubes,
- (n) Laryngoscope,
- (o) Cannulas,
- (p) Nasogastric tubes,
- (q) Glucometer and glucostick,
- (r) Pulseoximeter,
- (s) Wheelchair,
- (t) Over bed table(for feeding),
- (u) Bed side cabinet,
- (v) Curtain fixed with the ceiling,
- (w) Kick buckets,
- (x) Cup board,
- (y) Wall clock,
- (z) Trolley for vital sign monitoring,
- (aa) Refrigerator with temperature control for medication,

- (bb) Medication Cupboard (cc) Patient chart holder, with lock,
- 6.21.4.3 Dialysis Unit:
  - (a) Dialysis machine with red alarm light and an audible beep
  - (b) Water treatment facility
    - Sand filter,
    - Carbon filter and
    - Reverse osmosis machine.
  - (c) Separate leak proof containers on trolley for used dialysis sets and waste products
- 6.21.4.4 The renal unit shall have the following equipments, not limited to:
  - (a) Extracorporal shock wave Lithotripsy machine
  - (b) Percutaneous lithotripsy machine
  - (c) Dura bascket,
  - (d) Ureteroscope,
  - (e) Cyctoscope,
  - (f) Suprapubic puncture with trocar,
  - (g) Railroading/ Urethral dilators,
  - (h) General surgery set,
  - (i) Retroperitoneal set/Kidney set,
- 6.21.4.5 The unit shall have emergency medicines at all times as per the national medicines list of Ethiopia.

### 6.22 Rehabilitation Services

#### 6.22.1 Practices:

- 6.22.1.1 At least two of the following services shall be available in the hospital:
  - (a) Physical therapy/ physiotherapy: treatment aimed at the attainment or recovery of optimal neuro-musculoskeletal function to help ones strength, mobility and fitness,
  - (b) Occupational therapy: therapy aimed at giving people "skills for the job of living" or "the skills for employment." to help with ones daily activities.
  - (c) Vocational Rehabilitation: The continuous and coordinated process of rehabilitation which involves the provision of vocational guidance, vocational training and selective placement, designed to enable a person with a disability to secure and retain suitable employment
  - (d) Drug dependency rehabilitation: for dependency on psychoactive substances such as alcohol, prescription medicines, and illicit drugs such as cocaine, heroin or amphetamines
  - (e) Speech therapy
  - (f) Pain management
- 6.22.1.2 There shall be written policies and protocols that ensure rehabilitation services are properly provided,
- 6.22.1.3 There shall be specific treatment and/or procedure protocols for each service available and rendered in the unit,
- 6.22.1.4 There shall be a policy for patient referral and inter discipline consultation,
- 6.22.1.5 There shall be a policy that the therapist (occupational therapist/ physiotherapist) shall document the entire plan on the patient's medical records. A note shall be entered into the medical record at least weekly or more frequently if there is a significant change in the patient's status or treatment needs.
- 6.22.1.6 The physical therapist shall discuss the plan of care with the patient and family, if possible.

- 6.22.1.7 The physical therapy service shall offer services at least during working hours.
- 6.22.1.8 Visual and Auditory privacy shall be offered and provided to all patients during evaluation and treatment, when clinically indicated.
- 6.22.1.9 There shall be a policy that states written orders shall be given to patients when patients are discharged with exercise or treatment to continue at home.
- 6.22.1.10 There shall be a protocol or policy for safety and ethical practice of physical therapy, identifying six precepts for health care in the future, namely, that the health care system must be: safe, effective, patient-centered, timely, efficient, and equitable.
- 6.22.1.11 There shall be patient education on prevention of:
  - (a) pressure sores in clients with sensory loss,
  - (b) contractures in clients with limb and/or trunk paralysis,

#### 6.22.2 Professionals:

- 6.22.2.1 The service shall be directed by a licensed physiotherapist or practitioner therapist graduated from recognized university or institute.
- 6.22.2.2 The hospital shall have at least a chiropractor, physiotherapist, occupational therapist, clinical psychologist/health psychologist, speech therapist for each respective service areas.
- 6.22.2.3 All practitioners shall be licensed and only licensed practitioners shall provide service.
- 6.22.2.4 There shall be multidisciplinary team in the rehabilitation service to plan for individual patients.
- 6.22.2.5 Continued improvement of technical skills and knowledge should be encouraged and such opportunities shall be facilitated by the hospital.
- 6.22.2.6 Trained and certified therapist shall be available or shall supervise daily sessions of physiotherapy.
- 6.22.2.7 The service shall have dedicated cleaners.

### 6.22.3 Premises

- 6.22.3.1 There shall be physically separated room or area for rehabilitation and therapy.
- 6.22.3.2 There shall be direct access to inpatients and outpatients with clearly written labels.
- 6.22.3.3 The premises shall be friendly for persons with disability and shall have smooth pavement rail for wheelchairs.
- 6.22.3.4 There shall be enough space for assistive devices and appropriate accessories
- 6.22.3.5 There shall be waiting area with shade.
- 6.22.3.6 Staff room for developing documentation and storing reference books and personal items shall be available.
- 6.22.3.7 Private room for patients and staff when they need to change closing before and after treatment shall be available.
- 6.22.3.8 Separate toilet with hand washing facility in an accessible location, handicapped accessible, handicapped adapted, and well-ventilated shall be available
- 6.22.3.9 Call bells/beeper bells shall be provided to patients in the physical therapy service who are not under visual supervision.
- 6.22.3.10 Workshop for production of prostheses, walking sticks: auxiliary and/or elbow crutches shall be available or there shall be a documented mechanism of accessing such services
- 6.22.3.11 There shall be a separate room for exercise therapy

### 6.22.4 Products:

- 6.22.4.1 All equipment shall be clean and function.
- 6.22.4.2 Equipment shall be stored in a safe and accessible place and shall not be stored in a public walkways and hallways.
- 6.22.4.3 Standard equipments and consumables which shall be available for rehabilitation services include:
  - (a) Physiotherapy mats,
  - (b) Splinting materials,

- (c) Bobath balls,
- (d) Balance boards,
- (e) Mirror,
- (f) Waking rail/ parallel bars,
- (g) Pressure garment materials,
- (h) Goniometers,
- (i) Spring,
- (j) Rollers,
- (k) Infrared,
- (l) Ultraviolet/ blue lamp,
- (m) Paraffin bath,
- (n) Muscle stimulator,
- (o) Ultrasound therapy equipment,
- (p) Diathermy,
- (q) Electro-massage apparatus for hands, legs, spine,
- (r) Massaging coach,
- (s) Organ protection pad,
- (t) Educational toys,
- (u) Material for making assistive devices for daily living functions,
- (v) Specific assessment tools for occupational-, speech-, and physiotherapy,
- (w) Screening audiometer,
- (x) Developmental screening charts for detecting speech abnormality,
- (y) Disposable glove,
- (z) Cotton roll,

# 6.23 Oncology Services

#### 6.23.1 Practices

- 6.23.1.1 The oncology outpatient services shall include:
  - (a) New patient services,
  - (b) Follow-up services,
  - (c) Radiotherapy planning services,
  - (d) Radiotherapy treatment sessions,
  - (e) Weekly Radiotherapy treatment checks,
  - (f) Chemotherapy sessions,
  - (g) Oncologic emergency services including emergency procedures,
  - (h) Health education on cancer related topics
  - (i) Pain clinics if possible,
- 6.23.1.2 The oncology inpatient services shall include:
  - (a) Delivering chemotherapy sessions,
  - (b) Nursing care according to individual patients' needs
  - (c) Brach therapy (Low dose rate or high dose rate, preferably high dose rate sources)
- 6.23.1.3 There shall be a multidisciplinary cancer committee, chaired by a physician for a defined period that is responsible for at least the development of oncology policies and procedures, tumor review, and tumor registry.
- 6.23.1.4 The multidisciplinary team shall consist of clinical oncologist designated leader, surgeon who deals with the respective tumor type, pathologist, radiologist, nuclear medicine physician depending on the type of malignancy, oncology nurse and there shall be meetings on a regular basis.
- 6.23.1.5 The service shall have written policies and procedures that are reviewed at least once every five years, revised more frequently as needed, and implemented. They shall include at least:
  - a) Criteria for admission
  - b) Guidelines for mixing chemotherapy, when performed on the unit,
  - c) Guidelines for administering chemotherapy

- d) Training of nursing and housekeeping staff in the disposal of chemotherapeutic agents;
- Use, handling, storage, and disposal of specific chemicals, agents, and body wastes;
- f) Assuring informed consents to chemotherapy; and
- g) Psychological/social and spiritual aspects of patient care.
- 6.23.1.6 There shall be a formal mechanism for communication between the oncology service and each of the following clinical areas: nursing, dietary, social work, nuclear medicine, laboratory, pathology and pharmacy.
- 6.23.1.7 All patients with cancer shall be managed by a multidisciplinary process. It includes diagnosis and all aspects of treatment and care, including symptom management and end-of-life care. It considers each individual patient's need and preference for care and treatment. The multidisciplinary process shall include the followings:
  - a) There shall be a multidisciplinary management protocols covering systems for referral (including to medical, surgical, oncology and palliative care services), investigation, diagnostics, staging for treatment, treatment, follow-up and end-of-life care for patients with cancer.
  - b) All patients shall have access to palliative and supportive care appropriate to their needs
  - c) There shall be written local protocols for discharge planning, which includes details for pre-discharge, actual discharge and post-discharge arrangements.
  - d) All patients with cancer shall have individualized care plans, developed jointly and agreed between the patient and members of the multidisciplinary care team, documenting clinical and non-clinical issues and the proposed action to address such issues.
  - e) A comprehensive, single care plan shall be available to the patient and members of the multidisciplinary care team including health professionals
- 6.23.1.8 Care, support and services for cancer shall be provided in partnership with patients and care givers. There shall be a clear record of what the patient or

- care givers has been told about the condition, treatment and care options, outcomes, risks and side-effects.
- 6.23.1.9 Patients with cancer shall be enabled and supported to make decisions throughout their care experience. All patients with cancer shall have access to a healthcare worker with experience and knowledge of their current care needs and the skills to facilitate informed decision-making.
- 6.23.1.10 Patient and family teaching shall be provided in any case where the patient and family are in need of and able to receive instruction.
- 6.23.1.11 Criteria shall be developed in consultation with the social work department for identifying patients in need of social work services and/or discharge planning and making referrals as needed.
- 6.23.1.12 There shall be a system to refer patients and family and direct staff to in-house and community support groups and services.
- 6.23.1.13 There shall be a program of continuous quality improvement for oncology that is integrated into the hospital 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.
- 6.23.1.14 There shall be a pain clinic if possible, but there should be the national pain management guidelines and be utilized properly and accordingly.
- 6.23.1.15 Pain shall be considered as a 5th vital sign. The Oncology nurse shall utilize appropriate pain assessment tools and will encourage the patient "self-report" of pain.
- 6.23.1.16 Principles of pain management including non-pharmacological methods of pain management may be taught.
- 6.23.1.17 The oncology nurse shall document pain assessment and interventions.
- 6.23.1.18 The patient will be protected from infection and cross contamination according to infection prevention section of this standard. Nursing personnel shall institute specific precautions to prevent infection in patients with an absolute neutrophil count (ANC) of less than 1,000
- 6.23.1.19 Medications shall be administered per written policies and procedures.
  - a) Chemotherapy shall be administered as per written procedures.

- b) The pharmacist and nursing staff shall wear protective gloves and approved chemotherapy gowns when compounding/preparing and administering chemotherapy to patients
- c) Licensed nurses shall take necessary steps to prevent and treat extravasations of chemotherapeutic agents so that the patient will have minimum complications
- d) Treatments, medications, and IV's ordered by the physician shall be instituted
- 6.23.1.20 Patients shall be admitted to patient care areas according to their physical and psychosocial needs, unit admission criteria, and bed availability.
- 6.23.1.21 The patient shall be oriented to the room, service unit and to their assigned nurse upon arrival.
- 6.23.1.22 Identified patient needs and subsequent nursing interventions shall be evaluated and documented in the Integrated Notes.
  - a) The nursing staff shall provide assessment and care during every shift to the patient with mucositis, an inflammatory response to chemotherapeutic agents. Patient education will be provided.
  - b) The nursing staff shall initiate and teach appropriate precautions for the patient with myelosuppression
  - c) The nursing staff shall provide assessment, care, and evaluation of interventions to the patient receiving chemotherapy with high emetogenic potential.
- 6.23.1.23 Patient teaching shall begin during the admission process and shall be ongoing. Documentation shall include the teaching plan and patient response.
- 6.23.1.24 Nursing personnel shall provide information to patients regarding administered chemotherapeutic agents
- 6.23.1.25 Nursing staff shall seek input from the patient and other health care professionals to plan and implement care. Oncology nursing staff shall utilize the nursing process to provide for the physical, emotional, and spiritual needs of oncology patients and make referrals as appropriate.
- 6.23.1.26 The nurse shall utilize available resources to facilitate an optimal transition between health care settings. The patient or family who is complex, unable to

- cope, or being discharged which requires coordination by the multidisciplinary team will be followed by Integrated Case Management.
- 6.23.1.27 Patient's comfort level shall be assessed and comfort measures/pain management will be provided to meet patient needs.
- 6.23.1.28 Consent for procedure and patient understanding shall be verified prior to implementation.
- 6.23.1.29 Additional information regarding advance directives shall be provided as requested by patient.
- 6.23.1.30 Patient's spiritual and cultural beliefs shall be considered when planning and implementing care. The nursing staff shall utilize the nursing process to assess the patient and family's ability to cope with his/her diagnosis and treatment of disease. Interventions shall be congruent with the patient/family belief system.
- 6.23.1.31 Available resources shall be utilized to maximize patient's support and care giver as needs are identified. Patients who are assessed by oncology staff as unable to cope shall be referred to the social worker or appropriate support group.

## 6.23.1.32 Chemotherapy

- a) All chemotherapy regimens shall be given according to the treatment guidelines
  - Staff dealing with cytotoxic drugs shall follow the safety guidelines;
  - Vertical Laminar Air Flow Hood shall be used during the preparation of all chemotherapy on the unit.
  - Goggles, masks, gloves shall be worn when dealing with chemotherapy.
  - Office of Occupational Medicine shall be used to develop procedures for preparing chemotherapy. Example using Fume hood for chemotherapy mixing
- b) Inpatient chemotherapy shall only be given in wards where it is agreed as the whole of, the wards allowed activities.
- c) Out-patient chemotherapy shall only be given in outpatient areas where it is agreed as part of, or the whole of, that areas allowed activity.

- d) While out-patient chemotherapy is being given the area shall only be used for this purpose and other aseptic treatments and procedures on cancer patients.
- e) Oncology nurse administers parentheral chemotherapy as prescribed by the oncologist in the presence of oncologist or other trained physician

## 6.23.1.33 Radiotherapy

- a) The safety standards of radiotherapy shall be according to the Ethiopian National Radiation Protection Authority (ENRPA) /IAEA standards
- b) The radiotherapy technician can deliver Radiation in the presence of a radiation oncologist
- c) Both acceptance and commissioning test should be done by experienced medical physicist for Barchytherapy and teletherapy machine before being used for patients' treatment.
- 6.23.1.34 There shall be one oncologist available during working hours and on call basis at all times for consultation.
- 6.23.1.35 As the patient's condition or nursing interventions warrant, the bed will be kept in the low position with the wheels locked and upper side rails in the up position and call light within reach of patient. Oncology nursing staff will implement thrombocytopenic precautions for patients with platelets less than or equal to 20,000
- 6.23.1.36 An allergy label shall be placed on the front of each patient's chart with "Allergies" or "No Known Allergies" listed as appropriate. Allergies" or "No Known Allergies" will be entered into the patient's medical record (Care vision) during the admission process and updated as appropriate
- 6.23.1.37 Vital signs shall be completed, unit routine, physician order, or as patient condition warrants.
  - a) Patients receiving blood or blood products shall have vital signs monitored
  - b) Patients with neutropenia shall have vital signs taken
- 6.23.1.38 Patient hygiene shall be ensured by providing a bath or shower for each patient daily. Daily morning care will include offering mouth care, a wet washcloth, and repositioning the patient for breakfast.
- 6.23.1.39 Psychological and psychiatric services shall be available in the premises
- 6.23.1.40 Chaplin or related religious counseling may be facilitated upon patient request

### 6.23.2 Premises

- 6.23.2.1 Buildings and rooming styles shall generally be in accordance with the Ethiopian Radiation Protection Authority's standards
- 6.23.2.2 Minimal requirements for outpatient section
  - Three examination rooms with indirect laryngoscope head lights, spirit lamps & screen, a gynecology examination coach in at least one of the rooms
  - Nurses office in between the examination rooms
  - Staff offices
  - Radiotherapy planning room with planning coach & measuring utensils
  - Dedicated Chemotherapy room with reclining chairs
  - Store for immobilizers and consumables and
  - Conference room.
  - Separate toilet for patients with hand washing basin (male/female)
  - Separate toilet for staff with hand washing basin (male/female)
- 6.23.2.3 Minimal requirements for radiotherapy treatment rooms
  - Therathrone
  - Linear accelerator room
  - Simulation room
  - Brach therapy room
  - Office of Occupational Medicine (to prepare chemotherapy.)
  - Chemotherapy rooms with at least 3 coaches/ reclining chairs each
  - Library with shelves for quick reference
  - Patient toilets separate for male and female
  - staff toilets separate for male and female
- 6.23.2.4 Minimum requirements for inpatient section
  - (a) Nurses office
  - (b) Single bed rooms with ensuite bath room with toilets. The single bedrooms shall be available as needed to accommodate patients with Neutrogena, or critically ill patient and the other single bed room will be a

septic room for those with offensive smelling wounds, that needs wound care

- (c) Rooms with 3 beds (the distance between the beds shall be at least 1.2m)
- (d) Rooms with 4 beds (the distance between the beds shall be at least 1.2m)
- (e) Duty rooms
- (f) Shared toilets for the patients (separate for male and female)
- (g) Separate toilets for staff (separate for male and female)
- (h) Inpatient store
- (i) Molding Room
- (j) Physics Laboratory with planning computers
- (k) The inpatient environment shall be conducive for rest and recovery.

### 6.23.3 Professionals

- 6.23.3.1 The oncology service shall be directed by a licensed oncologist
- 6.23.3.2 The oncology service shall have at least the following category of professionals
  - a) Clinical oncologists
  - b) General practitioners with adequate on job training in the care of malignancies
  - c) Medical physicists
  - d) Radiotherapy technicians
  - e) Radiographers with adequate on job training and assist the RTT
  - f) Full time Maintenance Technician
  - g) Biomedical Engineer (Shared)
  - h) Oncology trained nurses
  - i) Nurses with adequate on job training
- 6.23.3.3 Other core allied licensed health professionals required are:
  - a) Dietitian
  - b) Physiotherapist
  - c) Speech therapist
  - d) Occupational therapist
  - e) Oncology pharmacist
- 6.23.3.4 Designated social worker/s who is a member of social work services of the hospital shall be assigned to the unit to provide psychosocial services, assist

with discharge planning, and provide information regarding financial aspects of care

## 6.23.3.5 One data manager for the service is required

### 6.23.4 Products

- 6.23.4.1 Antineoplastic medicines and pain medications shall be available in line with the national medicines list of Ethiopia.
- 6.23.4.2 The oncology service shall have the following supplies
  - a) Lead Bars (supply)
  - b) Goggles for chemotherapy
  - c) Orfit Packs 5 per year
  - d) Molding foams
  - e) Leaded Aprons at least 3, for RT planning, and simulation and C-Arm imaging
- 6.23.4.3 The oncology shall have the following equipments
  - a) Teletherapy machines
  - b) CO-60 machine
  - c) Linear Accelerator
  - d) Orthovoltage X-Ray 100KvP
  - e) CT simulator
  - f) C-Arm machines
  - g) Brach therapy machines
  - h) High dose rate source of CO-60 or low dose rate Cesium source
  - i) Immobilization devices
  - j) Breast BoardMinimum 2, Plastichead rests A, B, C, D,

E, F Total Two Sets, thermoplastic head casts, head and neck uniframe immobilizer set

- k) Digitizer
- l) Molding Machine( cutter)
- m) Planning computerswith color printerswith backup system
- n) Boiler for orfit preparation
- o) Lead Melting machine for molding lead
- p) Fume hood for chemotherapy mixing
- q) Perfuser

- r) Brachytherapy machine
- s) Simulation
  equipment: one CT
  simulator and C-Arm
  x-ray unit
- t) Mould room equipment
- u) Alloy melting pot
- v) Steriofoam cutter
- w) Boiler for orfit preparation
- x) Coach
- y) Dosimeter equipment
- z) Farmer dosimeter
- aa) Electrometer
- bb)Personal dosimeter
- cc) Survey meter
- dd)Appropriate Ion chambers to radiotherapy machines used
- ee) Water phantom
- ff) Barometer
- gg) Digital thermometer
- hh)Treatment planning system

- ii) Computers with printers ( one of the printers should be colour printer)
- jj) Treatment planning software
- kk) Digitizer
- ll) Immobilizers
- mm) Breast board
- nn)Plastic head rests (
  with size A, B, C, D, E,
  F)
- oo) Head and Neck
  uniframe
  immobilizers two sets
- pp)Pelvi-meter
- qq)Flexi curve ruler
- rr) Orfit packs as required
- ss) Chemotherapy
  equipment: One
  fume hood and two
  perfuser for
  chemotherapy

### 6.24 Nuclear Medicine Services

### 6.24.1 Practices:

- 6.24.1.1 The hospital shall have written procedure for in vitro techniques such as radio-immunoassay (RIA) and immuno-radiometric assay (IRMA).
- 6.24.1.2 The hospital shall have written procedure for the diagnosis of different health problems using radiopharmaceuticals or radionuclides for both in vivo imaging and non-imaging diagnostic techniques.
- 6.24.1.3 Any loaner unit that is in use for more than one month will be required to submit evidence of testing by a qualified medical physicist within 90 days of installation. If the loaner is in place for longer than six months, the facility must submit the unit for accreditation evaluation, including clinical and phantom image assessment and the corresponding fee.
- 6.24.1.4 Acceptance testing and commissioning shall be performed based on written policies and procedures. The procedures shall address the followings;
  - a) Major nuclear medicine instruments like Rectilinear Scanner, Whole Body Scanner, Planar Gamma Camera, SPECT, PET, SPECT/CT, PET/CT etc shall be tested during installation.
  - b) A qualified practicing medical physicist, nuclear medicine technologist or medical physicist shall perform these tests using internationally accepted protocols.
  - c) The test results shall be reviewed by the qualified medical physicist and documented in the annual survey report. Based on this report the supervising physician is responsible for assuring compliance with the recommendations of the medical physicist.
  - d) External auditing shall be done at least annually. The performance tests listed below shall be performed on all units as per the ENRPA or NEMA and/or the IAEA QC protocols:
    - Intrinsic Uniformity
    - System Uniformity
    - Intrinsic or System Spatial Resolution

- Image Resolution Test
- Linearity Test
- Sensitivity
- Center of Rotation Test and Caliberation
- Energy Resolution
- Count Rate Parameters
- Formatter/Video Display
- Overall System Performance for SPECT Systems
- System Interlocks
- Dose Calibrators (Radionuclide Calibrator) Performed as per the protocol of NEMA or/and the IAEA to verify that readings from this instrument are accurate (accuracy test). All basic measurements of performance must be done at the time of installation and repeated after major repair. This test must be done according to protocols accepted by the appropriate National Regulatory Authority (Ethiopian Radiation Protection Authority (ERPA)).
  - o "Test" measurement of battery voltage (if applicable)
  - o Zero adjustment (if applicable)
  - o Background adjustment
  - o Accuracy and precision tests with NIST traceable standard
  - Linearity
  - o Geometry
  - Constancy test
  - Operational Checks (Check of Reproducibility and Background Response)
- Thyroid Uptake Probe and Other Counting Systems for gamma
   radiation measurements for in vitro (e.g. Gamma spectrometers/well type scintillation counters) performed to verify, integral background
   count rate, function of scalar timer/rate meter, energy calibration,
   energy linearity, energy resolution, sensitivity, and reliability (Chi squared test) for the measurement of organ function, the assay of

patient samples and for counting of other related radioactivity sources using short and long lived radionuclides like:

- o I-123 or I-131 capsule
- o Tc-99m and
- o long-lived standard calibration sources(e.g. Cs-137, Co-57)
- 6.24.1.5 The nuclear medicine technologist shall be responsible for verifying day-to-day operation of instruments and performing a few additional tests on a quarterly basis.
- 6.24.1.6 The following quality control tests shall be made by the nuclear medicine technologist:
  - a) Intrinsic or System Uniformity (each day of use)
  - b) Intrinsic or System Spatial Resolution (weekly)
  - c) Center-of-Rotation or Multiple Detector Registration Calibration/Test for SPECT Systems (monthly).
  - d) High-Count Floods for Uniformity Correction for SPECT Systems (frequency as recommended by a qualified medical physicist).
  - e) Overall System Performance for SPECT Systems (quarterly).
  - f) Dose Calibrators (daily, quarterly, and semiannual)
    - Daily Tests are performed to verify that the calibrator is accurate and reliable for the assay of doses administered to patients.
    - Quarterly A linearity test must be performed to document that accurate readings are provided through the entire range of activities used clinically. Other qualified personnel may do these tests.
    - Semiannual All non-exempt radionuclide sources must be tested to verify that radioactivity is not leaking from the sources.
       Other qualified personnel may also do these tests.
  - g) Thyroid Uptake and Counting Systems (each day of use) Standards are measured to verify energy calibration and sensitivity for the measurement of organ function and the assay of patient samples.
- 6.24.1.7 Documentation of compliance with all quality control tests and corrective action shall be required as part of the application process.

- 6.24.1.8 Policies and procedures related to quality, patient education, infection control, and safety shall be developed and implemented in accordance with the IAEA Policy on Quality Control and Improvement, Safety, Infection Control and Patient Education Concerns.
- 6.24.1.9 The site shall have a quality assurance program that incorporates the following two elements:
  - a) Physician Peer Review: Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility using written procedures.
  - b) Appropriateness/outcomes analysis: The results of an appropriateness/outcomes analysis and the actions taken to correct any deficiencies should be maintained as quality assurance records at the facility. Policy and procedures should be in place to look at the diagnostic accuracy and outcome of nuclear medicine examinations.

    Documentation may be requested as part of an on-site survey.
- 6.24.1.10 Data shall be collected and processed according to the instructions provided in the testing package. The procedures may differ from those normally used by the applicant but were designed to minimize the variability in the images submitted by different facilities.
- 6.24.1.11 All films (or hard copies) or/and burned CDs are an important part of the medical record. The following shall be permanently recorded on each image of the study: patient name, patient age (or date of birth), patient identification number, date of exam, and institution name. The technologist's name, initials, or other means of identifying the technologist who performed the study shall also be indicated.
- 6.24.1.12 A corresponding, dated physician report that clearly states the type of examination performed and the clinical history shall accompany all examinations. The parameters that will be scored on the clinical images include: radiopharmaceutical bio-distribution, image acquisition, processing, and display, as well as film and report identification. Patient films or/and the corresponding hard copy or burned CDs shall be returned as required with the final report.

6.24.1.13 The hospital shall notify the regulatory body if they have permanently withdrawn (i.e., removed) a unit from service, if they have replaced that unit with a new one or have added another unit.

### Radiopharmacy

- 6.24.1.14 The hospital shall have written procedure(s) for the preparation of various radiopharmaceuticals.
- 6.24.1.15 The compounding and dispensing area for radioactive medicines shall be separate from that of non-radioactive medicines, and shall be secured from unauthorized personnel.
- 6.24.1.16 In addition to any labeling requirements for non-radioactive medicines, the immediate outer container of a radioactive medicine to be transported, stored and/or dispensed shall also be labeled with:
  - a) the standard radiation symbol;
  - b) the words "Caution Radioactive Material";
  - c) the radionuclide;
  - d) the chemical form;
  - e) the amount of radioactive material contained, in millicuries or microcuries;
  - f) if a liquid, the volume;
  - g) the calibration time for the amount of radioactivity contained;
  - h) the expiration time; and
  - i) the name, address, and telephone number of the nuclear pharmacy practice site.
- 6.24.1.17 The immediate container shall be labeled with:
  - a) The standard radiation symbol;
  - b) The words "caution radioactive material";
  - c) The name of the medicine; and
  - d) The medical or prescription order number.
- 6.24.1.18 The amount of radioactivity shall be determined by radiometric methods for each product immediately prior to dispensing.

- 6.24.1.19 A nuclear pharmacy practice site shall conduct and keep proper records of appropriate internal test assessments on all radiopharmaceuticals, with interpretation of the resulting data to determine suitability for use in humans.
- 6.24.1.20 A nuclear pharmacy practice site shall conduct authentication of product history by identifying and keeping proper records of the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceuticals.
- 6.24.1.21 Products shall be protected from unintended discharges arising during its preparation and the environment shall be protected from unintended discharge of radioactive materials from the radiopharmacy
- 6.24.1.22 The hospital shall have written procedure for the management and disposal of radiopharmaceutical and other nuclear medicine wastes.

#### 6.24.2 Premises

- 6.24.2.1 Adequate facilities shall be provided for the overall service delivery so that patient comfort, safety, dignity, and privacy are ensured as well as staff comfort and safety. Areas must have sufficient space, be well maintained and be clean. This includes:
  - (j) Interpretation areas
  - (k) Patient records, reports, and digital data storage areas
  - (l) Administration records and support areas
  - (m) Equipment/supply storage areas
  - (n) Therapeutic procedures areas, if applicable
  - (o) Waiting, reception, and patient/staff bathrooms
  - (p) Radioactive materials use and storage areas
  - (q) Diagnostic imaging and processing areas which shall include adequate space and proper orientation to eliminate "cross talk" (counts being acquired from other than the patient being imaged) into images from other patients, radioactive materials, or radioactive waste.
  - (r) Patient education, consultation and examination areas including accessible hand washing for staff

- (s) Performance of stress procedures within appropriate proximity of the imaging area including adequate space for performing resuscitation in case of emergency
- 6.24.2.2 Adequate space, facility configuration, and doorways for the emergency transport of patients from patient care areas and for emergency exit of staff.
- 6.24.2.3 Adequate utilities shall be available, based upon the types of procedures and workload. These include water taps, lighting, electrical outlets, emergency power, telephones, heating/cooling and ventilation.
- 6.24.2.4 All surfaces of Radiopharmacy: walls, floors, benches, tables and seats shall be smooth, impervious and non-absorbent, to allow for easy cleaning and decontamination.
- 6.24.2.5 Adequate space shall be provided for the storage of digital data. The storage must ensure confidentiality of data and should be safe from fire/flood.
- 6.24.2.6 In-vitro section of the nuclear medicine shall have a minimum of 24 meter square space to conduct all RIA/IMRA procedures.
- 6.24.2.7 A nuclear pharmacy practice site shall contain adequate space, commensurate with the scope of services required and provided.
- 6.24.2.8 All pharmacy practice sites handling radiopharmaceuticals shall provide adequate radioactive storage and product decay area, preferably at the hot laboratory. Besides, there shall be the compounding, dispensing, quality control/assurance and office areas.
- 6.24.2.9 Radiopharmacy shall have a minimum of 40 m2 space with two or more rooms.
- 6.24.2.10 Imaging section of the nuclear medicine service shall have a minimum of 30 meter square space to install and use one SPECT machine
- 6.24.2.11 Additionally, minimum space requirement for examination room 30 m2, patient waiting area 20 m2 (two rooms for active and passive patients), injection room 10 m2 and office rooms 50 m2
- 6.24.2.12 Others like staff and patient toilets separate for male and female, office and reception area shall be available

### 6.24.3 Professionals

- 6.24.3.1 The clinical nuclear medicine service of the hospital shall be directed by a licensed specialized medical doctor who has been trained in nuclear medicine.
- 6.24.3.2 The Radiopharmacy service of the hospital shall be directed by a licensed pharmacist who has been trained in nuclear pharmacy.
- 6.24.3.3 In addition, the nuclear medicine service of the hospital shall have at least the following licensed professionals
  - a) Nuclear medicine technologist: A radiographer with B.Sc degree in Radiography and who has been trained in nuclear medicine technology
  - b) Nuclear medicine technician: A radiographer with Diploma in Radiography and who has been trained in nuclear medicine technology
  - c) RIA/IRMA Technologist: A biologist/ chemist /laboratory technologist/ pharmacist who has been trained in RIA/IMRA techniques.
  - d) Nuclear medicine physicist: A physicist who has been trained in nuclear medicine physics
  - e) Radiopharmacy technician: A pharmacy technician who has been trained in nuclear pharmacy services
  - f) Nuclear medicine nurse: A nurse who has been trained in nuclear medicine services.
  - g) Nuclear medicine engineer/Biomedical engineer (may not be necessary as full time job).
  - h) Radiation protection committee presided by Radiation Protection Officer or Radiation Safety Officer.

### 6.24.4 Products

- 6.24.4.1 The following shall be minimum equipment requirements for RIA/IMRA work:
  - a) Refrigerator
  - b) Deep freezer
  - c) Centrifuge to hold 60-100 tubes
  - d) Thermostatically controlled water bath
  - e) Ice bath
  - f) RIA Counter
  - g) Distilling or de-ionizing water
  - h) Voltage stabilizer,

- i) Precision balance
- j) Semi-analytical balance
- k) Magnetic stirrer with Teflon coated stirring bars,
- l) Vortex mixer,
- m) Automatic pipette washer,
- n) Scientific calculator
- o) Ultrasonic cleaner
- p) Foot-operated dustbin
- q) Air conditioner
- r) Centrifuge
- s) Survey meter data 'monitor'
- 6.24.4.2 The following equipment shall be needed for the QC of Scintillation Gamma Camera:
  - a) Sufficient Supply of Tc-99m Generators
  - b) Co-57 Flood Source
  - c) Four Quadrant Bar Phantom
  - d) SPECT Phantom
  - e) Disposable; Petri dish, Capillary tubes
  - f) The following Equipments are also recommended in order to follow good work practices:
    - Refillable flood source
    - Copper plates for evaluation of count rate response
    - Computer generated test image
- 6.24.4.3 The following shall be the list of Equipment and Instrumentation used in the imaging and clinical nuclear medicine section:
  - a) Dose calibrator or decay correction calculation system
  - b) Imaging/counting equipment
  - c) Radiation monitoring devices including
    - portable survey meter (required)
    - removable contamination counting equipment (as applicable)
    - fixed area survey meter for dose preparation/storage areas (as applicable)

- d) Resuscitation equipment and supplies (appropriate to the types of procedures being performed)
  - oxygen
  - defibrillator/AED (checks scored in B3.3.1)
  - emergency medicines (including a master list; all unexpired)
- e) Exercise equipment (as applicable)
- f) ECG equipment (as applicable)
- g) Ancillary monitoring equipment (as applicable)
- h) Infusion pumps/automated injectors (as applicable)
- i) Glucometers (as applicable)
- j) Hood for volatile radionuclides or cell handling (as applicable)
- k) Xenon (or other gas) trap (as applicable)
- l) Lead apron, decontamination solution, goggle and thyroid shield
- 6.24.4.4 Each nuclear pharmacy practice site shall contain at least the following list of products (equipment):
  - a) Radiopharmaceuticals and non-radioactive supplies as per the national medicines list
  - b) Vertical laminar flow hood;
  - c) Dose calibrator;
  - d) Gamma spectrometer;
  - e) Analytical balances and PH Meters
  - f) Lead pot, lead syringe carrier and lead bencher with glasses
  - g) Refrigerator, dry and wet autoclaves
  - h) Radiation exposure monitor;
  - i) Portable survey meter;
  - i) Single or multiple channel scintillation counter;
  - k) Microscope, test tubes, different supplies;
  - l) Radio chemical exhaust hood and filter system
  - m) Lead apron, decontamination solution, goggle and thyroid shield

## 6.25 Radiology Services

#### 6.25.1 Practices

- 6.25.1.1 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) Radiation protection and safety practices;
  - b) Emergencies;
  - c) Adverse reactions;
  - d) Management of the critically ill patient;
  - e) Infection control, including patients in isolation;
  - f) Diagnostic imaging and result delivery
  - g) Quality control program covering the inspection, maintenance, and calibration of all equipment
- 6.25.1.2 Policies and procedures for radiology services shall be available to all staff in the radiology unit.
- 6.25.1.3 All digital X-Rays shall be taken by licensed radiological technologists.
- 6.25.1.4 All x-rays imaging requests shall be done by licensed physician.
- 6.25.1.5 There shall be a written protocol for managing medical emergencies in the radiological suite. All radiological staff shall be instructed in this protocol and know their roles in the case of such an emergency.
- 6.25.1.6 Radiologists shall supervise and interpret all radiologic procedures, unless performed by clinical practitioners in specialty areas who are trained and experienced in the procedures.
- 6.25.1.7 All radiologic tests shall be interpreted on a preliminary basis within 24 hours at all times.
- 6.25.1.8 Ultrasound service shall be given by a radiologist or any health professional trained and certified on ultrasound.
- 6.25.1.9 The radiology service of the hospital shall have the following services at all times
  - (a) Digital X-Ray,
  - (b) Computer tomography (CT) service and/ or MRI ( magnetic resonance imaging) services,

- (c) Ultrasound service.
- (d) Mammography,
- (e) Special procedures such as angiography and interventional procedures,
- 6.25.1.10 The radiology staff shall make every effort to ensure that patients waiting for radiology services or transport from radiology are comfortable while waiting and that the service responsible for transporting the patient back to the unit is notified when the patient is ready to be returned.
- 6.25.1.11 The radiology service unit shall be free of hazards to patients and personnel.
- 6.25.1.12 Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards, and radiation hazards.
- 6.25.1.13 The hospital shall get approval from the Ethiopian Radiation Protection Authority through periodic inspection and hazards shall be promptly corrected if identified
- 6.25.1.14 Radiation workers shall be checked periodically for amount of radiation exposure by the use of exposure meters or badge tests and this shall be documented
- 6.25.1.15 With fluoroscopes, attention shall be paid to modern safety design and operating procedures and records all fluoroscopes' output shall be maintained.
- 6.25.1.16 Signed reports shall be filed with the patient's medical record and duplicate copies kept in the service unit.
- 6.25.1.17 Requests by the attending physician for x-ray examination shall contain a concise statement of reason for the examination.
- 6.25.1.18 Reports of interpretations shall be written or dictated and signed by the radiologist.
- 6.25.1.19 The reporting form shall have minimum information such as name of institution, date, patient name, age, gender, findings and name and signature of radiologist.
- 6.25.1.20 X-ray reports and roentgenographies shall be preserved or microfilmed according to the country's laws.
- 6.25.1.21 X-ray films shall be labeled with a minimum of the following information:
  - (a) date.

(d) name of the institution and

- (b) name, age, gender,
- (c) right/left mark

- (e) Name of professional who took the film.
- 6.25.1.22 A radiation protection and safety program including timely reporting of radiation safety findings shall be in place, followed, and documented.
- 6.25.1.23 The professional/ practitioner who delivered the radiology service shall be responsible for claims arising from wrong findings.
- 6.25.1.24 Radiology services shall physically accessible to all requiring medical service units.
- 6.25.1.25 Safety provision shall be available based on minimum criteria set by the Ethiopian Radiation Protection Authority.
- 6.25.1.26 Radiological equipment quality assurance/control test shall be available.
- 6.25.1.27 Dark room design and accessories as appropriate shall meet the requirements set by Ethiopian Radiation Protection Authority (ERPA)

#### **6.25.2 Premises**

- 6.25.2.1 Design requirements for radiology rooms shall be according to Ethiopian Radiation Protection Authority guidelines and this standard.
- 6.25.2.2 All radiation generating equipment shall be installed with a building wall thickness that fulfills the minimum criteria set by the Ethiopian Radiation Protection Authority and this standard.
- 6.25.2.3 Radiology service equipments shall be installed at central areas to all clinical services.
- 6.25.2.4 The radiology service shall have the following minimum rooms:

Type of premises	Number required	Size(m <sup>2</sup> )
Digital x-ray rooms	2	As per ERPA
Fluoroscopy room	1	
CT room*	1	
MRI room*	1	
Mammography room	1	
Ultrasound room	3	
Angiography room	1	
Dark room as appropriate	1	]
Quality control room	1	]

Staff and Patients toilets	4	
Patient dressing rooms	4	
Waiting area	1	
Recording and reporting room	1	
Doctors rooms	1	
Duty room	2	
Store room	1	
Conference and data room	1	
Staff room	1	
Film library/Archive	1	

<sup>\*</sup> The hospital may have either of CT or MRI or can have both.

### 6.25.3 Professionals

- 6.25.3.1 The radiology service of the hospital shall be directed by licensed radiologists.
- 6.25.3.2 A radiologist shall be available in the hospital during working hours all the time and shall arrive within 30 minutes of being summoned after working hours.
- 6.25.3.3 A licensed radiology technologist or radiographer shall be present in the hospital at all times.
- 6.25.3.4 A licensed interventional radiologist shall be available preferably all the times and is responsible to conduct interventional procedures like angiography, vascular catheterization, stent placement, image guided biopsy and fluid drainage.
- 6.25.3.5 A licensed radiology technologist shall participate in digital x-ray taking, assisting the radiologist during special procedures and compiling and reporting departmental activities.
- 6.25.3.6 A licensed professional nurse shall be available in the radiology service to administer medications and perform other nursing duties.
- 6.25.3.7 Equipment maintenance engineer as part time shall be available to ensure the proper functioning of all diagnostic radiology equipment.

professionals:  (f) Radiologist, (g) Interventional (k) Receptionist, radiologist, (l) Porter, (h) Radiologic technologist, (i) Biomedical Engineer, (pulled),  6.25.4 Products  6.25.4 Products  6.25.4 Products  6.25.4 Color duplex k) Video recorder ultrasound machines. (b) Echocardiography m) Refrigerator with ultrasound machine thermometer with cardiac probe. (c) Digital X-ray machines. (d) Combined x-ray o) Emergency medicines machine (x-ray with fluoroscopy) (e) Mobile X-Ray machine (f) CT machine (g) MRI machine (High typewriter Tesla) (h) Mammography as appropriate (h) Mammography as appropriate (i) Ctimic marker	6.25.3.8
(g) Interventional (k) Receptionist, radiologist, (l) Porter,  (h) Radiologic technologist, (i) Biomedical Engineer, (pulled),  6.25.4 Products  6.25.4.1 The hospital shall have the following radiological equipments: a) Color duplex k) Video recorder ultrasound machines. l) Viewing boxes b) Echocardiography m) Refrigerator with ultrasound machine thermometer with cardiac probe. n) Resuscitation c) Digital X-ray machines. equipments d) Combined x-ray o) Emergency medicines machine (x-ray with / supplies fluoroscopy) p) Procedure sets e) Mobile X-Ray machine q) Telephone service f) CT machine p) Procedure sets e) Mobile X-Ray machine q) Telephone service f) CT machine p) Pocedure sets e) MRI machine (High typewriter Tesla) s) Dark room accessories as appropriate h) Mammography as appropriate machine t) Actinic marker	
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machine t) Actinic marker	
,	
i) Manual & digital	
processor	
j) Quality controls kit	
6.25.4.2 At least the following radiation protection equipments shall be available in	6.25.4.2
radiology services:	
a) lead gloves e) Dosimeter/TLD for	
b) lead apron each radiology	
c) Gonad shield professional, d) lead eye-glass/goggle	

6.25.4.3 Safety procedures during practices and disposal of unfit for use equipments shall be installed as per the requirements set by the Ethiopian Radiation Protection Authority and this standard.

## 6.26 Pathology Services

### 6.26.1 Practices

- 6.26.1.1 There shall be written procedures and protocols for pathology service.
- 6.26.1.2 The pathology service shall be available during working hours.
- 6.26.1.3 In the absence of a pathologist there shall be an established procedure for sending to a pathologist outside the hospital all tissues requiring examination.
- 6.26.1.4 All tissues removed during surgery and sent to pathology unit shall be subjected to examination by the pathologist macroscopically, and/or microscopically.
- 6.26.1.5 A list of tissues which routinely require microscopic examination shall be developed in writing by the pathologist or designated physician with the approval of the medical staff All pathology result reports shall be signed by the pathologist
- 6.26.1.6 All Pathological examination results shall be signed by the pathologist.
- 6.26.1.7 Signed reports of tissue examinations shall be filed within the patient's medical record and duplicate copies kept in the pathology service unit.
- 6.26.1.8 A tissue file paraffin blocks and slides shall be maintained in the hospital.
- 6.26.1.9 There shall be a Quality Assurance and Quality control (QA & QC) mechanism for Pathology services.

### 6.26.2 Premises

- 6.26.2.1 The hospital shall have an organized separate pathology service area including
  - (a) Surgical Pathology unit:
    - Reception & Recording room
    - Gross room
    - Tissue processing room
    - Special stain room
  - (b) Histochemistry Unit:
    - Immunostaining room
    - Microscope reading room
    - Store with two shelves (Chemical & Reagent)
  - (c) Cytology Examination Unit:

- · Reception room
- Waiting room
- Procedure room
- Superficial organ aspiration room
- Aspiration of internal organs room
- (d) Autopsy Unit shall be together with morgue with the following requirements:
  - Procedure room
  - Dressing room with locker, toilet and shower
  - Reception & Record room,
  - post mortem technician/assistant room
- (e) Frozen section room near the Operation Theatre (Optional)
- (f) Forensic Autopsy: (Optional)
- 6.26.2.2 In addition, the pathology service shall have the following rooms for:
  - (a) Pathologists office,
  - (b) Photography room,
  - (c) Staff room(s) with lockers,
  - (d) Store room for Chemical Reagents and Paraffin blocks,
  - (e) Toilet rooms for staff and patients (Male and Female)

### 6.26.3 Professionals

- 6.26.3.1 The pathology services shall be directed by a licensed pathologist.
- 6.26.3.2 All tissues removed from patients during surgery shall be macroscopically, and if necessary, microscopically examined by the pathologist.
- 6.26.3.3 A list of tissues which routinely require microscopic examination shall be developed in writing by the pathologist or designated physician.
- 6.26.3.4 The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis).
- 6.26.3.5 The pathology service shall have the following staffing: (m)Pathologists,
  - (n) Laboratory technologist or technician with training in tissue processing,
  - (o) Autopsy assistants,
  - (p) Post mortem technicians/assistants,

- (q) Receptionist,
- (r) Cleaner,

### 6.26.4 Products

- 6.26.4.1 The pathology service shall have the following equipments for Autopsy service:
  - (a) Procedure Room:
    - body table with cold and warm water sinks
    - Display table with glass curtail
    - Cupboard for instruments
    - Refrigerator
    - Scale
    - Pedaled tape recorder
    - Video camera with screen/Camera with stand
  - (b) Dressing Room with documentation facility:
    - Lockers
    - Reading table with two chairs
    - Book shelves
    - Computer
  - (c) Reception and Record Room:
    - Shelf with locker
    - File cabinet
    - A table with two chairs
    - Computer
  - (d) Postmortem Technician/Assistant Room:
    - Personal locker
    - A table with two chairs
- 6.26.4.2 The pathology service shall have the following equipments for Surgical Pathology Unit:
  - (a) Reception and Record Room (can be shared with gross room):
    - Lab. table or counter
    - Computer
    - Shelf

## (b) Gross Room:

- One dissection table with cold and warm water
- one dissect table cutting board placed in metal box and ready access to a sink with cold and warm water
- One wheeled chair
- Pedaled recording tape
- · Camera with stand
- Lidded garbage container
- Tissue shelf store
- X-ray
- Electric skull saw
- Box for instruments
  - o Heavy & small scissors
  - o Different size smooth & toothed forceps
  - o Malleable probe
  - o Scalpel handle
  - o Disposable bladders
  - o King knife
  - o Pins for attaching specimen to a cork surface.
- (c) Tissue Processing Room:
  - Two embedding system lab tables
  - Tissue processor –vacuum processor and Rotary processor
  - Dry air oven
  - Refrigerator large & small
  - Freezer
  - Balancer weighing scale
  - Microtome
  - Box with cassettes and labels
  - A large formalin container
  - Water bath
  - HE staining table
  - Fume extractor
  - Knife sharpener
  - Large sink for dissection of wage specimens

- Central table for multiple use
- Ruler
- (d) Special stain rooms with fume extractor
- (e) Histochemistry Room:
  - Lab table
  - Rotary chair
  - Refrigerator
  - Microtones
  - Water bath
  - PH meter
  - Staining bench
- (f) Immunostaining Room:
  - Refrigerator
  - Microtones
  - Water bath
  - PH meter
  - Staining bench
- (g) Microscopy Reading Room:
  - Multiple headed microscopes >6 heads at a time
  - Laboratory stools
- (h) Chemical Reagent Store:
  - Shelves
  - Lab. Table two rotary chairs
  - Fume extractor
- 6.26.4.3 The pathology service shall have the following equipments for Cytology

Examination unit:

- (a) Procedure Room:
  - Coach table
  - Office table
  - Reading table
  - Mobile illumination
  - Rotary chair
  - Locker

- 6.26.4.4 The pathology service shall have the following equipments for Office Facilities
  - (a) Service head/ Pathologist office
    - Office tables arranged in T-pattern
    - Book shelf
    - File cabinet
    - Bi-headed microscope
    - Swivel chair
    - Normal chair
    - Computer
  - (b) Secretary office
  - (c) Photography room
    - Bi-headed microscope fitted to video camera
    - Camera (normal and video)
    - Chair
    - Computer
    - Video
    - TV
  - (d) Laboratory Technicians room:
    - Microscope
    - Office table
    - Chair
    - Computer
    - File cabinet
    - Meeting room

# 6.27 Medical Laboratory Services

#### 6.27.1 Practices

- 6.27.1.1 The laboratory shall have written policies and procedures and include at least the followings:
  - a) Procedure manuals (Standard Operating Procedure, SOP) or guidelines for all tests and equipment
  - b) Report times for results (Established turn around time)
  - c) Quality assurance and control processes
  - d) Inspection, maintenance, calibration, and testing of all equipment
  - e) Management of reagents, including availability, storage, and testing for accuracy
  - f) Procedures for collecting, identifying, processing, and disposing of specimens
  - g) All normal ranges for all tests shall be stated
  - h) Laboratory safety program, including infection control
  - i) There shall be documentation of quality control data (internal and external quality control), calibration report, refrigerator readings and so on.
- 6.27.1.2 The hospital shall have policies and procedures for the availability of paper based or electronic laboratory information management system (LIMS). The data management system shall include the followings:
  - a) Periodic reporting(monthly, quarterly)
  - b) Preliminary analysis and utilization of results
  - c) Collection of useful and appropriate information
  - d) Archiving and retrieval
- 6.27.1.3 The hospital shall have standardized data collection instruments and including at least the followings:

- a) Laboratory request forms
- b) Laboratory report forms
- c) Laboratory specimen and results registers
- d) Quarterly/monthly reporting forms including
  - · Summary of tests conducted
  - Summary of tests referred
  - Summary of quality assurance report
- e) Equipment and supplies inventory registers
- f) Quality assurance record forms
- g) Referral forms
- 6.27.1.4 The hospital shall develop monitoring and evaluation tools to assess activities including:
  - a) adherence to SOPs
  - b) adherence to safety guidelines
  - c) QA activities
  - d) Laboratory performance and workload
  - e) Laboratory services
- 6.27.1.5 The hospital shall have policies and procedures for the availability of laboratory services including the emergency services for 24 hours a day and seven days a week, including holidays.
- 6.27.1.6 The laboratory shall have procedures or (SOP) for proper specimen collection that address specific collection requirements such as:
  - a) Preferred sample type (venous, arterial, capillary, urine, spinal fluid)
  - b) Type of anticoagulant
  - c) Sample volume considered acceptable
  - d) Patient identification

- e) Requirements for patient preparation and storage of specimens.
- 6.27.1.7 Policies and procedures shall be documented and communicated to concerned personnel.
- 6.27.1.8 The laboratory shall have a policy for making amendments and corrections to laboratory procedures and all amended laboratory procedures shall be reviewed and approved for use.
- 6.27.1.9 Test procedures developed by the laboratory (in-house procedures) must be validated and fully documented before being put into use. All procedures shall be in a language commonly understood by laboratory staff.
- 6.27.1.10 The laboratory shall follow standard operating procedures (SOP) and conduct routine quality assessments to ensure reliable and cost-effective testing of patient specimens.
- 6.27.1.11 Laboratory management shall review all operational procedures at regular intervals. The frequency should be every four month (at least annually).
- 6.27.1.12 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.
- 6.27.1.13 Laboratory staff shall test quality control materials every eight hour and document in combinations suitable to detect analytical error.
- 6.27.1.14 The right patient with the right request form shall be identified during collection and delivery of result.
- 6.27.1.15 Requests for testing shall provide:
  - a) The name of the ordering physician or other person authorized to order testing
  - b) The clinician's working address
  - c) Type of primary sample collected
  - d) The anatomic site where appropriate
  - e) The test requested
  - f) Patient gender
  - g) Age

- h) Pertinent clinical information as appropriate for purposes of test interpretation (Clinical Diagnosis)
- i) Date and time of sample collection and receipt in the laboratory
- 6.27.1.16 There shall be SOP or criteria developed for acceptance or rejection of clinical samples.
- 6.27.1.17 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.
- 6.27.1.18 The laboratory shall maintain a record of all samples received.
- 6.27.1.19 Laboratory shall have a procedure for storage of clinical samples if it is not immediately examined.
- 6.27.1.20 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.
- 6.27.1.21 Once a sample is used, it shall be maintained in the laboratory for a specified period of time (or as required by regulation) and at a temperature that ensures stability of the sample in the event the sample is needed for retesting.
- 6.27.1.22 The hospital shall carry out clinical laboratory examinations including clinical chemistry, microbiology, hematology, coagulation, general immunology, serology, parasitology, urine and body fluid analysis, mycology and clinical microscopy
- 6.27.1.23 There shall be documentation of inspection and quality control of the tests done under the hospital.
- 6.27.1.24 Laboratory report
  - a) All laboratory test result/reports shall have reference (normal) ranges specific for age and gender.
  - b) Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained shall be 5 years for legal reason minimal errors or loss of patient test results.

- c) Reports shall be filed with the patient's medical record and duplicate copies shall be filed in the laboratory in a manner which permits ready identification and accessibility and with appropriate backup.
- d) In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be contained in the medical record.
- e) Quality assured test results shall be reported on standard forms to the physician 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 laboratory interpretation where appropriate,
  - 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.
  - Hospital address
- f) Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them such as the ordering physician or nursing staff in a hospital environment
- 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, correct billing or modify computer programs.
- 6.27.1.25 When reports altered, the record shall show the time, date and name of the person responsible for the change.
- 6.27.1.26 Safe disposal of samples shall be in line with standards prescribed under infection prevention
- 6.27.1.27 No eating, drinking, smoking or other application of cosmetics in laboratory work areas or in any area where workplace materials are handled.
- 6.27.1.28 No food and drink to be stored in the laboratory (may be stored in the rest area)

- 6.27.1.29 The medical laboratory shall have safety guideline. In addition, the laboratory shall protect the environment and public by assuring the health laboratory waste is disposed of legally and an environmentally friendly manner
- 6.27.1.30 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
- 6.27.1.31 At regular intervals, the laboratory shall review any contracts for services to its clients (including but not limited to clinicians, health care bodies, pharmaceutical companies, other departments such as pharmacy or nursing within the hospital structure) to ensure that the laboratory can meet the contractual requirements such as methodologies, turn-around times, availability of expert opinion, etc. Records of these reviews shall be kept and maintained by the laboratory, including deviations from contracts.
- 6.27.1.32 Where services are provided by an outside laboratory, the conditions, procedures, and availability of services offered shall be in writing and available in the hospital.
- 6.27.1.33 The laboratory shall meet regularly with clinical staff regarding services and clinical interpretations.
- 6.27.1.34 The laboratory must keep a record of the complaint. The record shall include the nature of the complaint, the date of occurrence, individuals involved, any investigations undertaken by the laboratory and resolution.

## 6.27.2 Laboratory Premises

- 6.27.2.1 The hospital shall have a well organized, adequately supervised and staffed clinical laboratory with the necessary space, facilities and equipment to perform those services commensurate with the hospital's needs for its patients.
- 6.27.2.2 The laboratory working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste material to ensure patient and staff protection from unnecessary risks at all time.
- 6.27.2.3 The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, and safety of personnel or patient care services.

- 6.27.2.4 The laboratory shall have adequate space and a safe environment to perform testing. It must provide adequate lighting, ventilation, water, waste and refuse disposal. Work areas shall be clean and well maintained. Precautions must be taken to prevent cross contamination.
- 6.27.2.5 The laboratory shall have controlled temperature of refrigerator for reagents, blood sample, calibrator, control materials which affect the analytical results.
- 6.27.2.6 Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.
- 6.27.2.7 The laboratory shall be located and designed to
  - provide suitable, direct access for patients
  - allow reception of deliveries of chemicals
  - allow safe disposal of laboratory materials and specimens.
- 6.27.2.8 Doors shall be located in places where entry and exit is easy and does not interfere with the laboratory benches or equipment. Laboratory doors shall not be less than 1 m wide to allow easy access of equipment. In some areas, double doors, 1.2 m wide, shall be provided for passage of large equipment, such as deep-freezes. All doors shall be opened towards the corridor.
- 6.27.2.9 There shall be effective separation between adjacent laboratory sections in which there are incompatible activities.
- 6.27.2.10 The laboratory of the hospital shall have the following premises setup
  - a) One main working room for recording and reporting
  - b) Specimen collection room
  - c) Medical Microbiology room
  - d) Serology room
  - e) Parasitology and urine analysis room
  - f) Viral load rooms
  - g) Hematology room
  - h) Clinical chemistry room
  - i) Sterilization, disinfection and media preparation room
  - j) Store-room
  - k) Staff room and office
  - 1) Separate Toilets for patients (2 for Male and 2 for female)
  - m) Separate Toilet for staff (Male and female)

- n) There shall be access to shower upon emergency
- 6.27.2.11 The laboratory facilities shall meet at least the following:
  - a) The laboratory shall have a reliable supply of running water. At least two sinks shall be provided in each room, one for general laboratory use and the other reserved for hand washing and shall have access to hospitals reserve tank whenever there is water interruption.
  - b) Continuous power supply
  - c) Working surface covered with appropriate materials
  - d) Suitable stools for the benches. Bench tops shall be impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.
  - e) Internal surfaces, i.e. of floors, walls, and ceilings shall be:
    - Smooth, impervious, free from cracks, cavities, recesses, projecting ledges and other features that could harbor dust or spillage
    - Easy to clean and decontaminate effectively
    - Constructed of materials that are non-combustible or have high fire-resistance and low flame-spread characteristics
  - f) Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
  - g) Lockable doors and cupboards
  - h) Closed drainage from laboratory sinks to a septic tank
  - i) Facilities for disposal of contaminated materials and solid waste
  - j) Separate toilets/latrines for staff and patients
  - k) 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
  - l) Telephone or radio communication.

#### 6.27.3 Laboratory Professionals

6.27.3.1 All laboratory services shall be directed by a licensed medical laboratory technologist.

- 6.27.3.2 Medical Laboratory staff shall be present at the hospital to provide laboratory service at all times.
- 6.27.3.3 Students and other staff on attachment shall work under the direct supervision of a licensed medical laboratory technologist.
- 6.27.3.4 The Laboratory service shall have and maintain job descriptions, including qualifications to perform specific functions.
- 6.27.3.5 The Laboratory management shall provide adequate training, continuing education or access to training for technical staff, and assess staff competency at regular intervals.
- 6.27.3.6 Laboratory staff shall, at all times, perform their functions with adherence to the highest ethical and professional standards of the laboratory profession.
- 6.27.3.7 The laboratory of this hospital shall have the following minimum staffing requirements.
  - a) One professional with masters of degree in any of the clinical laboratory science specialties (Hematology , clinical chemistry, laboratory management and Medical microbiology)
  - b) Two Medical Laboratory Technologists (BSc) for hematology
  - c) One Medical Laboratory Technologists (BSc) for clinical chemistry
  - d) Four Medical Laboratory Technologists (BSc) for parasitology, serology and urinalysis
  - e) One Medical Laboratory Technologists (BSc) for virology
  - f) Two Medical Laboratory Technologists (BSc) for microbiology and mycology
  - g) One Medical Laboratory Technologist (BSc) for QC/QA
  - h) Supportive staff (clerks, cleaners, trained sample collectors)
- 6.27.3.8 In addition to the above mentioned professionals, the hospital may have additional laboratory technicians.

#### 6.27.4 Products

6.27.4.1 Laboratory shall be furnished with all items of equipment required for the provision of services.

- 6.27.4.2 All equipment shall be in good working order, routinely quality controlled, and precise in terms of calibration.
- 6.27.4.3 Laboratory shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It shall also have a document.
- 6.27.4.4 When equipment is removed from the direct control of the laboratory or is repaired or serviced, the laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.
- 6.27.4.5 Laboratory shall have a documented and recorded programme of preventive maintenance which at a minimum follows the manufacturer's recommendation.
- 6.27.4.6 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.
- 6.27.4.7 There shall be a written chemical hygiene plan that defines the safety procedures to be followed for all hazardous chemicals used in the laboratory. The plan defines at least the following:
  - a) The storage requirements
  - b) Handling procedures
  - c) Requirements for personal protective equipment
  - d) Procedures following accidental contact or overexposure
  - e) The plan is reviewed annually, and updated if needed, and is part of new employee orientation and the continuing education program.
- 6.27.4.8 The following minimum equipments and consumables shall be required

Tests	Major Equipment
Clinical chemistry:	> Autoclave
Blood glucose	➤ Timer
Lipid profile	<ul><li>Clinical chemistry analyzer (Automated)</li></ul>
<ul> <li>Cholesterol</li> </ul>	Chemistry analyzer (semi automated)
<ul> <li>Triglyceride</li> </ul>	> Glucometer
o LDL	PC and a printer
o HDL	Bunsen burner
Serum electrolytes	Power surge protectors
o Na+,K+,Cl-	Weighing balance
<ul> <li>Liver function tests</li> </ul>	Spectrophotometer/ Colorimeter
$\circ$ ALKP, AST, ALT, $\delta$ GT	Micropipettes of different :
o Total bilirubine	> Hemacytometers
<ul> <li>Direct bilirubine</li> </ul>	Hemacytometer cover slips
o Total protein	(standardized thickness)
<ul> <li>Albumin</li> </ul>	Microcapillary tubes (if dilutions are not
<ul> <li>Renal function tests</li> </ul>	needed)
o Urea	> WBC pipette
<ul> <li>Creatinine</li> </ul>	> RBC pipette
o Uric acid	Pipette bulb Petri dish and cover
<ul> <li>Cardiac function tests</li> </ul>	➤ Timer with alarm
o LDH	Hormonal assay analyzer
o CK-MB	
<ul> <li>Troponine</li> </ul>	
o СРК	
<ul> <li>Hormonal tests</li> </ul>	
o T3, T4, TSH, FSH, LH	
<ul> <li>Testosterone</li> </ul>	
<ul> <li>Prolactine</li> </ul>	

Parasitology:	
<ul> <li>Stool microscopy</li> </ul>	
<ul> <li>Blood film for malaria and other</li> </ul>	
hemoparasite/ Malaria Rapid Test	
Occult blood	
Urine and body fluid analysis:	
<ul> <li>Urinalysis</li> </ul>	
CSF analysis	
Mycology:	
KOH test	
Fungal culture	
Microbiology Smear and Culture	

# Hematology:

- Haemoglobin
- Total WBC count
- Differential white cell count
- Peripheral blood film
- ESR
- Hematocrit
- Platelet count
- Bleeding time
- Reticulocyte count
- prothrombin time
- Hb electrophoresis
- Lupus Erythematosus

## Serology:

- H.Pylori
- Troponin
- HBs Ag
- HCV
- Toxoplasma latex
- ASO
- RF
- CD4 count
- RPR
- TPHA
- CRP
- Salmonella Typhi-O
- Salmonella Typhi-H
- Proteus-OX<sub>19</sub>
- HIV-test
- Viral load
- Blood Group (Anti-A, Anti-B, Anti-D, Compatibility testing and Cross match)

### **Bacteriology:**

- Gram stain
- Ziehl Neelson stain
- India Ink,
- Culture and sensitivity test

- > Haemoglobinometer
- ➤ Automated Hematology analyzer
- Blood roller/mixer
- Water bath
- Coagulometer
- Refrigerator
- ➤ Electrophoresis machine
- ➤ Binocular microscope x10, x40, x100
- > Haemocytometer
- Microhematocrit centrifuge
- Microhematocrit reader
- Differential counter
- > Tally counter
- Deep freezer
- Centrifuge
- > Timer
- Vortex mixer
- Distillation unit
- ➤ CD4 machine
- Viral load machine
- Autoclave
- Dry oven
- Safety cabinet
- Refrigerator
- Deepfrezer
- Waterbath
- Incubator
- > PH meter
- Digital balance
- Microscope
- And other major culture and sensitivity equipments

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#### 6.28 Pharmaceutical Services

#### 6.28.1 Practices

### **Dispensing and Medication Use Counseling:**

- 6.28.1.1 Standard operating procedure for dispensing and medication use counseling shall be established to ensure patients' safety and correct use of medications.
- 6.28.1.2 Dispensers shall make sure that prescriptions are legible, written by authorized prescriber and complete. Prescription papers shall be standardized and must contain at least the following information and the prescriber and dispensers shall complete all these information:
  - (a) Name of patient, sex, age, weight and card number
  - (b) Diagnosis and allergy
  - (c) Name of the medicine, strength, dosage form, dose, frequency, and route of administration
  - (d) Duration of treatment
  - (e) Prescriber's name, qualification, license number and signature
  - (f) Dispenser's name, qualification, license number and signature
  - (g) Hospital name and address
- 6.28.1.3 The pharmacist shall check the correctness of prescriptions in terms of appropriateness for the patient, dosage, and medicine interactions based on approved standard treatment guidelines before use.
- 6.28.1.4 All medicines shall be dispensed with adequate and appropriate information and counseling to patients for correct use of their medications.
- 6.28.1.5 Pharmacists shall be required to 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.
- 6.28.1.6 The containers used for dispensing shall be appropriate for the product dispensed and all containers intended for medicines shall be protected and kept free from contamination, moisture and light.
- 6.28.1.7 All medicines 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 medicine;
- (b) The name of each active ingredient for compounded preparations;
- (c) The strength, dose, frequency of administration and total quantity;
- (d) The name of the person for whom the medicines are dispensed;
- (e) The directions for use and route of administration tailored to patient or caregiver literacy and language;
- (f) The name and business address of the dispenser;
- (g) Date of dispensing;
- (h) Expiry date or beyond use date and
- (i) Special precautions as applicable
- 6.28.1.8 Filled prescriptions shall be signed and accountability must be accepted by the dispensing pharmacist.
- 6.28.1.9 Each hospital 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.
- 6.28.1.10 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.
- 6.28.1.11 The counseling of patients or their caregivers shall be undertaken to promote the correct and safe use of medicines. The responsible pharmacist must ensure that patients are counseled before they receive medicines that they are to self-administer.
- 6.28.1.12 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.
- 6.28.1.13 Cautionary instructions and ancillary information about medications shall be communicated in writing to the personnel responsible for administering medications.

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

- 6.28.1.14 The specialized hospital 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.
- 6.28.1.15 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.
- 6.28.1.16 All controlled substances (narcotic and psychotropic drugs) shall be dispensed to the authorized health professional designated to handle controlled substances by a licensed pharmacist in the hospital. 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 authorized health professional 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.
- 6.28.1.17 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.
- 6.28.1.18 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, if any
- (f) The balance of controlled substances remaining after the administration of any quantity of the controlled substance
- (g) Day-ending or shift-evening verification of count of balances of controlled substances remaining and controlling substances administered shall be accomplished by two (2) designated licensed persons whose signatures shall be affixed to a permanent record.
- 6.28.1.19 All partially used quantities of controlled substances shall be recorded in to the control substance record and returned back to the responsible pharmacist for control substances for disposal.
- 6.28.1.20 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.
- 6.28.1.21 Any return of controlled substances to the pharmacy in the hospital shall be documented by a licensed pharmacist responsible for controlled substance handing in the hospital.
- 6.28.1.22 The hospital shall implement procedures whereby, on a periodic basis, a licensed pharmacist shall reconcile quantities of controlled substances dispensed in the hospital against the controlled substance record. Any discrepancies shall be reported to the Director of the respective medical services and to the Chief Clinical Officer/Chief Executive Officer of the hospital. Upon completion, all controlled substance records shall be returned to the hospital's pharmacy by the designated responsible person.
- 6.28.1.23 The hospital shall submit regular report to the appropriate organ regarding the consumption and stock of controlled drugs.

#### **Hospital Based Medicine Preparations:**

6.28.1.24 Written procedures/SOPs for hospital based medicine preparations shall be established for preventing errors, medicine-medicine interactions and medicine 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.
- 6.28.1.25 Licensed pharmacists shall be responsible for the preparations of various medicine formulations such as eye drop preparations, dosage form changes, extemporaneous preparations, IV infusions and IV admixture when deemed necessary by the hospital.
- 6.28.1.26 The hospital 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.
- 6.28.1.27 The pharmacist responsible for medicine preparations shall ensure that quality is built into the preparations of products.
- 6.28.1.28 Ingredients used in preparations shall have their expected identity, quality, and purity, and shall be from legally licensed sources.
- 6.28.1.29 Medicine preparations shall be of acceptable strength, quality, and purity, with appropriate packaging and labeling, and prepared in accordance with good compounding practices, official 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

- 6.28.1.30 Critical processes shall be validated to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
- 6.28.1.31 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.
- 6.28.1.32 Written procedures and records shall exist for investigating and correcting failures or problems in compounding, testing, or in the preparation itself.
- 6.28.1.33 Medicine preparations compounded in the hospital shall be packaged in containers meeting standard requirements mentioned under the official national or international standards for such preparations.

# **Clinical Pharmacy Services:**

- 6.28.1.34 The hospital through drug and therapeutic committee shall establish policies and procedures for the provision of clinical pharmacy services
- 6.28.1.35 Depending on the number of beds available and convenience for service delivery, the hospital shall have inpatient pharmacy or ward pharmacies each managed by a licensed clinical pharmacist or a licensed pharmacist trained on clinical pharmacy practice.
- 6.28.1.36 The responsible pharmacist for clinical pharmacy services shall have access to patient specific medication therapy information
- 6.28.1.37 Patient-specific medication therapy information must be evaluated and a medicine therapy plan shall be developed by the pharmacist mutually with the patient, the prescriber and nurse.
- 6.28.1.38 The pharmacist shall review, monitor and propose for modification of the therapeutic plan in case of adverse effects, patient noncompliance, evidence-based efficacy problem and as appropriate, in consultation with the patient, prescriber and nurse.
- 6.28.1.39 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 medicines
- 6.28.1.40 The processes of prescribing, dispensing and administering medicines are inherently risk-laden and hence the clinical pharmacy services shall take

- responsibility for ensuring safe, appropriate and effective use of medicines (minimizing risk) at all stages of the patient medication journey.
- 6.28.1.41 Medication education shall be delivered to patients or their caregivers upon discharge by the clinical pharmacist.
- 6.28.1.42 The pharmacist shall make sure that the patient has all supplies, information and knowledge necessary to carry out the medicine therapy plan.
- 6.28.1.43 As a member of the health care team, the pharmacist shall attend and participate at multidisciplinary ward rounds/morning meetings and contribute to patient care through the provision of medicine information, dose calculations and adjustment, assisting in the rational prescribing decision, alternative regimens and reducing the frequency and duration of medication errors.
- 6.28.1.44 The drug and therapeutic committee of the hospital shall develop/adopt and implement antimicrobial prescribing, dispensing and usage policy

# **Emergency Pharmacy Services:**

- 6.28.1.45 Emergency pharmacy service shall be opened for 24 hours and directed by a licensed pharmacist who is accountable to the emergency unit of the hospital.
- 6.28.1.46 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.
- 6.28.1.47 The responsible pharmacist shall take the duty to coordinate and prepare emergency medicines lists and ambulance kits for the hospital and he/she has to exert all the necessary efforts to ensure continuous availability of medicines for emergency unit and hospital ambulances.
- 6.28.1.48 The emergency pharmacy, in addition to supply of medicines, shall record patient medication information and ensure correct use of medications.

#### Adverse Drug Event, ADE/ Pharmacovigilance:

- 6.28.1.49 The specialized hospital pharmacy 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 then finally to FMHACA.
- 6.28.1.50 Health professionals of the hospital shall be responsible to report suspected ADE cases to the ADE focal person.
- 6.28.1.51 DTC shall discuss and make necessary recommendations to the hospital management for decision on adverse drug event reported within the health facility.
- 6.28.1.52 The specialized hospital pharmacy 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.
- 6.28.1.53 Adverse medication effects shall be noted in the patient's medication record
- 6.28.1.54 All the ADE reports, patient identity, reporters and medicine trade names shall be kept confidential until verified by concerned authority.
- 6.28.1.55 The reporting of ADE shall be done by the national ADE prepaid yellow form prepared by FMHACA.

# **Medicine Supply and Management:**

- 6.28.1.56 A drug and therapeutics committee (DTC) representing different service units of the hospital shall be in place for selection of medicines and other medical items and developing the formulary list as well as policies and guidelines on managing medicines based on the national medicine lists.
- 6.28.1.57 The purchase of medicines shall be the responsibility of a pharmacist who is assigned to manage and control the hospital central medical store.
- 6.28.1.58 The specialized hospital shall have written policies for the procurement of medicines from government and private suppliers shall be available in the pharmacy. These policies shall be prepared by the DTC and approved by the management/board of the hospital. The procurement policy must ensure at least:
  - (a) The right source of medicines
  - (b) Medicines availability
  - (c) Safety, quality and efficacy of medicines

- (d) Transparency of the procedure and documentation
- (e) Minimal decision points
- (f) Flexibility to respond for emergency situations
- (g) Compatibility with the state and national laws of the country
- (h) Effective batch recall of medicines when necessary
- 6.28.1.59 A pharmacist shall not purchase any medicinal product where he/she has any reason to doubt its safety, quality or efficacy.
- 6.28.1.60 The pharmacist shall ensure that both the supplier and the manufacturer of any medicine purchased are reputable and licensed by FMHACA.
- 6.28.1.61 The hospital central medical store shall be responsible to display or disseminate new arrivals or alternative medicines to each service delivery points.
- 6.28.1.62 The hospital shall be responsible to make sure that medicines promotion made by suppliers or manufacturers in the hospital premises is made by a licensed pharmacist in accordance with the country's laws.
- 6.28.1.63 The hospital shall be responsible to make sure that donation of medicines has been made in accordance with the relevant medicine related laws.
- 6.28.1.64 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
- 6.28.1.65 The storage condition shall provide adequate protection to the medicines from all environmental factors until the medicine is delivered to the patient.
- 6.28.1.66 The responsible pharmacist must ensure that all areas where medicines are stored are of acceptable standards (palletized or shelved, ventilated, easy for free movement, rodent free, temperature and moisture controlled and others) for a medicine store.
- 6.28.1.67 The responsible pharmacist shall ensure that all medicine storage areas are inspected regularly to ensure that:
  - (a) Medicines are stored and handled in accordance with the medicines manufacturer's requirements and this standard
  - (b) Expired or obsolete medicines are stocked separately until disposition

- (c) Medicines requiring special storage 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 medicine at all times, including the availability of essential medicines.
- (f) Inflammable substance are stored separately and in an appropriate manner
- (g) Disinfectants and preparations for external use are stored separately from medicines for internal use
- 6.28.1.68 Special storage conditions shall be maintained for medicines requiring cold chain system, controlled substances, radiopharmaceuticals and medical gases.
- 6.28.1.69 Firefighting equipment or system shall be installed to medicine storage places
- 6.28.1.70 Distribution of medicines within a hospital 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 youchers.
- 6.28.1.71 There shall be written SOPs on how supplies of stock are to be obtained from the medical store. Procedures must define normal action to be taken by pharmacy staff for routine stock replacement and action to be taken in the case of incomplete documentation or other queries.
- 6.28.1.72 Written procedures shall be available for the return of expired, damaged, leftover and empty packs from outlets to medical store to prevent potential misuse.
- 6.28.1.73 The hospital shall maintain stock control system (manual and/or computerized system) in the central medical store and dispensaries.
- 6.28.1.74 The responsible pharmacist shall ensure that adequate control procedures are in place for all stock circulating at all outlets within the hospital.
- 6.28.1.75 Daily medicine consumption at different outlets of the hospital shall be recorded, compiled and analyzed for the appropriate supply and use of medicines.
- 6.28.1.76 The hospital pharmacist who is responsible for the management of medicines should conduct regular medicine use studies to ensure maximum patient benefit.

- 6.28.1.77 The specialized hospital shall make every attempt to minimize the amount of medicines waste generated in the hospital.
- 6.28.1.78 The DTC should be responsible for developing policies and guidelines on how to organize and conduct medicines use studies.

## **Medicines/Drug Information Services:**

- 6.28.1.79 The hospital shall establish a medicine information center which provides medicine information services and shall be directed by a licensed pharmacist trained in the provision of medicine information services.
- 6.28.1.80 The medicine information pharmacist shall be member of the hospital DTC
- 6.28.1.81 The medicine information service shall be part and parcel of the day-to-day activities of a hospital and shall provide relevant and unbiased information to health care professionals and the public. It shall receive and respond to medicine information queries as per written SOPs and provide continuing education on medicine-related topics to health professionals.
- 6.28.1.82 Provision of medicines information services to patients and community shall be in accordance with the standard operating procedures that will be developed by the Authority and adopted by the hospital. Procedures shall include:
  - (a) Details of standards of practice;
  - (b) Range of services provided;
  - (c) Availability of service;
  - (d) Procedures for enquiry receipt and retrieval of data;
  - (e) Details of available resources;
  - (f) Quality assurance practices;
  - (g) Job descriptions for all staff and local practices including site-specific regulations or procedures.
- 6.28.1.83 The medicine information center shall provide reference materials such as medical and medicine related books, journals, medicine profiles, electronic information, CD-ROM, relevant formularies and manufacturers' information and updated list of medicines available in the hospital central medical store to health care professionals
- 6.28.1.84 The service shall be available at least during normal working hours.

## **Medicine Waste Management and Disposal:**

- 6.28.1.85 The disposal of medicine wastes shall be in compliance with the medicines waste management and disposal directives issued by FMHACA.
- 6.28.1.86 Hospital pharmacy shall take responsibility, through supportive policies and procedures for the environmental and societal safety by efficiently managing the medicine wastes.
- 6.28.1.87 All personnels involved in medicines waste handling shall be trained and/or well informed about the potential risks of hazardous medicines waste and their management.
- 6.28.1.88 All personnels involved in medicines waste handling shall wear protective devices like apron, plastic shoes, gloves, head gears and eye glasses when appropriate
- 6.28.1.89 General wastes shall be collected daily from the pharmacy and placed in a convenient place outside the pharmacy to facilitate coordinated disposal by the hospital.
- 6.28.1.90 Solid wastes from the pharmacy shall be categorized as "hazardous" and 'non-hazardous" and shall be collected separately for proper treatment.
- 6.28.1.91 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.
- 6.28.1.92 Spillages of low toxicity shall be swept into a dust pan and placed into a suitable container for that particular chemical and dispose accordingly.
- 6.28.1.93 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 returned to the pharmacy for disposal.
- 6.28.1.94 The hospital shall form a medicines disposal committee to ensure safety, accountability and transparency.
- 6.28.1.95 Disposal of medicines waste shall be supported by proper documentation including the price of the products for audit, regulatory or other legal requirements.

6.28.1.96 Those items which can't be disposed by the capacity of the hospital shall be managed by one central body (e.g. radiopharmaceuticals)

### **Recording:**

- 6.28.1.97 Each hospital shall maintain records to assure that patients receive the medications prescribed by a prescriber and maintain records to protect medications against theft and loss.
- 6.28.1.98 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.
- 6.28.1.99 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.
- 6.28.1.100 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.
- 6.28.1.101 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
- 6.28.1.102 Every transaction related with medicines should be recorded on stock control cards and/or computerized stock control system in the medical store and dispensaries.

## Billing:

- 6.28.1.103 Medicines shall be received and issued using standard receiving and issuing vouchers with serial number licensed by the appropriate finance bureau of the government. Issuing and receiving of medicines 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 prices
- (e) Date received and issued
- (f) Name and signature of receiver and issuer
- (g) Address of the hospital
- 6.28.1.104 All medicines issued from the dispensary shall be dispensed/sold using standard sales ticket with serial number licensed by the appropriate finance bureau. Sales tickets have to be signed and stamped.
- 6.28.1.105 Dispensing pharmacies shall use a standard stamp and seal for approving legal transactions
- 6.28.1.106 Writing one bill for two clients shall be forbidden
- 6.28.1.107 The consumer has the right to know the exact price of a prescription before it is filled
- 6.28.1.108 The hospital 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 prices
  - (e) Date
  - (f) Signature of dispenser and cashier
  - (g) Address of the hospital

## **Organization Management and Quality Improvement:**

- 6.28.1.109 A multidisciplinary drug and therapeutic committee chaired by the CCO and supported by a licensed pharmacist representing the hospital pharmacy services as a secretary must be functional for the overall improvement of pharmaceutical services in the hospital
- 6.28.1.110 The pharmaceutical services shall be represented by a licensed senior pharmacist in every management meetings of the hospital.
- 6.28.1.111 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.

- 6.28.1.112 There shall be a program of continuous quality improvement for the pharmaceutical service that is integrated into the hospital 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.
- 6.28.1.113 The pharmaceutical service shall have in effect a patient profile system for monitoring medicine therapy. This system shall be used by the hospital to identify inappropriate prescribing practices and develop interventions.
- 6.28.1.114 The medicines supply and management officer shall inspect all patient care areas in the hospital, 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.
- 6.28.1.115 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.

#### 6.28.2 Premises

- 6.28.2.1 The design and layout of the pharmacy shall permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimize the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of medicines and service delivery.
- 6.28.2.2 The area(s) of counseling shall be arranged or constructed in such a manner that it provides adequate space, have professional look and ensure reasonable privacy to the patient at all times and eliminate background noise as much as possible.
- 6.28.2.3 Dispensing counter shall be designed to secure patient privacy and confidentiality
- 6.28.2.4 All parts of the premises shall be maintained in an orderly and tidy condition.

- 6.28.2.5 The external appearance of pharmacies shall be painted white and inspire confidence in the nature of the health care service that is provided and portray a professional image.
- 6.28.2.6 Entrances, dispensing counters and doorways shall be accessible to persons with disability.
- 6.28.2.7 The dispensing environment (dispensing counter and counseling area) shall ensure confidentiality and allow simultaneous service delivery for multiple customers by multiple providers.
- 6.28.2.8 A waiting area(s), which is under cover, shall be situated near the dispensing area, areas for counseling/consultation and the provision of information.
- 6.28.2.9 The pharmacy premises shall be clearly demarcated and identified from the premises of any other business or practice. The location of the pharmacy premises shall take into account patient convenience and ease of loading and unloading of medicines.
- 6.28.2.10 Careful consideration shall be given to the overall security of the pharmacy. It must be lockable and shall prevent any unauthorized entry.
- 6.28.2.11 A security policy shall be implemented which is designed to ensure the safety of both staff and medicines, and shall take account of local crime prevention advice.
- 6.28.2.12 The responsible pharmacist of a pharmacy shall ensure that every key which allows access to a pharmacy is kept only with him/her or the designated personnel.
- 6.28.2.13 A procedure shall be in place to ensure access to pharmacy premises in an emergency situation.
- 6.28.2.14 Compounding premise shall be maintained adequate, clean and ventilated.
- 6.28.2.15 Ceilings and walls of dispensaries and store shall be constructed to protect safety of medicines from burglary, rodents, direct sunlight, moisture and damages.
- 6.28.2.16 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.

- 6.28.2.17 The pharmacy premises shall have the following minimum space at different service delivery points.
  - (a) Waiting area
    - (b) Inpatient dispensing room
    - (c) Outpatient dispensing with counseling room
    - (d) Emergency dispensing room
    - (e) Compounding room
    - (f) Cold room, optional
    - (g) Medicine information center room(s)
    - (h) Cashier room
    - (i) Medical store intended for medicines, vaccines, lab reagents and
    - (j) Medical equipment storage
    - (k) Office and duty room
    - (l) Staff toilet (female and male)

#### 6.28.3 Professionals

- 6.28.3.1 The overall hospital pharmaceutical service shall be directed by a licensed pharmacist
- 6.28.3.2 In addition, the hospital shall have the following licensed pharmacist for each of the following service delivery points.
  - Two for outpatient pharmacy,
  - Two for inpatient pharmacy (clinical pharmacist),
  - One for emergency pharmacy,
  - One for compounding service,
  - One for medicines information center, and
  - Two for central medical store and overall medicine supply management.
- 6.28.3.3 The hospital pharmacy may have additional pharmacy technicians as appropriate
- 6.28.3.4 The pharmacist who is working at the inpatient pharmacy shall serve as ADE focal person for the hospital

- 6.28.3.5 The hospital shall have written policies and procedures for pharmacy workforce determination for additional pharmacy staff based on the workload analysis to ensure quality service standard.
- 6.28.3.6 The hospital pharmacy shall have an accountant from finance division, clerks, cashiers, cleaners and porters.
- 6.28.3.7 The responsible pharmacist shall ensure that written job descriptions are prepared for all staff and that all staff are acquainted with their job descriptions and responsibilities.
- 6.28.3.8 All staff shall receive appropriate training, information and orientation at the time of appointment to any position in the pharmacy
- 6.28.3.9 The requirements of the national and/or state medicine related laws with respect to persons handling medicines and related products shall be adhered.
- 6.28.3.10 Pharmacists responsible for the practical training of pharmacy students shall comply with the necessary duties and responsibilities stated in the country's medicine related laws.
- 6.28.3.11 The pharmacy personnel shall wear white gown or any color accepted by the hospital with easily readable name tag (badge) that include their name and status, such as junior pharmacist, senior pharmacist, pharmacy technicians or any other.
- 6.28.3.12 A pharmacist shall be on duty or on call at all times outside working hours.

#### 6.28.4 Products

- 6.28.4.1 The hospital may have its own medicine list within the framework of the national medicine list prepared by the FMHACA.
- 6.28.4.2 There shall be adequate, suitable dispensing equipment in the dispensary.

  Each item must be clean, in good repair and of suitable material. Equipment shall be specific for each service which may be provided in the pharmacy.
- 6.28.4.3 The hospital's outpatient, inpatient and emergency pharmacies and its central medical store shall have fire extinguisher, refrigerators, deep freezers, security alarms and racks/shelves.
- 6.28.4.4 Equipment used for measuring and weighing shall be designed and maintained in such a way as to be suitable for its intended use; facilitate

- thorough cleaning when necessary; minimize any contamination of medicines and their containers; and minimize the risk of confusion or the omission of a processing step such as filtration or sterilization.
- 6.28.4.5 There shall be a suitable, clean wash hand basin made of a smooth, washable and impermeable material which is easy to maintain in a hygienic condition and has a source of hot and cold tap water and a closed drainage system.
- 6.28.4.6 The medicine information center shall be equipped with furniture and equipment including a dedicated telephone, computer, internet and lockable filing cabinets, current collection of reference materials such as books, journals, medicine profiles, electronic information, relevant formularies and manufacturers' information.
- 6.28.4.7 Toilet facilities shall be kept clean and in good order. Hand-washing facilities shall be provided in the toilet area together. Facilities must include readily available water, soap and clean towels or other satisfactory means of drying the hands.
- 6.28.4.8 The hospital pharmacy shall be provided with consistent electricity, telephone, internet services (optional) and office facilities such as computers, furniture and other necessary supplies.
- 6.28.4.9 In general, minimum standard for pharmacy equipment and facilities at different service delivery points shall be as follows.

		Pharmaceutical Service Delivery Points				
Eq	uipment and facilities	Inpatient	Outpatient	Emergency	Medical	Compounding
		Pharmacy	Pharmacy	Pharmacy	Store	Pharmacy
1.	Working bench: Level, smooth,					Х
	impervious, free of cracks and					
	crevices and non-shedding;					
	covered with protector sheets					
	of plastic, rubber or absorbable					
	paper when appropriate					
2.	Mortar and pestle: 250 ml					Х
	capacity or more; glass type and					
	porcelain type					

3.	Water distiller: Stainless steel of			X
	20 liter capacity or more			
4.	Water bath: Stainless steel of 4			X
	openings or more			
5.	Electrical hotplate: Various			Х
	Sizes and Features			
6.	Evaporating dish: Stainless steel			X
	(glazed inside) and porcelain			
	type; with/without handling			
7.	Spatula: Stainless steel and			x
	plastic type, flexible and non-			
	flexible, different blade lengths.			
8.	Gloves: disposable, non-sterile			X
9.	Glass rod: Different length and			X
	thicknesses			
10.	. Wash bottle: 250ml capacity,			X
	polyethylene			
11.	. Funnel: Glass type and plastic			X
	type (polyethylene)			
12.	. Beakers: Glass type; different			X
	capacity			
13.	. Volumetric flask: Glass type;			X
	different capacity			
14.	. Balances: Prescription, torsion,			X
	manual triple beam, electronic;			
	capacities of not less than 300			
	gm; sensitivity of not less than			
	0.1 mg.			
15.	. Ointment tile: Glass type			X
		t .		

16. Micropipettes: Glass type;					X
different capacities (less than					
1ml); with pipette bulb					
17. Glass type; different capacities					X
(1ml-100ml); with pipette bulb					
18. Cylindrical graduate: Glass and					X
plastic type; different capacity					
19. Conical graduate: Glass and					X
plastic type; different capacity					
20. Weighing dishes: Plastic,					X
aluminum, stainless steel type					
21. Weighing paper: Normal paper;					X
grease-proof for semisolids					
22. Refrigerators and deep freezers	Х	Х	Х	Х	X
with thermometer					
23. Wall thermometers	Х	X	Х	х	X
24. Ventilator or AC as required	Х	X	Х	Х	Х
25. Hygrometer	Х	X	X	Х	Х
26. Tablet counter	Х	X	Х		
27. Scientific calculator	X	Х	Х	X	X
28. Table and chair	X	Х	Х	Х	х
29. Scissors	X	X	Х	Х	Х
30. Adult and pediatric weighing	X	Х			
balance					
31. Telephone line	X	X	Х	Х	
32. Internet facility access					
(optional)					

# 6.29 Blood Transfusion Services

### 6.29.1 Practices

- 6.1.1.2 The hospital shall have blood transfusion services 24 hours a day and 365 days a year
- 6.1.1.3 Transfusion of blood and blood products shall be provided or readily available consistent with the size and scope of operation of the hospital.
- 6.1.1.4 Blood shall be prescribed by a licensed physician.
- 6.1.1.5 There shall be written procedure for blood typing, cross-matching, risk assessment and testing, storage and transportation activities
- 6.1.1.6 There shall be written procedure for laboratory investigation of transfusion reactions under the direct supervision of a physician.
- 6.1.1.7 For emergency situations the hospital shall maintain at least a minimum blood supply in the hospital at all times, be able to obtain blood quickly from Regional blood banks, or have an up-to-date list of donors.
- 6.1.1.8 Blood shall be transported in appropriate containers that can maintain the cold chain system from the centre to the hospital blood store
- 6.1.1.9 Blood shall be counter checked by two health professionals for proper labeling consisting of the name, expiry date, blood type and RH and the serial number at each delivery points.
- 6.1.1.10 Blood storage facilities in the hospital shall have a functional alarm system in case of power failure and out of range temperature, which is regularly inspected and is otherwise safe and adequate.
- 6.1.1.11 Records shall be kept on file indicating the receipt and disposition of all blood provided to patients in the hospital.
- 6.1.1.12 Samples of each unit of blood used at the hospital shall be retained for further retesting in the event of reactions. Blood which has exceeded its expiration date shall be disposed promptly.
- 6.1.1.13 There shall be a hospital transfusion committee that shall review all transfusions of blood or blood products and make recommendations concerning policies governing such practices.

- 6.1.1.14 The hospital transfusion committee shall receive patient complaints and investigate all transfusion reactions occurring in the hospital and make recommendations to the medical staff regarding improvements in transfusion procedures
- 6.1.1.15 A hospital transfusion committee shall report all transfusion reactions occurring in the hospital at least on quarterly basis to the Chief Clinical Officer/Medical Director
- 6.1.1.16 Written Consent shall be signed before blood transfusion by the recipient or care giver in case the recipient is incompetent and this shall be recorded in the patient medical record.
- 6.1.1.17 Facilities and testing procedures to ensure safety of blood shall be installed in the hospital
- 6.1.1.18 The hospital shall make sure that bloods are properly labeled with all the appropriate identifications, date of collection and expiry date.
- 6.1.1.19 There shall be written procedure for the disposal of unfit-for-use blood as per the waste management section of this standard.
- 6.1.1.20 There shall be a standardized blood request paper prepared and approved by the hospital

### 6.29.2 Premises

- 6.1.1.21 The hospital shall have a minimum of one room for blood storage unit that can accommodate the cold chain facilities
- 6.1.1.22 The blood storage unit shall be clearly demarcated and identified from the premises of any other business or practice.
- 6.1.1.23 The hospital blood storage unit shall have record keeping and documentation facility
- 6.1.1.24 The hospital blood storage unit shall have consistent electricity, telephone and water supply
- 6.1.1.25 Toilet facilities shall be kept clean and in good order. Hand-washing facilities shall be provided in the toilet area together.

## 6.29.3 Professionals

- 6.1.1.26 A licensed laboratory technologist shall be responsible for blood typing and cross-matching
- 6.1.1.27 A licensed nurse or laboratory technician shall be assigned to manage the blood storage unit and its stock management.
- 6.1.1.28 There shall be a mechanism to utilize laboratory staff to clean blood storage unit.

#### 6.29.4 Products

- 6.1.1.29 The hospital blood storage unit shall have at least the following equipment and facilities:
  - a) Two refrigerators which is specially designed for blood storage
  - b) A deep freezer
  - c) Incubator
  - d) Thermometer
  - e) Timer
  - f) Pipette
  - g) Reagent dispenser

- h) Cold boxes
- i) Anti A antisera
- j) Anti B antisera
- k) Anti D (RH Typing)
- l) Antihuman globulin
- m) One heating block
- n) One water bath for crossmatching

## 6.30 Ambulance Services

## 6.30.1 Practice

- 6.1.1.30 The ambulance service shall be provided to every emergency patient who needs the service without any prerequisite and discrimination
- 6.1.1.31 The ambulance service shall be available 24 hrs a day and 365 days a year
- 6.1.1.32 The ambulance service shall provide the following services to patients with urgent need of medical attention or in a medical emergency
  - (a) Transportation service to the hospital and from the hospital to other health facilities
  - (b) Clinical examinations including brief history, vital signs, very pertinent physical examination and glucose test when needed
  - (c) Clinical life saving support that includes:
    - Fluid resuscitation
    - Bleeding control
    - Air way cleaning, oxygen administration, sever asthma management
    - Attending labor
    - Immobilizing a fracture
    - Providing anti-pain
    - Managing seizure
    - Providing emergency medicines like adrenaline, hydralazine, glucose etc
- 6.1.1.33 The ambulance service shall comply with the patient rights standards stated under this standard.
- 6.1.1.34 Every procedure, medication and clinical condition shall be communicated to the patient or family member or caregivers or next of kin
- 6.1.1.35 Up on arrival to the hospital the ambulance staff shall transfer the patient to the emergency service. The handover of patients shall be accompanied by written a document which at least includes identification, date, time and services provided until arrival to the hospital.

- 6.1.1.36 If death happens on the way to a hospital the dead body shall be taken to the hospital and death shall be confirmed. Dead body care shall be provided as per the standards stated under this standard.
- 6.1.1.37 Ambulances of the hospital shall serve only for designated emergency medical services
- 6.1.1.38 After providing a service the vehicle shall be cleaned and made standby.
- 6.1.1.39 The ambulance kit shall be checked every time after providing a service

#### 6.30.2 Premises

- 6.1.1.40 The parking of the ambulance car shall be within the hospital around emergency service.
- 6.1.1.41 The hospital ambulance shall have telephone/radio communication means with the emergency service unit
- 6.1.1.42 The hospital shall have ambulance service unit under the emergency service of the hospital equipped with a telephone/radio to communicate with the public and the ambulance team
- 6.1.1.43 The ambulance car shall have adequate space for accommodating the following:
  - (a) A couch
  - (b) One family attendant and
  - (c) At least two nurses
  - (d) Medical items needed for providing immediate life saving support
- 6.1.1.44 The vehicle shall be labeled and have a siren
- 6.1.1.45 The vehicle shall have adequate internal light and ventilation
- 6.1.1.46 The vehicle shall fulfill requirements of road transport authority

#### 6.30.3 Professionals

- 6.1.1.47 Minimum standards for personnel of the ambulance service shall include:
  - (a) Nurses pulled from emergency service unit
  - (b) Licensed driver for all shifts
  - (c) Telephone operator
- 6.1.1.48 The nurses shall be trained on emergency medical services
- 6.1.1.49 The driver shall be oriented on emergency situation management

#### 6.30.4 Products

- 6.1.1.50 The ambulance service shall include the following medicines, supplies and medical equipments:
  - (a) Medicines:
    - Anti pains, adrenaline, hydralazine, IV fluids (all types), dextrose 40%, diazepam iv, phenytoin iv, atropine iv, etc.
  - (b) Supplies
    - IV cannula, IV stand, syringe with needle, tourniquet, plaster, gauze, bandage, spatula, antiseptic solution, catheters
    - Personal protective devices (gown, mask, gloves, goggles)
    - Waste disposing containers
    - Support material for immobilization purpose
  - (c) Equipment:
    - Minor surgical set (forceps, scissors, kidney dish, stitch, sterile gauze, needle holder) in a drum
    - Oxygen supply, ambubag, suction machine
    - Stethoscope, sphygmomanometer, thermometer
    - Portable radio or telephone
    - Emergency trachiostomy (wide bore needle insertion), air way, laryngeal mask, intubation set
    - Glucometer
  - (d) Log book (stating time of call, time of arrival, time of return)
  - (e) Bed (couches) with fixed chair that is designed for ambulances, wheel chair, emergency light
  - (f) Standby ambulances (depending on the workload):

## 6.31 Infection Prevention

#### 6.1.2 Practices

- 6.1.2.1 All activities performed for infection prevention shall comply with the national infection prevention guidelines.
- 6.1.2.2 Infection prevention and control shall be effectively and efficiently governed and managed.
- 6.1.2.3 The hospital shall identify the procedures and processes associated with the risk of infection and shall implement strategies to reduce infection risk.
- 6.1.2.4 Infection risk-reduction activities shall include:
  - a) Equipment cleaning and sterilization, in particular, invasive equipment;
  - b) Laundry and linen management;
  - c) Disposal of infectious waste and body fluids;
  - d) The handling and disposal of blood and blood components;
  - e) Kitchen sanitation and food preparation and handling;
  - f) Operation of the mortuary and postmortem area;
  - g) Disposal of sharps and needles;
  - h) Separation of patients with communicable diseases from patients and staff who are at greater risk due to immunosuppression or other reasons;
  - i) Management of hemorrhagic (bleeding) patients; and
  - j) Engineering controls, such as positive ventilation systems, biological hoods in laboratories, and thermostats on water heaters.
- 6.1.2.5 The hospital shall be maintained following policies and procedures
  - a) Hand hygiene
    - Standard precautions for hand hygiene
    - Personal protective measures
    - Monitoring and surveillance of hand hygiene practices
  - b) Transmission-based precautions
    - Contact precautions
    - Droplet precautions

- Airborne precautions
- c) Post-Exposure Prophylaxis programs (PEP) for some communicable diseases like rabies, HIV, meningitis, hepatitis
  - Standard precautions to follow
  - PEP policy
  - Procedures for PEP
- d) Environmental infection prevention
  - General hospital hygiene
  - Structural infection prevention
  - Physical hospital organization
- e) Waste management
  - Cleaning medical instruments
  - Implementation of a disposal system
  - Handling medical waste
  - Waste removal
- 6.1.2.6 Standard precautions shall be practiced and the hospital shall have its own guidelines including the followings:
  - a) Hand hygiene shall be performed after touching blood, body fluids, secretions, excretions, and contaminated items, both immediately after removing gloves and between patient contacts.
    - Consider every patient is infectious:
    - Thorough hand washing:
    - Use high-level disinfectants:
    - Standard procedure for using a high-level anti-septic cleaner:
  - b) Personal protective equipment shall include gloves, mask, eye protection (goggles) and face shield
  - c) Gloves shall be worn in the following situations but not limited to:
    - When there is direct contact with exposed wounds, blood, body fluids, body organs or any type of lesion.
    - When drawing blood or handling medical instruments involved with invasive procedures (catheters, IV insertion, probes, etc.).
    - When there is contact with a patient who might be infectious.

- When handling contaminated items.
- When cleaning patient areas.
- d) Gowns shall be worn when but not limited to:
  - Performing surgical procedures,
  - Splattering of blood or body fluids is possible,
  - Handling bulk soiled linen (housekeeping),
  - Performing waste collection for infectious waste,
  - Handling any type of medical waste, and
  - Conducting hospital laundry washing.
- e) Masks, goggles, or other types of face shields shall be worn when but not limited to:
  - Splattering of blood or body fluids to the face is possible,
  - Handling biohazardous, soiled linens, and
  - Performing waste collection for hazardous or non-hazardous waste.
- f) Soiled patient-care equipment, textiles, and laundry shall be handled appropriately
- g) Any type of face shield that is apparently soiled or splattered with body fluids shall be washed and sterilized with a disinfectant.
- h) Procedures shall be developed and implemented for routine care, cleaning, and disinfecting environmental surfaces, especially frequently touched surfaces in patient care areas.
- i) Used needles shall not be recapped, bent, broken, or manipulated by hand.
   Handed scoop technique only shall be used when recapping is required.
- j) Safety features shall be used when available and used "sharps" shall be placed in a puncture-resistant container specially designated bin for hazardous waste.
- 6.1.2.7 There shall be transmission-based precautions and the hospital shall have its own guideline for the followings:
  - a) Contact precautions as described in article 6.32.1.7
  - b) Droplet precautions
  - c) Airborne precautions (for diseases like SARS, TB, Swine flu, etc)
    - Isolation room

- Negative pressure in relation to surrounding areas
- A minimum of 6-9 air exchanges per hour
- Air discharged outside the building and away from intake ducts, or through a high-efficiency filter if re-circulated
- Door kept closed whether or not patient is in the room
- After discharge door kept closed until sufficient time has elapsed to allow removal of airborne organisms
- Patient confined to room
- Room shall have toilet, hand washing and bathing facilities.
- 6.1.2.8 The hospital shall have procedures in place to minimize crowding and manage the flow of patients and visitors. This shall include
  - a) Patient crowd control
  - b) Assess urgent and non urgent cases
  - c) Patient sign-in
  - d) Caregiver and visitor control.
- 6.1.2.9 The hospital shall train all staff on how to minimize exposure to blood-borne infections. These include:
  - a) Immediate first aid
  - b) Reporting exposures
  - c) Assign area for starter packs 24-hours access per day
  - d) Counseling and testing for exposed staff
  - e) Reporting and monitoring protocols
  - f) Evaluate PEP program
- 6.1.2.10 The hospital shall provides regular training on infection prevention and control practice to staff, patients, and as appropriate, to family, visitors and caregivers including the followings.
  - a) Prevention of the spread of infections,
  - b) Improving the quality of patient care,
  - c) Promoting safe environment for both patients, caregivers and staff

## 6.1.3 Premises

- 6.1.3.1 There shall be the following facilities:
  - a) Working Office for IP officer
  - b) Meeting rooms for IP-committee

### 6.1.3.2 The hospital shall have a designated sterilization room

#### 6.1.4 Professionals

- 6.1.4.1 The hospital shall have an IP committee coordinated by a full time infection prevention and control officer.
- 6.1.4.2 The officer shall be a licensed infectious diseases specialist or IP trained health professional (physician or BSc nurse), or a public health specialist knowledgeable on infection prevention principles and hospital epidemiology.
- 6.1.4.3 IP committee shall be trained on infection prevention as well as hospital epidemiology
- 6.1.4.4 The IP committee shall be composed of professionals at least from the following service units
  - a) Nursing care service
- g) Laboratory

b) Medical services

- h) Laundry
- c) Environmental health
- i) Kitchen

d) Housekeeping

j) Instrument sterilization and supply

e) Administration

k) Occupational health and safety

f) Pharmacy

- l) Quality management
- 6.1.4.5 The infection prevention committee or designate shall have written protocols, procedures and shall oversee the following activities and this shall be documented:
  - a) Developing the health facility annual infection prevention and control plan with costing, budgeting and financing
  - Monitoring and evaluating the performance of the infection prevention program by assessing implementation progress as well as adherence to IPC practice
  - c) Conducting surveillance to monitor nosocomial infections, antimicrobial resistance, antimicrobial use, and outbreaks of infectious diseases.
  - d) Formulating a system for surveillance, prevention, and control of nosocomial infections.
  - e) Reviewing surveillance data, reporting findings to management and other staff and identifying areas for intervention
  - f) Assessing and promoting improved practice at all levels of the hospital

- g) Developing an IEC strategy for health-care workers
- h) Ensuring the continuous availability of supplies and equipment for patient care management
- i) Monitoring, providing data and measuring the overall impact of interventions on reducing infection risk
- j) The hospital's overall quality improvement program and shall receive formal advice from all other services upon its request.

#### 6.1.5 Products

- 6.1.5.1 The hospital shall ensure that equipment and supplies necessary for infection prevention are available.
- 6.1.5.2 The hospital shall have the following adequate supplies and equipment needed for infection prevention and control practice.
  - a) Waste management equipment and supplies:
    - Incinerator
    - Placenta pit
    - Wheelbarrows
    - Ash pit
    - Burial pit
  - b) Cleaning
    - Mop
    - Bucket
    - Broom
    - Dust mop
  - c) Laundry
    - Washing machine
    - Sink
    - Washing basin
    - (for decontamination of linens)
    - Drying rack/line
    - Dryers
    - Irons

- Garbage bins
- Large garbage bin
- Plastic garbage bags (optional)
- Safety boxes
- Cleaning cloth
- Detergent
- Bleach
- Wheelbarrows (to transport linens to/from wards)
- Detergent
- Bleach

- d) Instrument processing
  - Autoclaves and steam sterilizers,
  - Test strips
  - Chemicals
  - Commercial steamer
  - Boiler
  - Oven
  - 0.5% chlorine solution (diluted bleach)
- e) Hand hygiene
  - Sinks (ward and other areas)
  - Water container with faucet
  - Soap
- f) Personal Protective Equipment
  - Heavy duty glove
  - Surgical glove
  - Examination glove (latex or nitrile)
  - Other types (ex. those worn by cleaning and laundry staff)
  - Eye shield
  - Goggle
  - Visors
  - Dust mask

- Storage shelves for the medical equipment
- Disinfectant chemicals
- Brushes (tooth brush for small items)

- Alcohol based hand rub
- Personal Towels
- Paper Towels
- Surgical/Disposable
- · Respiratory mask
- Other type of face mask
- Plastic apron
- Other types
- Boots
- Nurse shoes
- Other protective shoes
- Caps
- Face shield

## 6.32 Medical Recording

#### 6.1.6 Practices

- 6.1.6.1 Medical record shall be maintained in written form for every patient seen at all points of care including emergency, outpatient, labor & delivery, inpatient and operation theatre.
- 6.1.6.2 The hospital shall maintain individual medical records in a manner to ensure accuracy and easy retrieval. A patient shall have only one medical record in the hospital.
- 6.1.6.3 The medical information of a patient during ambulance service including medication administered shall be documented and attached into the medical record
- 6.1.6.4 The hospital shall establish a master patient index with a unique number for each patient
- 6.1.6.5 Each piece of paper that contains a medical record shall have the appropriate identification on the paper
- 6.1.6.6 The hospital shall have a written policy and procedure that are reviewed at least once every three years 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.
- 6.1.6.7 When a medical record is taken out and returned to the record room it shall be documented to create a good tracking mechanism
- 6.1.6.8 Any medical record shall be kept confidential, available only for use by authorized persons or as otherwise permitted by law.
- 6.1.6.9 All entries in the patient's medical record shall be written legibly in permanent ink, dated, and signed by the custodian/recording person.
- 6.1.6.10The medical record forms shall be prepared in line with the national/state guideline and approved by the hospital management.
- 6.1.6.11 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
- (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.
- 6.1.6.12Any consent form for medical treatment that the patient signs shall be printed in an understandable format and the text written in clear, legible, non technical language.
- 6.1.6.13There 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.
- 6.1.6.14There 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.
- 6.1.6.15The patient's death shall be documented in the patient's medical record upon death.
- 6.1.6.16Original medical records shall not leave hospital premises unless they are under court order or in order to safeguard the record in case of a physical plant emergency or natural disaster.
- 6.1.6.17If a patient or the patient's legally authorized representative requests, in writing, a copy of the medical record shall be given.
- 6.1.6.18If the patient is provided with medical certificates, copies of certificates and other records shall be documented and/or recorded on the original medical record
- 6.1.6.19If the patient is transferred to another hospital on a non emergency basis, the hospital shall maintain a transfer record reflecting the patient's immediate needs and send a copy of this record to the receiving hospital at the time of transfer.
- 6.1.6.20If the hospital ceases to operate, the regulatory body 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. Patient will get information from the regulatory body regarding the location of their medical records.
- 6.1.6.21. The hospital shall establish a procedure for removal of inactive medical records from the central medical record room.
- 6.1.6.22Medical records shall be destroyed as per the law by using techniques that are effective enough to assure confidentiality of medical records. However, records which are active for more than ten years shall not be destroyed.

#### 6.1.7 Premises

- 6.1.7.1 There shall be a separate medical record room
- 6.1.7.2 The premises shall have one meter wide space in between and around shelves.

  The medical records shall be shelved 20-30cm above from the floor.
- 6.1.7.3 The medical record room shall have adequate space to accommodate the following:
  - (a) Central filing space
  - (b) Work space
  - (c) Archive space
  - (d) Supply/Storage room
- 6.1.7.4 The medical record room shall have adequate light and ventilation
- 6.1.7.5 The medical record room shall be built far from fire sources
- 6.1.7.6 There shall be a room for archiving dead files until they are permanently destroyed

#### 6.1.8 Professionals

- 6.1.8.1 There shall be a full-time medical record personnel (Health Information Technician) with basic computer skill and ability to organize medical records responsible for medical records management
- 6.1.8.2 Other additional staffs (like card sorter and runner) to perform patient registration, retrieving, filing and recording chart location.
- 6.1.8.3 The actual number of staff shall be determined based upon the total number of active charts in a day (Workload analysis)
- 6.1.8.4 The hospital shall provide basic training on medical record keeping to the staffs

## 6.1.9 Products

# 6.1.9.1 The Medical record room shall have:

- (a) Shelves made from metal and must be fire proof
- (b) Master patient index boxes
- (c) Computer
- (d) Cart
- (e) Ladder
- (f) Water proof patient folder
- (g) MPI Cards
- (h) Log book
- (i) Fire extinguisher

## 6.33 Food and Dietary Services

#### 6.1.10 Practices

- 6.1.10.1 The hospital shall provide nutritionally adequate meals, food supplement supplies for inpatients and staffs on duty
- 6.1.10.2 The dietary service shall be available for 24 hours a day and 365 days a year
- 6.1.10.3 The dietary service shall have written policies and procedures for all dietary services including
  - a) Preparation and handling
  - b) Meal distribution and/or request and receive special event service for inpatients.
  - c) Special diet order
  - d) Holidays
  - e) A diet manual detailing nutritional and therapeutic standards for meals and snacks, and a nutrient analysis of menus.
  - f) Nutritional assessment guide for patients' nutritional needs for food and food supplements.
- 6.1.10.4 A current diet manual shall be available at each nurse's station and in the dietary service unit and medical library.
- 6.1.10.5 There shall be a policy to promote the participation of the dietary service in meetings of multidisciplinary health care teams to assess patients.
- 6.1.10.6 All new admissions shall be listed with the dietary service
- 6.1.10.7 Each patient's diet shall be recorded in the medical record. records of diet instructions shall include:
  - a) The diet instruction provided to the patient and/or responsible person.
  - b) Patient response, participation and understanding.
  - c) Written instructional material provided to the patient and/or responsible person.
- 6.1.10.8 A physician shall write a specific dietary order and /or nutritional supplements for each patient.
- 6.1.10.9 All diets shall be prepared in conformity with the hospital's dietary manual.

- 6.1.10.10 At least three meals (breakfast, lunch and dinner) shall be served daily, and no more than 15 hours shall elapse between dinner and breakfast.
- 6.1.10.11 Nourishment may be provided between meals and at night.
- 6.1.10.12 Changes in physician orders for diets shall be effected by the next mealtime,
- 6.1.10.13 The dietary service shall follow the policies and procedures developed by the drug and therapeutics committee or any responsible government body regarding possible food/medicine interactions.
- 6.1.10.14 There shall be a mechanism for evaluating patients on each nursing unit to ensure they are being adequately nourished.
- 6.1.10.15 There shall be a mechanism for the dietary service to be informed if the patient does not receive the diet that has been ordered, or is unable to consume the diet.
- 6.1.10.16 There shall be a mechanism for patients and their families to interact with the dietary service.
- 6.1.10.17 Patients with special dietary needs, based on criteria established by the hospital, shall receive dietary instruction from a dietician or authorized designee during hospitalization.
- 6.1.10.18 The dietitian shall provide diet information to the Canteen staff to help the nursing / rehabilitation staff guide appropriate purchase selections of food items.
- 6.1.10.19 The dietitian shall provide nutrition information as requested by the patient, family, or treatment team including
  - a) Diet instructions,
  - b) Written instructional material,
  - c) Community dietary referrals regarding special diets
  - d) Current diet order,
  - e) Nutritional problems,
  - f) Appetite,
  - g) Nutritional counseling,
  - h) Comprehension of diet instruction,
- 6.1.10.20 The dietitian shall provide timely discharge diet instructions upon notification with a physician-ordered diet consultation or as planned by the treatment team.

- 6.1.10.21 Inpatient's or discharged patient's diet instructions shall include education involving:
  - a) Therapeutic or modified diets
  - b) Food-drug interactions
  - c) Nutritional care for certain diagnoses/conditions
  - d) Recommendations for changes in diet order,
  - e) Treatment plan,
  - f) Significant food allergy (lactose, wheat gluten, soya, egg, dairy)

#### 6.1.10.22 Nutrition consultations

- a) The dietitian shall provide nutrition consultations upon notification with a physician-ordered consultation. The order shall include a brief reason for the consultation.
- b) Nutrition consultations shall be completed immediately after physician's order.
- Nutrition consultations shall be individual or group, and may include family and/or responsible person.
- d) The dietitian shall determine the type and frequency of follow-up care after the initial consultation. Follow-up consultation may include evaluation of nutritional care, diet education, or other nutritional concerns.

#### 6.1.10.23 Treatment Planning

- a) Therapeutic goals related to nutritional needs shall be based on the following standards
  - Standard Height/Weight
  - Dietary Reference Intakes
  - Nutrition-related laboratory values
  - Body Mass Index for Adults

#### 6.1.10.24 Diet Orders and Nutritional Supplements

- a) Physician diet orders shall be legible, concise, and written in an understandable manner. The following information shall be included in diet orders:
  - Patient Name
  - Unit

- Date
- Specific diet order; including food allergies/intolerances
- Physician's signature
- b) Dietary services shall receive written notification of:
  - New diet orders
  - Change in diet order
  - Discontinued or canceled diet orders
  - Unit transfers
  - Isolation or special trays
- c) All written diet orders shall be sent to dietary services immediately.
- d) Special requests for meals or supplemental foods shall be provided as ordered to accommodate alterations in diets or meal service schedules due to new admissions, personal dietary needs, or other circumstances.
- e) Diabetic and Calorie-Controlled diet orders shall include the calorie level desired.
- f) The dietitian shall recommend appropriate nutritional food supplement according to physician orders.
- g) An electronic or manual spreadsheet of all diet orders shall be maintained by the dietitian to provide a current resource of all regular and therapeutic diets.
- h) Dietary and nursing services shall be responsible to ensure dietary compliance and quality nutritional care of patients.
- 6.1.10.25 There shall be appropriate food safety and sanitations to ensure safe food service for the patients.
- 6.1.10.26 Dry or staple food items shall be stored at least 12 inches off the floor in a ventilated room which is not subject to sewage or waste water back-flow, or contamination by condensation, leakage, rodents or vermin.
- 6.1.10.27 All perishable foods shall be refrigerated at the appropriate temperature and in an orderly food safety manner (cold and hot holding principle).
- 6.1.10.28 Each refrigerator shall contain a thermometer in good working order.
- 6.1.10.29 Foods being displayed or transported shall be protected from contamination.

- 6.1.10.30 Three compartments dish washing procedures and techniques shall be developed and carried out in compliance with the national hotel and restaurants sanitary control guideline.
- 6.1.10.31 All garbage and kitchen refuse which is not disposed of shall be kept in leak proof non-absorbent containers with close fitting covers and be disposed of routinely in a manner that will not permit transmission of disease, a nuisance, or a breeding place for flies.
- 6.1.10.32 All garbage containers shall be thoroughly cleaned inside and outside each time emptied.
- 6.1.10.33 Requests for alternative food supplies shall be considered on an individual basis.
- 6.1.10.34 Foods shall be transported and served as close to preparation/ Rethermalization time as possible. Maximum cold food temperatures shall be 41° F (5°C) and minimum hot food temperatures shall be 135° F (60°C) at time of service.
- 6.1.10.35 Dietary Services shall ensure prescribed diet compliance as well as minimize food-borne illness.
- 6.1.10.36 Cancellations of ordered diets shall be made as soon as possible to avoid possible spoilage and/or waste of food items.
- 6.1.10.37 Hospitals may provide dietary services by one of the followings:
  - a) In traditional configuration where the kitchen is located in the hospital premise;
  - b) Provide the service directly, but may prepare the bulk of the meals in a kitchen owned by the hospital, located off-site; and
  - c) Contract out for dietary services through an off-site vendor and the contract shall be documented. However, regardless of how the hospital provides the service, the hospital shall ultimately be responsible for meeting the dietary service standards.
- 6.1.10.38 When dietary services are provided from an off-site location, the hospital shall be responsible to ensure:
  - a) Compliance with the quality assurance system
  - b) Compliance with the infection prevention standard

- c) Compliance with the dietetic policies and procedures in regards to meal service for off hours' admissions, late trays, food substitutions, reasonable meal schedules, posting of current menus in the hospital as well as in the off-site kitchen, tray accuracy, food handling safety practices, emergency food supplies and deliveries, staffing and patient satisfaction,
- d) The presence of a current therapeutic diet manual approved by the dietitian and medical staff,
- e) The presence of nutritional assessment indicating nutritional needs are in accordance with recognized dietary practices as well as with orders of the practitioners responsible for the care of the patients.

### 6.1.10.39 Catering hygiene shall fulfill the following conditions

- a) There shall be guidelines for pest control and restricting the presence of animals (eg. cats, dogs etc) visibly posted in the kitchen.
- b) There shall be a system to screen and control the health of kitchen personnel.
- c) The responsible kitchen personnel health shall be controlled for:
  - Personal hygiene including uniform (protective clothes)
  - Periodical medical check-up for acute and chronic diarrhea and other infectious diseases
  - Those with infected open skin lesions are not allowed to work as kitchen personnel.

## 6.1.11 Premises

- 6.1.11.1 The following minimum facilities shall be available for dietary services
  - a) Food preparation room with
    - All cooking appliances shall have ventilating hood
    - Washing facility with three compartment
    - Pot washing facilities with appropriate Sink
    - Cart cleaning facilities with appropriate Sink
    - Can wash facilities with appropriate Sink
  - b) Storage room
  - c) Cart storage.
  - d) Dietitian's office.

- e) Janitor's closet
- f) Personnel toilets with hand washing facilities
- g) Approved automatic fire extinguisher system in range hood.
- h) Continuous electricity (power) supply
- i) Ample and safe water supply

#### 6.1.12 Professionals

- 6.1.12.1 The hospital shall have an organized dietary service unit directed by a licensed dietitian or food sciences & /or food technologist. The dietitian shall be a full-time employee.
- 6.1.12.2 In addition, the hospital shall have the following Food personnels:
  - (a) Meal distributor

(d) Store keeper

(b) Catering Chef

(e) Bakers

(c) Kitchen workers

- (f) Dishwashers
- 6.1.12.3 The adequate number of personnel, such as cookers, bakers, dishwashers and clerks shall be available in the hospital (based on workload analysis).
- 6.1.12.4 There shall be procedures to control dietary employees with infectious and open lesions.
- 6.1.12.5 Food handlers shall meet routine health examinations according to the *Ethiopian Food Handlers' Hygiene Guideline* for food service personnel.
- 6.1.12.6 There shall be an in-service training program on proper handling of food and personal grooming to dietary employees.
- 6.1.12.7 All kitchen workers shall wear protective kitchen clothes according to the *Ethiopian Food Handlers' Hygiene Guideline*.
- 6.1.12.8 Written job descriptions for all dietary employees shall be given, oriented and documented.

## 6.1.13 Products

- 6.1.13.1 The following products shall be available for dietary services:
  - a) Refrigerator (size and number shall be based on

e) Dishes

f) Oven

demand)

g) Knives

i) Pressure cooker

b) Kitchen utensils

h) Detergent materials

c) Pots and Jars

.. ...

d) Carts

- k) Lockers convenient to, but not in the kitchen proper.
- Working closes (like apron, boots, hair cover, gown, hand gloves)
- m)Barrel (garbage containers) for kitchen rest handling

## 6.34 Sanitation and Waste Management

#### 6.1.14 Practices

- 6.1.14.1 The hospital environment shall be sanitary, clean and safe environment and there shall be access to continuous, safe and ample water supply.
- 6.1.14.2 There shall be written procedures for the use of aseptic techniques and procedures in all areas of the hospital and the procedures and techniques shall be regularly reviewed and documented by the infection prevention committee as per the infection prevention section of these standard.
- 6.1.14.3 There shall be a written policy and procedures for ground water treatment.
- 6.1.14.4 Infectious medical wastes shall be handled and managed according to the recent *Health Care Facility Waste Management National Guideline*.
- 6.1.14.5 Infectious and non infectious medical waste containers shall be leak proof, have tight-fitting covers and be kept clean and in good repair until disposal.
- 6.1.14.6 Infectious and non infectious medical waste management and disposal shall be done as per recent *Health Care Facility Waste Management National Guideline* and this standard.
- 6.1.14.7 Placenta disposal pit shall be available in the hospital and shall be secured
- 6.1.14.8 Wastes shall be segregated and Segregation of healthcare waste shall include the following procedures.
  - a) Separate different types of waste as per the national guideline
  - b) The hospital shall provide colored waste receptacles specifically suited for each category of waste
  - c) Segregation shall take place at the source, like ward bedside, OR, laboratory etc
  - d) There shall be 3 bin systems used to segregate different types of waste in the hospital

Segregation category	Color	Container
Non risk waste	Black	bag or bin
Infectious waste	yellow	bag or bin
Sharp waste	yellow	safety box

Heavy Metal	red	secure container
medicine vials, ampoules	white	bag or bin
Hazardous medicines and cytotoxic	yellow	bag or bin
wastes		

- 6.1.14.9 Treatment or disposal of infectious medical waste shall be performed according to *Health Care Facilities Waste Management National Guideline* by one of the following methods:
  - a) By incineration
  - b) By steam sterilization
  - c) By discharge via approved sewerage system
  - d) Recognizable human anatomical remains shall be disposed of by incineration or internment, unless burial at an approved landfill is authorized.
  - e) Chemical sterilization
  - f) Gas sterilization (shall be handled safely)
- 6.1.14.10 The hospital shall routinely clean and sanitize patient areas and waiting rooms at least twice daily and more when ever needed.
- 6.1.14.11 Medical waste which is not infectious shall be disposed according to *Health*\*Care Facilities Waste Management National Guideline\* by one of the following methods:
  - a) By incineration
  - b) By sanitary landfill,
- 6.1.14.12 In order to maintain a clean and safe environment, the hospital shall have an organized method for the transport and washing of linens.
- 6.1.14.13 The hospital shall have an organized waste disposal and removal system and shall ensure the safe handling of all waste
- 7.1.1.1 Chemicals and radioactive waste shall be disposed according to national guidelines or directives up on approval appropriate organ.
  - 6.1.14.14 All generators of infectious medical waste and general medical waste shall have a medical waste management plan that shall include the following:
    - a) Storage of medical waste
    - b) Segregation of medical waste

- c) Transport of medical waste
- d) Disposal of medical waste
- 6.1.14.15 Sewage disposal shall be according to Health Care Facilities Waste Management National Guideline and fulfill the following conditions:
  - a) Hospitals shall have a functional sewerage system
  - b) Hospitals shall dispose of all sanitary waste through connection to a suitable municipal sewerage system
  - c) The hospital shall have only flushing toilet system
  - d) The hospital shall have a designated waste storage room for solid waste or septic tank for liquid waste
  - e) There shall be written procedures defining instrument processing procedures (disinfection and sterilization).
  - f) There shall be written procedures to govern the use of aseptic techniques and procedures in all areas of the hospital.
  - g) All fixtures located in the kitchen, including the dishwasher, shall be installed so as to empty into a drain which is not directly connected to the sanitary house drain.
  - h) Kitchen drain shall empty into a manhole or catch basin having a perforated cover with an elevation of at least 24 inches below the kitchen floor evaluation, and then to the sewer.

#### 6.1.15 Premises

- 6.1.15.1 Placenta disposal pit shall have dimension of height 2.5m, width 2.5m and lateral to the disposal pit the two sides shall be filled with concrete.
- 6.1.15.2In addition, the hospital sanitary system shall have
  - a) Functional sewerage e) Sanitary office system f) Incinerator
  - b) Flushing toilet
  - c) Kitchen
  - d) Laundry

- g) Dumpster (Genda for solid waste accumulation)

#### **6.1.16 Professionals**

6.1.16.1 Hospital sanitation shall be administered by a licensed environmental health or any related licensed professional trained on sanitary sciences

- 6.1.16.2 The hospital shall have the following personnel to conduct sanitation activities. (see also Housekeeping, Maintenance and Laundry Standards)
  - a) Environmental health professional
  - b) Housekeeping staff such as cleaners and waste handlers
  - c) Laundry staff
  - d) Gardeners
  - e) Incinerator operator
  - f) Instrument processors (disinfector and sterilizer)
- 6.1.16.3 The hospital shall officially designate staff in charge of handling waste on a regular basis.
- 6.1.16.4 The assigned staff shall be responsible for the collection and disposal of waste products in the hospital.
- 6.1.16.5 Continuing education shall be provided to all personnel engaged in sanitation activities on the relevant procedures
- 6.1.16.6 Staff shall be oriented on personal protection methods

#### 6.1.17 Products

- 6.1.17.1 The hospital shall have equipment and supplies required for sanitation activities which includes:
  - a) Incinerator
  - b) Ash pit
  - c) Burial pit
  - d) Placenta pit
  - e) Garbage bins
  - f) Safety boxes
  - g) Trolley to transport waste
  - h) Dumpster (Genda) shall be placed in a clean isolated and fenced area.
  - i) PPE (personal protective equipment)
  - j) Autoclave
  - k) Pressure cooker
  - Cleaning supplies (detergents, disinfectants and other cleaning solutions etc)
  - m) Laundry washers,

- n) Laundry dryers,
- o) Mops and dustpans

## 6.35 Housekeeping, Laundry and Maintenance Services

#### 6.1.18 Practices

- 6.1.18.1 The housekeeping service shall have the following sanitary activities.
  - a) Basic cleaning such as dusting, sweeping, polishing and washing
  - b) Special cleaning of
    - Different types of floors
    - Wall & Ceiling
    - Doors & Windows
    - Furniture & Fixtures
    - Venetian Blinds
  - c) Cleaning and maintenance of toilet.
  - d) Water treatment, filtering & purification.
- 6.1.18.2 In the housekeeping service, the types and sources of unwanted odors in hospital premises shall be identified, controlled and removed
- 6.1.18.3 Collection, transportation and disposal of hospital wastes shall be supervised and controlled
- 6.1.18.4 The safety of fire, electrical and natural hazards in the risk areas in the hospital shall be supervised and controlled and shall work closely with hospital fire brigade and safety committee.
- 6.1.18.5 The designee/ environmental health professional shall identify, supervise and organize the control and eradication of pests, rodents and animal nuisance in the hospital.
- 6.1.18.6 The housekeeping staffs shall create pleasant environment to patients, staffs and visitors
- 6.1.18.7 The following LINEN services shall be provided in the hospital
  - a) Maintain an adequate supply of clean linens at all times
  - b) Obtain linen from stores and laundry.
  - c) Ensure proper storage of linen.
  - d) Supervise washing, sterilization in the laundry.
  - e) Maintain linen properly
  - f) Issues linen in service units like wards.

- g) Keep proper accounting of linen.
- h) Ensure proper sorting of linen.
- i) Understand different color scheme.
- 6.1.18.8 There shall be 24 hours maintenance service.
- 6.1.18.9 The Hospital shall conduct regular routine, preventative and corrective maintenance for all facilities and operating systems (e.g., electrical, water, ventilation).
- 6.1.18.10 Regular surveillance of overhead and underground tank, proper cover, regular chlorination and cleaning shall be undertaken
- 6.1.18.11 Maintenance shall consider the infection prevention and control principles and measures.
- 6.1.18.12 The maintenance staffs shall ensure proper lighting, water supply, fire safety and ventilation in hospital.
- 6.1.18.13 Potable water and electrical services shall be available 24 hours a day and 365 days a year through regular or alternate sources.
- 6.1.18.14 There shall be a hospital plant safety maintenance organization as described below:
  - a) A multidisciplinary safety committee that develops a comprehensive hospitalwide safety program and reviewed.
  - b) A mechanism to report all incidents, injuries and safety hazards to the safety committee.
  - c) The multidisciplinary safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.
- 6.1.18.15 Facility maintenance services
  - a) The building maintenance service shall have written policies and procedures for routine maintenance, preventive maintenance and renovation maintenance.
  - b) The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with accepted engineering practices.
  - c) Floors, ceilings, and walls shall be free of cracks and holes, discoloration, residue build-up, water stains, and other signs of disrepair.

- d) Routine inspections of elevators shall be conducted.
- 6.1.18.16 Construction and renovation
  - a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.
  - b) The infection control program shall review areas of potential risk and populations at risk.
- 6.1.18.17 There shall be written protocols and procedures for medical equipment maintenance including:
  - a) Plan for equipment maintenance (both preventive and curative), replacements, upgrades, and new equipments
  - b) Safe disposal procedures
  - c) An effective tracking system to monitor equipment maintenance activity.
  - d) A monitoring method that ensures medical equipment operates with predicted specificity and sensitivity.
- 6.1.18.18 The maintenance personnel including the management of the hospital shall take basic trainings on the following issues and this shall be documented.
  - a) Building fabrics and utilities
  - b) Building services and economics
  - c) Planning maintenance demand
  - d) Preventive and routine maintenance practice
  - e) Maintenance with regard to IP and hygiene
- 6.1.18.19 Fire and emergency preparedness
  - a) The hospital shall comply with the National Fire Protection standard
  - b) All employees, including part time employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and patient evacuation of hospital buildings as part of their initial orientation and shall receive printed instructions on procedures and at least annually thereafter.

- c) A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall in each patient care unit.
- d) Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydro-tested as required by manufacturer's instructions; and labeled with the date of the last inspection.
- e) Fire detectors, alarm systems, and fire suppression systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last two inspections shall be kept on file.
- f) There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.
- 6.1.18.20 The hospital does not have its own housekeeping, laundry and maintenance services; it may have a contract agreement with external organizations. The hospital shall check and maintain the sanitary standards of the hospital regarding the processing of its linens and shall maintain a satisfactory schedule of pickup and delivery.
- 6.1.18.21 If the hospitals contract out for housekeeping, laundry and maintenance services there shall be documented contractual agreement.
- 6.1.18.22 Housekeeping equipment or supplies used for cleaning in isolation or contaminated areas shall not be used in any other area of the hospital before it has been properly cleaned and sterilized.
- 6.1.18.23 All areas of the hospital, including the building and grounds shall be kept clean and orderly.
- 6.1.18.24 There shall be frequent cleaning of floors, walls, woodwork and windows.
- 6.1.18.25 The premises shall be kept free of rodent and insect infestations.
- 6.1.18.26 Accumulated waste material and rubbish shall be removed at frequent intervals.
- 6.1.18.27 No flammable cleaning agents or other flammable liquids or gases shall be stored in any janitor's closet or other area of the hospital except in a properly fire rated and properly ventilated storage area specifically designed for such storage.

#### **6.1.19 Premises**

- 6.1.19.1 If the hospital maintains its own laundry, it shall have separate areas for:
  - a) Collection of soiled linens.
  - b) Washing, drying and ironing.
  - c) Clean linen storage and mending area.
- 6.1.19.2 Boiler Room shall be available for the installation and maintenance of the required machinery.
- 6.1.19.3 The laundry design and operation shall comply with the manufacturer's requirements and/or institutional sanitation guideline
- 6.1.19.4 Clean linen storage shall be readily accessible to nurses' stations
- 6.1.19.5 Soiled linen storage shall be well ventilated and shall be located convenient to the laundry or service entrance of the hospital. The storage of appreciable quantities of soiled linens is discouraged.
- 6.1.19.6 There shall be separate space provided for the storage of housekeeping equipment and supplies
- 6.1.19.7 A separate office shall be available for the maintenance personnels and the housekeeper.
- 6.1.19.8 Adequate space shall be available for service specific janitor's closets and cleaning equipment & supplies which shall be maintained separately for the following areas (shall not be used for cleaning in any other location):
  - f) Surgical Suites.
  - g) Delivery Suites.
  - h) Newborn Nursery.
  - i) Dietary Department.
  - j) Emergency Service Area.
  - k) Patient Areas.
  - l) laboratories, radiology, offices, locker rooms and other areas
- 6.1.19.9 Exits, stairways, doors, and corridors shall be kept free of obstructions.
- 6.1.19.10 The hospital shall have an alternate emergency power supply. If such emergency power supply is a diesel emergency power generator, there shall be enough stored fuel to maintain power for at least 24 hours.
- 6.1.19.11 There shall be dedicated premises for workshop.

## 6.1.20 Professionals

- 6.1.20.1 The housekeeping, maintenance and laundry functions of the hospital shall be under the direction of a licensed environmental health professional or engineer.
- 6.1.20.2 The designated officer shall plan, organize, co-ordinate, control and monitor all housekeeping, maintenance and laundry activities.
- 6.1.20.3 The housekeeping, maintenance and laundry personnels shall take basic trainings on the following issues and this shall be documented in their personal profile.
  - a) Basic principles of sanitation and peculiarity to hospital environment.
  - b) Basic principles of personal hygiene
  - c) Basic knowledge about different detergent and disinfectants
  - d) Different cleaning procedures applicable to different hospital areas
  - e) Basic knowledge about cleaning equipments operation techniques and their maintenance.
  - f) Different processes of water treatment & purification, removing bacteria.
  - g) Basic principles of ventilation, composition of Air, Air flow, Humidity and temperature.
  - h) Common types of odors and their sources of origin, identification and control.
  - i) Removal and control technique of different types of odors.
  - j) Various equipments and materials used for odor control operation.
  - k) Hospital Waste, Source and generation of waste
  - l) Hazards of hospital waste to hospital population and community.
  - m) Principles of collection of different types of hospital wastes
  - n) Operational procedures of equipments
  - o) Safety measures in operation
  - p) Infection prevention principles
  - q) Hospital lay out, configuration work, flow of men, material and equipment in different hospital areas. Air, water, noise, pollution, causes of pollution and their control and prevention in hospital.
- 6.1.20.4 The following professions shall be available (the number of professionals depend on the workload)

- (a) Engineer (electrical, civil) or architect
- (b) Plumber or Painter.
- (c) Maintenance technician or Biomedical engineer for equipment maintenance
- (d) Cleaners

## 6.1.21 Products

- 6.1.21.1 There shall be appropriate tools and testing equipments for medical equipment maintenance, calibration and validation.
- 6.1.21.2 The hospital shall have the following tools, equipment & raw materials for housekeeping services.
  - a) Equipment:
    - Floor cleaning brush air
    - Floor wiping brush
    - Hockey type brush
    - Counter brush.
    - Ceiling brush
    - Glass cleaning/ wiping brush.
    - Scrappers
    - Dustbins paddles.
    - Waste paper basket.
    - Plastic Mug
    - Plastic Bucket
    - Plastic drum
    - · Wheel barrow
    - Water trolley
    - Ladder
    - Scraping pump
  - b) Cleaning material
  - c) Disinfectant and air freshener
  - d) Laundry cleaning material

- Spraying pump
- Flit pump.
- Rate trapping cage
- Gum boots
- Gown, masks & heavy duty gloves
- Torch
- Manual sweeping machine.
- Floor scrubbing/polishing machine
- Wet vacuum cleaner.
- Dry vacuum cleaner portable
- Fumigation machine (Oticare)
- Bed pan washer.

- e) Insecticides & rodenticides
- f) Stain removal
- 6.1.21.3 Workshop equipment and tools shall be available

### 6.36 Social Work Services

### 6.1.22 Practices

- 6.1.22.1 The hospital shall have an organized, supervised and well staffed social work services.
- 6.1.22.2 There shall be an organizational chart or alternative documentation clearly delineating the lines of responsibility, authority and communication for the social services.
- 6.1.22.3 The social work service shall have written policies and procedures that are reviewed at least once every three years, or revised more frequently as needed, and implemented.
- 6.1.22.4 The policies and procedures concerning the social work services shall address the following areas:
  - a) Counseling,
  - b) Discharge management and planning,
  - c) Social work assessment
  - d) Consultation and referral to support groups, centers and/or organizations
  - e) Patient advocacy
  - f) Community liaison and education.
- 6.1.22.5 The social work service shall have a protocol to ensure that social work services are offered to all needy patients.
- 6.1.22.6 Patient directory shall be available in the hospital and shall be updated regularly.
- 6.1.22.7 The social work services shall have criteria for identifying at the time of admission and promptly assessing high-risk patients in need of psychosocial intervention and/or discharge planning.
- 6.1.22.8 The social work service shall participate in the development and review of the hospital's agreements with extended and long-term care facilities.
- 6.1.22.9 There shall be a system for clinical staff to refer patients directly to the social work service
- 6.1.22.10 The social worker shall consult members of other disciplines providing patient care and services.

- 6.1.22.11 Each patient who has received social work intervention shall be informed that he or she may call the social work service unit for questions after discharge.
- 6.1.22.12 Patient's families or guardians should be included in services provided by the social work service unit, where indicated.
- 6.1.22.13 The social work service unit shall assist patients directly or indirectly in identifying the need for implementing and verifying guardianship as part of discharge planning.
- 6.1.22.14 The social work service unit shall report victims of abuse to the appropriate body.
- 6.1.22.15 When a patient is transferred or linked to another health care facility after discharge, the social work service unit shall assure that relevant social work service documentation or information is provided to the facility in order to assure continuity of care.
- 6.1.22.16 When social work intervention is provided, a record shall be kept in accordance with standards in the medical record. The record shall have at least the following information
  - a) The reason for intervention;
  - b) The name (s) of social workers involved and dates of intervention;
  - c) A social work assessment;
  - d) A treatment plan and referrals; and
  - e) Notes reflecting interventions before discharge.
- 6.1.22.17 Patients' files, at social work service unit, shall be kept physically secure and confidential.
- 6.1.22.18 All reasonable efforts shall be made for privacy in patient and family interviews and in the handling of confidential phone calls by social workers.
- 6.1.22.19 The hospital shall have a program of continuous quality improvement for social work that is integrated into the hospital continuous quality improvement program and pertains to the scope of social work services provided.
- 6.1.22.20 Adoptions by individuals or groups shall abide the laws and regulations of the country

#### 6.1.23 Premises

- 6.1.23.1 The hospital shall have a well organized, adequately staffed separate social work service unit or area
- 6.1.23.2 The following separate rooms shall be available:
  - a) Social worker office
  - b) Patient and family interview rooms
  - c) Handling of confidential phone calls room
  - d) Archive

#### **6.1.24 Professionals**

- 6.1.24.1 All social work services given by the hospital shall be under the direct supervision of a social worker graduated from a recognized College/University or psychologist or licensed nurse psychiatrist or a professional nurse with experience in social work.
- 6.1.24.2 All the social work staff shall take multidisciplinary patient care training at least annually and the information about their training shall be documented.

## 6.1.25 Products

- 6.1.25.1 The social work service unit shall have the following products and facilities:
  - a) Telephone
  - b) The necessary forms and documenting means for referral, adoption and transfer
  - c) Computer
  - d) Filing cabinet

## 6.37 Care after Death and Morgue Services

#### 6.1.26 Practices

- 6.1.26.1 The hospital shall have written policies and procedures for morgue (dead body care) services. These policies shall delineate the responsibilities of the medical staff, nursing, and morgue services staff, and shall include procedures for at least the following:
  - a. Confirmation of death by physician, identification of the body, recording and labeling;
  - b. Safe and proper handling of the body to prevent damage and this shall be according to the patient religion and culture;
  - c. Safeguarding personal effects of the deceased and release of personal effects to the appropriate individual or family;
  - d. Proper handling of toxic chemicals by morgue and housekeeping staff;
  - e. Infection control, including disinfection of equipment as per IP standard;
  - f. Identifying and handling high-risk and/or infectious bodies;
  - g. Release of the body to the family shall be as immediately as possible;
  - h. Autopsy service if available
- 6.1.26.2 There shall be a death certificate issued by authorized physician for each death and this shall be documented.
- 6.1.26.3 The service shall be available for 24 hours a day and 365 days of a year
- 6.1.26.4 Any dead body shall be treated in a human way that respects human dignity (postmortem autopsy shall not destroy the anatomical structure as much as possible and closure of open body shall respect again the dignity of human being)
- 6.1.26.5 Any dead body shall pass through morgue after the confirmation of death by the physician
- 6.1.26.6 Dead body discharge shall be through the morgue exit

### 6.1.27 Premises

- 6.1.27.1 The morgue shall be equipped with refrigerated space to store at least two bodies. Hospitals with more than 100 beds shall provide additional space using a ratio of one space to every additional 100 beds.
- 6.1.27.2 In addition, the morgue premises shall fulfill at least the followings:
  - (a) Dead body care taking room
  - (b) Postmortem room
  - (c) Adequate Water supply
  - (d) Well ventilated
  - (e) Adequate supply of light
  - (f) Attendant office

### 6.1.28 Professionals

- 6.1.28.1 There shall be a licensed pathologist, in hospitals where autopsy service is available.
- 6.1.28.2 Trained nurse or trained morgue attendant and cleaner

## 6.1.29 Products

- 6.1.29.1 Refrigerated spaces in the morgue shall be maintained at temperatures between 32 and 45 degrees Fahrenheit (0 and 6.6 degrees Celsius) and shall have an automatic alarm system that monitors the temperature.
- 6.1.29.2 In addition, the following products shall be available for morgue services:
  - (a) Plastic sheets
  - (b) Aprons
  - (c) Stretcher
  - (d) Knives, Scalpels, Scissor
  - (e) Formalin, Detergents,
    Disinfectants
  - (f) Cotton, bandage, gloves, boots, gowns, head cover
  - (g) Goggles

- (h) Plastic bags
- (i) White clothes
- (j) Body table with hot and cold water sink
- (k) Cupboard for instrument
- (l) Scale
- (m)Syringe & long needle &
- (n) Minor sets including retractor

# **Section 7: Physical Facility standards**

#### 7.1. General

Every specialized hospital subject to these Minimum Standards shall be housed in a safe building which contains all the facilities required to render the services contemplated in the application for license. The term "safe" used in this Section shall be interpreted in the light of compliance with the requirements of the latest country building codes presently in effect.

## 7.2. Site Selection Requirements

- 7.2.1. The entry points to the hospital shall be clearly defined from all major exterior circulation modes (roadways, bus stops, vehicle parking)
- 7.2.2. Boundaries of the hospital between public and private areas shall be well marked and clearly distinguished. And clearly visible and understandable signage and visual land marks for orientation shall be provided
- 7.2.3. The specialized hospital shall be located away from unordinary conditions of undue noises, smoke, dust or foul odors, and shall not be located adjacent to railroads, freight yards, grinding mills, chemical industries, gas depot and waste disposal sites.
- 7.2.4. The locations of a hospital shall comply with all national and state level regulations applicable to health facilities.
- 7.2.5. The site selection criteria shall consider or include the followings, but not limited to:
  - a) The minimum size of a specialized hospital premises shall be  $30,000\ m^2$  with two side adjacent road access.
  - b) The hospital shall be built preferably in a terrain with a gentle slop
  - c) The foundation schemes, soil test and investigation shall be done and it shall comply with the national building code and seismic requirements.
  - d) The hospital shall be provided with road access, water supply, electric city and communication facilities.

- e) The building shall be parallel to the wind direction, sun glare and heat. In case difficulties to fulfill these, there shall be technical solutions for such natural effects.
- f) The surroundings of the hospital shall be free from dangers of flooding, landslide, theft, intrusion of stray/wild animals, pollution of any kind (example air, water and sound) and health hazards.
- g) The hospital shall be landscaped, therapeutic, appealing scenery, attractive with green areas/beautiful trees and possible outdoor recreation facilities.

## 7.3. Construction Requirements

- 7.3.1. The Authority shall be consulted before commencement of any health facility physical development for new, remodeling and additions to an existing licensed hospital to ensure conformity to the standards.
- 7.3.2. The hospital or the investor shall sign memorandum of understanding of plan agreement prepared by the Authority in line with this standard.
- 7.3.3. Plans and specifications for any hospital construction or remodeling shall comply with Ethiopian Building Code. Based on the plan agreement, the following plans shall be submitted to the Authority for review:
  - a) Preliminary Design Report: Includes schematics of building designs, plot plans showing size and shape of entire site, existing structures, streets and location and characteristics of all needed utilities, floor plans of every floor dimensioned and with proposed use of each room or area shown and preliminary engineering estimates. If it is for additions or remodeling, provide plan of existing building showing all proposed alterations, outline specifications to include a general description of the construction, type of finishes, and type of heating, ventilating, plumbing and electrical systems proposed. In summary the design report shall include all requirements healthy facility premises stipulated under this document.
  - b) The hospital or the investor shall get consensus on preliminary design report in writing from the Authority.
- 7.3.4. The authority may be consulted on construction processes and milestones for conformity to the standards.
- 7.3.5. Upon completion of construction the authority shall inspect and issue a license for operation of the hospital if all the findings are in conformity to this standard.

- 7.3.6. Buildings designed for other purposes shall not be used for the operation of a hospital unless it is remodeled in accordance with this standard.
- 7.3.7. All hospitals shall be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided.
- 7.3.8. All hospitals shall have at least three entry/exit sites and they shall be accessible to roads.
  - a) Main public entrance
  - b) Emergency entrance
  - c) Staff and service entrance
  - d) Morgue entrance and/or exit
- 7.3.9. The construction shall comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:
  - a) The Ethiopian Building Proclamation 624/2009;
  - b) The Ethiopian Standard Building Code;
  - c) Life Safety Code (National Fire Protection Code);
  - d) National Electrical Design Code;
  - e) The Ethiopian Disability Code;
  - f) Other codes ex. Sanitation codes, environmental protection laws, water codes
- 7.3.10. Building entrances used to reach the outpatient & inpatient services and exit sites shall be easily accessible, clearly marked/labeled and located, in order to patients and visitors will have clear way finding.
- 7.3.11. Utilization of proper construction materials should be used in conformity to the Ethiopian Building Code, that suit the health services delivery.

## 7.4. Building Space and Elements

7.4.1. All horizontal and vertical circulation areas that include stairs, doors, windows, corridors, exits and entrances of the hospital shall be kept clear and free of obstructions and shall not be used for other functional purposes that include storages.

- 7.4.2. Rooms: All room size and space allocation shall consider room loadings based on the current staff, clients involved, usable medical equipments, furniture and applicable functions.
- 7.4.3. The hospital circulation (main and sub corridors): shall be wide enough to allow passage for its function
- 7.4.4. Patient serving corridors: should not be less than 240cm wide, and proportionally the openings to the corridor needs to be designed to allow easy movement of coaches and be equipped as needed by the patient with safety and all assistive devices (it includes: door stopper, protecting girders, alarms, self opening electronic devices, etc).
- 7.4.5. Doors: all Doors shall be able to easily open and close, doors swing into corridors shall be avoided.
- 7.4.6. Patient rooms: Each patient room shall meet the following requirements:
  - All patient functioning rooms, toilet, and bathing room doors shall provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.
  - b) Area: Shall contain  $9.20m^2$  ( $100ft^2$ ) of floor area for a single bedroom and  $7.50m^2$  ( $80ft^2$ ) per bed in multi-bedrooms.
  - c) Ceiling Height: Ceiling height needs to be determined based on the functional requirements considering air space, technical requirements, room size proportions, number of occupants and other parameters. The height of the ceiling of the rooms shall not less than 240cm high for support services, 220cm for technical corridors (operation theater 320 cm, X-ray 320 cm, room requiring interstitial floor needs to be more than 580cm) and 280cm for other clinical rooms.
  - d) Windows. All rooms housing patients shall have access to natural light and ventilation, or prove the availability of artificial ventilation and light at all times. Rooms shall have window area proportional to that of floor areas which is equal to 1'8" of the floor area. The sill shall not be higher than 36 inches above the floor and shall be above grade. For toilets and washing rooms, over desk laboratory tables, laundry and kitchen utensils, the height can be modified accordingly) Windows shall not have any

- obstruction to vision (wall, cooling tower, etc.) within 50 feet as measured perpendicular to the plane of the window.
- e) Storage: Each patient shall be provided with a hanging storage space of not less than 40.cm x 60.cm x 130cm (16" x 24" x 52") for his personal belongings.
- f) Furnishings: A hospital shall provide comfortable patient trigonometric designs, applicable functions, and technical requirements. They have to be hygienic (washable, dust and bacteria protective and resistant for cleansing reagents) durable that can control vandalism and avoid accidents.
- g) Curtains: rooms shall be equipped with curtains or blinds at windows. All curtains shall have a flame spread of 25 or less or as per the national fire protection code. And all as per the national infection prevention guidelines requirements.
- h) Cubicle curtains or equivalent built-in devices for privacy in all multi-bed rooms shall be provided. They shall have a flame spread of 25 or less or as per the national fire protection code.

## i) Finishing

- Walls, floors and ceilings of procedure rooms, isolation rooms, sterile
  processing rooms, work room, laundry and food-preparation areas
  shall be suitable for easily washing. All floors of the hospital clinical
  service areas shall be washable, smooth, non- adsorptive, surfaces
  which are not physically affected by routine housekeeping cleaning
  solutions and methods. Acoustic lay-in ceilings, if used, shall be nonperforated.
- Public spaces such as reception areas, waiting areas, cafeterias, areas
  requiring silence and sub specialty areas like psychiatry shall be
  designed with acoustic control and the lamination/lay shall be nonperforated.
- Scrub-able room finishes provided in operating rooms and isolation rooms shall have smooth, non-adsorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

 All walls and ceiling finishing materials used shall have a 1-hour fire rating (One hour rated products offer more than "one hour's" worth of fire protection).

## j) Sanitary Finishing

- A lavatory equipped with wrist action handles, shall be located in the room or in a private toilet room.
- For hospitals with multiple bed wards without private toilet room shall provide bedpan washer.
- All sanitary room facilities floors, walls and ceilings shall be completed with washable finishing materials
- Floors and walls penetrated by pipes, ducts and conduits shall be tightly sealed to minimize entry of rodents and insects

## k) Electrical Finishing

- Patient bed light shall be controlled by the patients.
- Room light luminescence shall be bright enough for staff activities but needs to be controlled not to disturb the patients.
- All electrical fixtures inlets, outlets shall fulfill Ethiopia Electrical
   Safety requirements and if applicable fitted with guards
- For psychiatry service area light fixtures, sprinkler heads and other apparatus shall be of a temper resistant type.
- 7.4.7. **Outdoor Areas:** the hospital outdoor area shall be equipped and situated to allow for the safety and abilities of patients, care givers, staff and visitors.
  - a) The landscape shall be designed with patient room visual acquit or access
  - b) Walkways, connection roads and elevation differences shall be designed to allow movements of coaches/stretchers and persons with disabilities.
  - c) The outdoor traffic arrangement shall not cross each other to avoid accidents
- 7.4.8. **Windows**: In all rooms, windows shall comply with lux requirements of room space without compromising room temperature and ventilation.
  - a) Windows shall be a minimum of 50 cm wide x 100cm high. However, in case of hot climate areas, this may not be applicable

- b) No window shall swing inside the room except those which require security and safety measures such as grid for theft and insect mesh for malaria porn areas.
- c) Windows that frequently left open for cross ventilation purpose (like TB clinic room windows) shall be equipped with insect screen. At least a top portion of a window shall be left open fitted with insect mesh for uninterrupted circulation of air.
- d) Safety glass, tempered glass or plastic glass materials shall be used for pediatrics and psychiatric service units to avoid possible injuries.
- 7.4.9. **Vertical Circulation:** All functioning hospital rooms shall be accessible horizontally.
  - a) **Stairs:** All stairways and ramps shall have handrails and their minimum width shall be 120cm.
    - All stairways shall have a 2-hour fire enclosure with a (1.5 hour) label door at all landings or as per the national fire protection code or law.
    - All stairways shall be fitted with non slippery finishing materials
    - All stair threads, riser and flight shall comply with patient type as per the Ethiopia Building proclamation
  - b) **Ramp**: Ramps shall be designed with a slope of 6 to 9 percent, minimum width of 120 cm and the landing floor of 240cm wide on both sides.
  - c) Shoots: Hospital buildings having services in the upper floor shall have shoots facility. Shoots shall be free of possible accidents and the inlets and outlets shall be confined in a lockable room.
  - d) **Elevators**: In the absence of engineered traffic study, at least two hospital type elevators shall be installed where 1-200 patient beds are located in the upper floors. In case of more than 200 beds, the number of elevators shall be determined from a study plan and expected vertical transportation requirements. Minimum cab dimensions required for elevators transporting patients is 195cm x 130cm inside clear measurements and minimum width for hatchway and cab doors shall be 100cm.

## 7.4.10. Fire Safety Considerations:

- a) One-Story Building: Wall, ceiling and roof construction shall be of 1-hour fire resistive construction as defined by National Fire Protection "Life Safety Code or law. Floor systems shall be of non-combustible construction.
- b) **Multi-Story Buildings**: Must be of two-hour fire resistive construction as defined in National Fire Protection "Life Safety Code or laws.
- c) Travel Distances and alternative vertical circulation: Hospital facilities travel distance from service giving room to the stairs should be as specified in the National Fire Protection "Life Safety Code or laws. Alternative fire escape stair should be provided otherwise.

### 7.4.11. Parking areas:

- a) The hospital shall have separate parking spaces for hospital ambulance.
- b) Parking space shall have a clear mark for Staff, Patients and Visitors with separate 10% of it for person with disability parking all as per Ethiopia Building Proclamation and building code.
- c) General services of the hospital that require loading unloading docks, heavier truck movement and temporary truck parking place shall be available.
- d) The parking space shall not cross pedestrian walkways, if it is mandatory to cross proper precaution measures such as Zebra Road, Speed Breaker, guiding notice and traffic stopping culverts or signals should be provided.

## 7.5. Building Systems

Hospitals shall have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort and well being of the patient.

### 7.5.1. Water supply and plumbing:

- a) Continuously circulated as per the type of fixture used, filtered and treated water systems shall be provided as required for the care and treatment in the hospital
- All hospitals subject to be connected to an approved municipal water system whose purity has been certified by the concerned body. The water

- supplies must be sampled, tested, and its purity certified at least twice annually and immediately following any repair or modification to the underground lines, the elevated tank, or to the well or pump.
- c) All hospitals subject to be connected to separate water supply system shall qualify and certified by the concerned body regularly. In house quality control shall be established, the water supplies must be sampled, tested, and its purity certified at least twice semi-annually and immediately following any repair or modification to the underground lines, the elevated tank, or to the well or pump.
- d) The hospital shall have and maintain an accessible, adequate both as to volume and pressure, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the hospital shall be connected to it and its supply used exclusively. Deficiencies in either safety and adequacy in volume or pressure must be remedied by the provision of auxiliary pumps, pressure tanks or elevated tanks as may be required.
- e) The collection, treatment, storage, and distribution potable water system of a hospital shall be constructed, maintained, and operated in accordance with all provisions of the Safe Drinking Water of the country.
- f) Supply piping within the building shall be in accordance with plumbing standards. Special care must be taken to avoid use of any device or installation which might cause contamination of the supply through backsiphonage or cross connections or the water distribution system shall be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.
- g) A treated backup water supply shall be readily available in the hospital like a reservoir or dedicated well. In case, if for any reason the main water supply is inaccessible. A contingency plan should be envisage in severe cases where supply disconnected and backup finished.
- h) The hospital shall have an approved method of supplying hot water for all hospital consumption. Water to lavatories and scrub sinks must be 37.8 54°C. Water to mechanical dishwashers must be delivered at 82 °C for rinsing.

## 7.5.2. Sewerage and Waste Processing Systems

- a) The hospital shall maintain a sanitary and functioning sewage system in accordance with the national healthcare waste management guidelines and Ethiopian building code.
  - b) In addition, the hospital shall fulfill the following requirements;
  - a) The hospital shall dispose all sanitary wastes produced in the hospital through connection to a suitable municipal sewerage system or through a private sewerage system if applicable. Where there is no municipal or private sewerage system the hospital shall provide a designed and well marked septic tank, or other similar facility according to the local environment and protected method that require the approval of the authority
  - b) The hospital sewage system shall be segregated from hazardous hospital waste before it enters the municipal or private sewage system.
  - c) The hospital shall provide areas to collect, contain, process, and dispose of medical and general waste produced within the hospital in such a manner as to prevent the attraction of rodents, flies and other insects and vermin, and to minimize the transmission of infectious diseases in accordance with waste management standards of this health facility.
  - d) The hospital shall have all the required waste management facilities (such proper segregation and disposal system by the nature of waste, over 600 degree Celsius combustor incinerator or sterilizer steam grinder, etc) as recommended by the national healthcare waste management guidelines.

## 7.5.3. Heating and Cooling, Ventilating and Air-Conditioning Systems:

- a) The hospital shall provide a heating and air conditioning system for the comfort of the patient and capable of maintaining the temperature in patient care and treatment areas.
- b) In the hospital, the system shall be capable of producing a temperature of at least seventy five degrees Fahrenheit (75°F) during heating conditions

- and a temperature that does not exceed eighty-five degrees Fahrenheit (85°F) during cooling conditions.
- c) The hospital to have a central air distribution and return systems which have the following percent dust spot rated filters:
  - General areas: thirty (30) +%; and
  - Care, treatment, and treatment processing areas: ninety (90) +%.
- d) Surgical areas shall have heating and cooling systems that are capable of producing a room temperatures at a range between sixty-eight Fahrenheit (68°F) and seventy-three degrees Fahrenheit (73°F) and humidity at a range between thirty (30%) and sixty percent (60%) relative humidity.
- e) Airflow shall move from clean to soiled locations. Air movement shall be designed to reduce the potential of contamination of clean areas.
- f) Floors in operating rooms, procedure rooms and other locations subject to wet cleaning methods or body fluids shall not have openings to the heating and cooling system.
- g) All hospitals shall provide adequate ventilation and/or clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patients and employees.
- h) Hospitals shall provide a mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens and similar rooms at ten air changes per hour.
- i) Hospitals shall provide mechanical ventilation system(s) capable of providing air changes per hour.
- j) Hospitals shall provide an emergency backup ventilation system for all patient rooms without operable windows.

## 7.6. Electrical System

- 7.6.1. The hospital shall have an electrical system that has sufficient capacity to maintain the care and treatment services and other services that are provided and that properly grounds care and treatment areas.
- 7.6.2. All facilities shall provide the minimum average illumination levels as follows or as per the Ethiopian Electrical Design Code:
  - a) General purpose areas: five (5) foot candles;
  - b) General corridors: ten (10) foot candles;

- c) Personal care and dining areas: twenty (20) foot candles;
- d) Reading and activity areas: thirty (30) foot candles;
- e) Food preparation areas: forty (40) foot candles;
- f) Hazardous work surfaces: fifty (50) foot candles;
- g) Care and treatment locations: seventy (70) foot candles;
- h) Examination task lighting: one hundred (100) foot candles;
- i) Procedure task lighting: two hundred (200) foot candles;
- j) Surgery task lighting: one thousand (1000) foot candles; and
- k) Reduced night lighting in patient rooms and corridors.
- Three hours Emergency light shall be provided in exit, entry and in all landing of staircase.
- 7.6.3. Essential Power System: Hospitals shall have an automatic power generator for all care and treatment locations which involve general anesthetics or electrical life support equipments, and in emergency procedure and treatment rooms.
  - a) Different generators shall be available, at least diesel generator and white fuel generator.
  - b) There shall be enough stored fuel to maintain power for at least 24 hours.
  - c) If a generator is used, there must be a staff member assigned to the regular maintenance of the generator to guarantee it will function properly when needed.
  - d) Staff member will also ensure a sufficient supply of diesel gas and charged batteries for start-up purposes
  - e) Solar panels are also an acceptable if used as backup power option.
  - f) Central UPS system for ups outlets of selected area (like ICU, delivery, Operation Theater, laboratory) shall be provided as backup power option.

### 7.7. Fire Protection System

- 7.7.1. The hospital shall comply with the National Fire Protection "Life Safety Code".
- 7.7.2. The Hospitals shall have an automatic fire alarm and smoke detector system for all care and treatment rooms.

- Heat detectors used for car park, kitchen, transformer room lift pit area.
- Sounder base photo electric smoke detector will be proposes for the bed room and all other rooms.
- Typical floor station located to convenient location in the lobby.
- 7.7.3. Essential Public Address System: Hospitals shall have an automatic voice communication /evacuation signal, from different sources; automatic control signal from fire alarm system, tape/CD player for pre recorded message to all care and treatment locations rooms.
- 7.7.4. Lightening Arrestor and Grounding System: Hospitals shall have technically advised lightning protection system, comprises air termination, down conductor and earth termination. Protection zone shall cover a minimum of the diameter of the building
- 7.7.5. All employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and patient evacuation of hospital buildings as part of their initial orientation and at least annually thereafter.
- 7.7.6. All employees shall receive printed instructions on procedures to be followed in case of emergency, including patient evacuation of the buildings.
- 7.7.7. A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall in each patient care unit.
- 7.7.8. Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydrotested as required by manufacturer's instructions; and labeled with the date of the last inspection.
- 7.7.9. Fire detectors and alarm systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last two inspections shall be kept on file.
- 7.7.10. There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.
- 7.7.11. There shall be a procedure for investigating and reporting fires. All fires that result in a patient or patients being moved shall be reported to the Authority. Immediately in writing within 72 hours. In addition, a written report of the

investigation shall be forwarded to the Authority as soon as it becomes available.

## 7.8. Call Systems

- 7.8.1. Call systems shall be operable from all patient private spaces. Such us from patient beds (except at psychiatric or mental hospital beds), procedure and operating rooms, and recovery bed, bathing and toilet locations.
- 7.8.2. The system shall transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.
- 7.8.3. In locations where patients are unable to activate the call, a dedicated staff assists or code call device shall promptly summon other staff for assistance or continuous visual connection to supper attending staff should be provided.

## 7.9. Medical Gas System

- 7.9.1. The hospital shall safely provide centrally managed medical gas and vacuum by means of portable equipment or building installation systems as required. Electromechanical system for central supply shall be installed for areas such as operation theater, Delivery, special procedure rooms, Intensive care unit, laboratory and sterilization,
- 7.9.2. The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems shall comply with the requirements of the Life Safety Code (National Fire Protection agency proclamation).
- 7.9.3. The hospital shall identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The hospital shall document such approvals for review and reference.

### 7.10. Health Facility Environment

- 7.10.1. The hospital shall provide and maintain a safe environment for patients, caregivers, visitors, staff and the general public.
- 7.10.2. All facilities shall comply with the following applicable codes, laws and standards for safe environment:

- a) Ethiopian Environmental requirements for hospital facilities
- b) National Fire Protection Life Safety Code and laws; and
- c) Other related Regulations
- 7.10.3. Existing and new hospital shall comply with the physical facility standards stated under this standard. The hospital shall maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

## 7.11. Specific Service Areas

- 7.11.1. The hospital may have dining areas as per the following requirements:
  - a) Dining areas for patients shall have an outside wall with windows for natural light and ventilation.
  - b) Dining areas shall be furnished with tables and chairs that accommodate or conform to patient needs.
  - c) Dining areas shall have a floor area of at least 15-20 square feet (1.4m² to1.9m²) per patient.
  - d) Dining areas shall allow for group dining at the same time in either separate dining areas or a common dining area, or dining in two (2) shifts, or dining during open dining hours.
  - e) Dining areas shall not be used for other services.

## 7.11.2. Bathing and Toilet Rooms:

- a) In case of common bathing and toilet room, one shall be dedicated for seven patients at all times.
- b) A hospital shall provide a bathing room consisting of a tub and/or shower adjacent to each bedroom or provide a central bathing room on each floor with patient rooms. Tubs and showers regardless of location shall be equipped with hand grips or other assistive devices as needed or desired by the bathing patient.
- c) The hospital shall provide toilet rooms with hand-washing sinks for patient and staffs shall use separately for each service units. In addition the following requirements shall be ensured
  - Flushable toilets shall be available throughout the workplace.

- Posted signs (written and/or visual messages) shall be indicated describing which is for ladies and gentle (or female and male)
- Indicating arrows shall be located on the corridors
- At least one toilet room shall be designated for patients with disability with all assisted services.
- 7.11.3. **Patient Rooms:** the hospital shall provide patient rooms which allow the provision of medical intervention, shall have space for sleeping, afford privacy, provide access to furniture and belongings, and accommodate inpatient care and treatment. In addition Patient Rooms:
  - a) Shall be arranged to maximize staff supervision and nursing assistances.
  - b) No patient room shall be located away from nursing stations without proper covered gang ways and travel premise requirements.
  - c) Shall not be accessed directly through a bathroom, food preparation area, laundry or another bedroom;
  - d) Shall be located on an outside wall with a window with a minimum glass size of 8 square feet or equivalent meter square per patient.
  - e) If they have multiple beds, shall allow for an accessible arrangement of furniture, which provides a minimum of three (3) feet or equivalent meter between beds.
- 7.11.4. **Isolation Rooms:** The number and type of isolation rooms in a hospital shall be determined by the hospital and direct caregiver. The determination shall be based upon an infection control risk assessment, patients' requirements and patients influence on other room occupants. In addition:
  - a) Hospitals shall make provisions for isolating patients with infectious diseases prevention.
  - b) An isolation room shall have an adjoining bath and toilet room.
  - c) Hospitals shall equip isolation rooms with hand-washing and gown changing facilities at the entrance of the room.
- 7.11.5. **Observation Areas:** If the hospital provides medical observation, extended recovery or behavior intervention methods, the hospital shall provide one or more appropriately equipped rooms for patients needing close supervision. Each room shall:
  - a) Have appropriate temperature control, ventilation and lighting;

- b) Be void of unsafe wall or ceiling fixtures and sharp edges;
- Have a way to observe the patient, such as an observation window or if necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room;
- d) Have a way to assure that the door cannot be held closed by the patient in the room which could deny staff immediate access to the room; and
- e) Be equipped to minimize the potential of the patient's escape, injury, suicide or hiding of restricted substances.
- f) Shall be provided with proper safety communication systems and emergency signaling.
- 7.11.6. **Critical Care Rooms/ICU:** If monitored complex nursing care is provided, the hospital shall provide one or more rooms for patients needing the care.
  - a) Each room shall be appropriately located and equipped to promote staff observation of patients.
  - b) Rooms with a single occupant shall have a minimum floor area of not less than one hundred and thirty (130) square feet or equivalent meter square.
  - c) Multiple bed locations shall contain at least one hundred and ten (110) square feet or equivalent meter square per bed with a minimum of four (4) feet or equivalent meter between beds.
  - d) The room shall include provision for life support, medical gas, sleeping, and convenient bathing and toileting facilities.
- 7.11.7. **Cubicles:** Patient care and treatment cubicles shall have a minimum floor area of sixty (60) square feet with at least three (3) feet between bedsides and adjacent side walls.
- 7.11.8. **Examination Rooms:** Each examination room shall have a minimum floor area of eighty (80) square feet and a minimum of three (3) feet clear dimension around three (3) sides of the examination table or chair.
- 7.11.9. **Treatment Rooms:** Treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation shall have a minimum floor area of one hundred and twenty (120) square feet and a minimum of ten (10) feet clear dimension.
- 7.11.10. **Procedure Rooms:** Procedure rooms for invasive and minor surgical procedures performed in conjunction with oral, parenteral, or intravenous

sedation or under analysesic or dissociative medicines shall have a minimum floor area of two hundred (200) square feet and a minimum of fourteen (14) feet clear dimension.

- 7.11.11. **Operating Rooms:** Operating rooms for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions shall have a minimum floor area of three hundred (300) square feet and a minimum of sixteen (16) feet clear dimension.
- 7.11.12. **Privacy:** In multiple bed patient rooms, visual privacy, and window curtains shall be provided for each patient. The curtain layout shall totally surround each care and treatment location which will not restrict access to the entrance to the room, layatory, toilet, or enclosed storage facilities.

### 7.12. Care and Treatment Areas

- 7.12.1. The hospital shall not share care and treatment areas for those services which require dedicated space
- 7.12.2. The hospital shall not provide services in detached structures unless the way of service delivery allows or proper building configuration established.
- 7.12.3. The care and treatment areas of the hospital shall comply with the requirements stipulated under the premises of each service standards.

## 7.13. Ancillary areas

- 7.13.1. **Dietary**: If food preparation is provided in the hospital, the hospital shall dedicate space and equipment for the preparation of meals and separate washing room (dishes and other food preparation equipments), refrigerated and non-refrigerated storage areas in accordance with the standards mentioned under the Food and dietary services section of this standard.
  - a) If contractual services are used for dietary services, the hospital shall have areas for immediate storage spaces, cleaning and disposal spaces.

- b) If contractual services are used, the hospital shall have a clear contractual agreement and the contractor shall comply with all the requirements prescribed under this standards.
- 7.13.2. **Laundry**: The hospital shall provide laundry services by contract or on-site.
  - a) Contract:
    - If contractual services are used, the hospital shall have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.
    - Separate clean linen supply storage area shall be conveniently located in each care and treatment locations
    - If contractual services are used, the hospital shall have a clear contractual agreement and the contractor shall comply with all the requirements prescribed under this standard.
  - b) On-site: If on-site services are provided, the hospital shall have areas dedicated to laundry in accordance with the following requirements:
    - The laundry areas shall be equipped with a washer and dryer.
       The hospital shall provide a conveniently located sink for soaking and hand-washing of laundry.
    - Hospital laundry area for hospital processed bulk laundry shall be divided into separate soiled (sort and wash areas) and clean (drying, folding, and mending areas) rooms. In new facilities a separate soaking and hand-washing sink and housekeeping room shall be provided in the laundry area.
    - Separate clean linen supply storage facilities shall be conveniently located in each care and treatment location.
    - In general the standards stipulated under housekeeping, laundry section of this standard shall be respected.
- 7.13.3. **Administrative Areas:** Administrative Offices shall be located separately from care and treatment areas and it shall be clearly labeled and easily accessible to patients, care givers and visitors. It includes;
  - a) Finance and business office.

- b) Administration office.
- c) Human resource management office
- d) Staff rooms with toilet separate for male and female
- e) Staff cafeteria
- f) Visitors cafeteria
- g) Spaces for conferences and in-service training
- h) General Library
- 7.13.4. **General Storage areas.** There shall be a two hour fire rated lockable room large enough to store.
- 7.13.5. **Boiler Room.** Space shall be adequate for the installation and maintenance of the required machinery.
- 7.13.6. **Maintenance Area:** Sufficient area for performing routine and preventive maintenance activities shall be provided (workshop area) and shall include office for maintenance personnels.
- 7.13.7. **Incinerator:** There shall be a dedicated area for incinerators and the hospital shall comply with the directives developed by the authority for health care waste management.
- 7.13.8. **Janitor rooms:** the hospital shall have separate janitor rooms in each care and treatment areas.
- 7.13.9. **Green area:** The hospital shall dedicate at least 20% of the total hospital compound for green area.

**Note:** All dimension, sizes and quantities noted herein will be determined by rounding fractions to the nearest whole number and measuring units like feet can be converted to country specific measuring units.

## 7.14. Bubble Diagrams











