GOVERNMENT OF PAKISTAN

Ministry of National Health Services Regulations and Coordination

Islamabad Healthcare Regulatory Authority (IHRA)

Notification

_____/2022 in exercise of the powers conferred under section 47 sub-section (1) and (2) of the Islamabad Healthcare Regulation Act, 2018 (XXIII of 2018), the Authority, with the previous sanction of the Federal Government, is pleased to make following regulations, namely:- "Islamabad Healthcare Regulatory Authority Regulations, 2022" and the same is hereby published for information of all persons likely to be affected thereby and notice is hereby given that comments, if any, received within fifteen days of the date of this notification will be taken into consideration.

ISALMABAD HEALTHCARE REGULATORY AUTHORITY REGULATIONS 2022

PART I

1. **Short Title, Commencement and application.- (1)**These regulations may be called the Islamabad Healthcare Regulatory Authority Regulations, 2022.

(2) They shall come into force at once.

(3) They shall apply to whole of the Islamabad Capital Territory.

2. **Definitions:**

i. "Act" means the Islamabad Healthcare Regulation Act, 2018;

ii. "Accounting Policies and Procedures Manual" means the Accounting Policies and Procedures Manual, issued by Government of Pakistan, on February 13, 1999;

iii. "Aggrieved Person" means a patient/client who is not satisfied with the services rendered to him by the Healthcare Establishment or healthcare professional and includes his next of kin or any other person duly authorized by him;

iv. "Ancillary Facilities" means and include any facility offered and/or provided by healthcare establishment which is not directly covered under the meaning of healthcare services but are ancillary or connected to provision of healthcare services;

v. "Applicant" means a healthcare service provider and /or a healthcare establishment requesting for registration, grant of license or renewal thereof and/or accreditation, as the case may be, in accordance with the provisions of the Act;

vi. "Assets" means all properties of the Authority, whether movable or immovable, consumable or non-consumable, owns or possessed by the Authority including but not limited to buildings, lands or anything attached to the building or land, vehicles, furniture, IT equipment, machinery, stock available in store of the authority;

vii. "Authority" means Islamabad Healthcare Regulatory Authority established under section 3 of the Islamabad Healthcare Regulation Act, 2018;

viii. "Bed" means such beds which are maintained and staffed for the care of admitted patients for overnight stay and shall include the following: -

a. Beds in all departments/ wards / rooms/ cots for sick babies and;
b. Unoccupied beds;
c. Exclusion Criteria; including but not limited to; Surgical tables, recovery trolleys/ beds, emergency stretchers, beds for same day care, cots for healthy infants, labor room beds; Beds in wards/ rooms/ store which were closed for any reason, and temporary beds;

ix. "Bin Card" means a document that records the status of goods held in stock of a store maintained by the storekeeper, showing the inflow and outflow movement of the stock;

x. "Board" means the Board of the Authority constituted under section 5 of the IHR Act, 2018;

xi. "Budget" means Annual Budget of the Authority;

xii. "Case" means any such matter which is taken by the Authority to probe and take further necessary action, within the scope of the Act and has not been filed before it as a complaint. The words 'Case' and 'Complaint', as the context may require, are being used interchangeably in the Regulations. Similarly, 'his' should be construed to mean 'her' or any intersex category;

xiii. "Category" means categorization of healthcare establishments based on the number of beds as notified by the Authority from time to time;

xiv. "CEO" means Chief Executive Officer of the Authority appointed under section 12 of the IHR Act, 2018;

xv. "Chairperson" means Chairperson of the Board; or chairperson of the Registration Board or a person heading a committee;

xvi. "Charter" means such Charter(s) as issued by the Authority from time to time, relating to the rights and responsibilities of the Patients/Clients and others, as well as that relating to the rights and responsibilities of the Healthcare Establishments;

xvii. "Client" includes a recipient of any Healthcare service or such services that are similar to forms of medical care including but not limited to Obstetric, Gynaecological, Paediatric, Dental, Surgical, Mental, Pharmaceutical, Physiotherapeutic, Veterinary, Hajama, Jarrahi, Vedic, Laboratory or Blood Bank related services etc. It also applies to Psychological and Spiritual healing services;

xviii. "Committee" or "Sub-Committee of the Authority" means and include;

a. the Management Committee of the Authority or such other Sub-Committees as may be constituted by the Authority for such specific purposes and with such powers as may be deemed appropriate by it, from time to time, for the purposes of the Act;
b. Committee formed by the CEO of the Authority from time to time as and when necessary for the performance of any function and purposes of Part II of the regulations; including but not limited to Internal Procurement Committee, Disposal and Auction Committee;
c. Inspection committees established under section 18 of the Act;

xix. "Competent Authority" means CEO or person authorized by the CEO to do a specific task such officers, or committee(s) comprising of one or more member(s), as nominated by the Authority, from within its staff, from time to time, authorized to take necessary action under the provisions of the Act and the regulations made thereunder, and also to pass such orders, including but not limited to interim orders, as deemed necessary, and exercise all or any such powers as provided for in the Act, including but not limited to issuing directions for complying with the standards, closure of services/ sealing of the healthcare establishment(s);

xx. "Commonly undertaken procedures" means and include all healthcare services and/ or procedures which are commonly carried out at healthcare establishments including but not limited to, consultation, OPD procedures, IPD procedures, Laboratory services, Imaging services etc. and notified by the Authority as from time to time;

xxi. "Complaint" means an application filed, under the Act and these regulations, by any person whether aggrieved or not against a healthcare establishment or a healthcare professional for grievance occurring in respect of any of such instances mentioned in the Act, regulations of rules;

xxii. "Complaint Hearing Committee" means a committee constituted by the Authority to hear and decide the complaints filed before the Authority;

xxiii. "Complaint Management Officer" means Director Legal & complaints or any other officer appointed or authorized in this behalf by the Authority;

xxiv. "Complaint Officer" means an officer of the Directorate of Complaints to whom a complaint has been entrusted with to probe or investigate, and to assist Complaint Hearing Committee on the facts of the complaint;

xxv. "Competent Authority" means the Chief Executive Officer or any other officer authorized by the Chief Executive Officer, as the case may be;

xxvi. "Complainant" includes an aggrieved person who files a complaint under the Act and these regulations, before the Authority;

xxvii. "Cost" means the actual cost incurred by a healthcare establishment for providing any healthcare service including services ancillary thereto, as determined in accordance with these Regulations;

xxviii. "Decision" includes an order of the Complaint Hearing Committee on the disposal of a complaint, an order of the Review Forum in disposal of Review Petition, Order in an appeal filed under section 31 of the Act;

xxix. "Directorate" means Directorate established under different parts of the regulation including; Directorate of Legal & Complaints, Directorate of Inspection;

xxx. "Employee" means any staff member of the healthcare establishment, whether serving under written or unwritten agreement(s) for service or of service;

xxxi. "Expert" means and includes

a. Expert for expert opinion is a person with a high degree of skills and knowledge in a particular subject, who has relevant and up to date expertise with regards to issues in the case/complaint and having qualifications and experience in the relevant field or speciality, as the case maybe;
b. member of an inspection team of the Authority having relevant qualification and experience, who will be designated as an inspection officer;

xxxii. "False Complaint" means a frivolous or vexatious Complaint made with an intention to harass, defame, embarrass, and/or to pressurize the party complained against and is so probed to be false, after the investigation by the Authority;

xxxiii. "Fee" means such sum(s) of money which is prescribed by the Authority from time to time for the purposes of granting registration, license and /or Accreditation to a healthcare establishment its renewal and includes such additional fee(s) as may be prescribed by the Authority, for any particular purpose(s), specified herein

xxxiv. "Government" means Federal Government of Pakistan;

xxxv. "Head of Account" means head of accounts mentioned in the annual budget of the Authority;

xxxvi. "Healthcare Personnel" means and includes such healthcare provider(s) which are or have been rendering any kind of services at the healthcare establishment, including but not limited to doctors, consultants, nurses, paramedics, homoeopathic doctors and Hakims, serving under written agreement(s) for, or of service;

xxxvii. "Hearing" includes proceeding before the Hearing Committee under part V,VI and VII, Review Forum and appellate Forum, as the case may be, in order to ascertain the facts or issues arising in a case by involving one, any or all concerned parties;

xxxviii. "Incident" means any or all of the following occurrences which must be reported to the Authority within forty-eight hours;

a. Fires causing injury to patient(s);
b. Fires requiring evacuation of patient(s);
c. Fires requiring to move patient(s);
d. Emergency evacuation of patient(s) from all or parts of a healthcare establishment and;

xxxix. Suspected violation of any law relating to the provision of healthcare services;

xl. "Inspection" means the process of examining any apparatus, appliances, equipment, instrument, record, price lists, product, goods or items used or found in, or any practice or procedure being carried out, at a Healthcare Establishment or by a healthcare professional by an inspection team of the Authority, on the direction of the Competent Authority or In-charge of the inspection directorate;

xli. "Inspection team" Means a team comprising more than two experts having relevant qualifications and experience constituted by the registration Board;

xlii. "Inquiry Committee" includes any person or panel of experts duly authorized by the competent Authority, to conduct an inquiry into any matter or complaint referred to it;

xliii. "Investigation Officer" means an officer of the Authority who is authorized by the Directorate to investigate and/or process complaints;

xliv. "Kinds of healthcare establishment" means classification of healthcare establishments based on the kinds of services provided and as such notified by the Authority from time to time. Kinds of Public healthcare establishment shall be as designated by the concerned government department. Kinds of Private healthcare establishments include but not limited to;

a. Addiction Treatment Center: A healthcare establishment providing outdoor and / or indoor services to the addicts;

b. Advanced Diagnostic Center: A healthcare establishment where both laboratory and advanced imaging diagnostic services are provided;
c. Advanced Imaging Center: A healthcare establishment where advanced Imaging diagnostic services including but not limited to CT scan, MRI, CT angio, with or without basic imaging services are provided;
d. Clinical Laboratory: A healthcare establishment where only laboratory diagnostic services are provided;
e. Collection Center: A center where only samples are collected for their analysis at a Clinical Laboratory;
f. Cosmetic Surgery Clinic: A healthcare establishment providing specialized cosmetic surgery services through a surgeon having a post-graduate degree and valid registration from Pakistan Medical Commission;
g. Dental Clinic: A healthcare establishment providing only outpatient dentistry services through a dental surgeon having valid registration from the Pakistan Medical Commission;
h. Diagnostic Center: A healthcare establishment where both laboratory and imaging diagnostic services are provided;
i. Dialysis Center: A healthcare establishment where only dialysis services are provided under supervision of a medical practitioner having valid registration from Pakistan Medical Commission;
j. Family Planning Clinic: A healthcare establishment where only family planning services are provided;
k. General Medical Practitioner Clinic/ Dispensary: A healthcare establishment providing only outpatient services through a general medical practitioner having valid registration from the Pakistan Medical Commission;
l. Hair Transplant Clinic: A healthcare establishment providing only hair transplant services through a surgeon having post-graduate degree and valid registration from Pakistan Medical Commission;
m. Homoeopathic Clinic: A healthcare establishment providing only outpatient homoeopathic services through a homoeopathic practitioner having valid registration with National Council for Homoeopathy;
n. Hospital: A healthcare establishment with indoor services;
o. Imaging Center: A healthcare establishment where only Imaging diagnostic services are provided;
p. Maternity Home: A healthcare establishment providing outpatient and midwifery services through a doctor, Nurse midwife, Lady Heath Visitor, Midwife and / or Community Midwife;
q. Mobile Clinic: Customized vehicles that provide preventive and curative healthcare services through a qualified practitioner having valid registration from the Pakistan Medical Commission;
r. Nursing Home: A healthcare establishment for people such as the aged or chronically ill who do not need to be in a hospital but cannot be cared for at home;
s. Poly Clinic: A healthcare establishment providing only outpatient services of multiple kinds of the same system of treatment including but not limited to the

combinations of General Medical Practitioner, dentistry, Lab services, imaging services, specialists etc;

t. Single Specialty Clinic: A healthcare establishment providing only outpatient services in a particular specialty through a specialist having valid registration from the Pakistan Medical Commission;

u. Tib Clinic: A healthcare establishment providing only tib services on outpatient basis through a Hakim / Tabib having valid registration from the National Council for Tib;

xlv. "Local Purchase" means a procurement less than 0.1 million Rupees;

xlvi. "Maladministration" means poor or failed administration by a Healthcare Establishment and includes;

(i) A decision, process, recommendation, act of omission or commission which:

(a) is contrary to law, rules or regulations or is a departure from established practice or procedure, unless it is bonafide and for valid reasons; or

(b) is perverse, arbitrary or unreasonable, unjust, biased, oppressive, or discriminatory; or

(c) is based on relevant grounds; or

(d) involves the exercise of powers or the failure or the refusal to do so; and

(ii) Neglect, inattention, delay, incompetence, inefficiency and/or ineptitude, in the administration or discharge of duties and responsibilities including but not limited to, administrative irregularities, abuse of power, any act of omission or commission, incorrect action or failure to take any action, failure to foresee and take comprehensive precautionary measures against possible mishaps, failure to provide the requisite information, failure to investigate, failure to reply, misleading or inaccurate statements, inadequate liaison, corrupt behaviour, incorrect or illegal administration of a drug to a patient/client, incorrect or incomplete entry in a document or violation of human rights;

xlvii. "Malpractice" includes improper, unskilled, immoral, illegal, or unethical professional conduct by a Healthcare Service Provider or a person working at a Healthcare Establishment and being the proximate cause of injury or harm to another person;

xlviii. "Medical Record" includes documents including but not limited to, comprehensive medical history, examination(s), investigation(s), and treatment of the patient/client along with the progress note and Forensic/Death Record;

xlix. "meeting" means meeting of the Board of the Authority; Registration Board or of a committee constituted under the Act or regulations;

l. "Member" means a member of the Board of the Authority; or Registration Board; or a member of a committee;

li. "Motion" means a matter which falls in the jurisdiction of the Authority referred to it by the Supreme Court or the Islamabad High Court for further necessary actions;

lii. "Non-development" means Expenditure provided for in grants, relating to the on-going costs of Government, such as salaries and allowances of employees and contingent expenditures;

liii. "Notice" means any information communiqué sent to the concerned party by the Competent Authority or Investigation Officer or any authorized officer, as the case may be;

liv. Other procedures" means procedures other than commonly undertaken procedures;

lv. "Pakistan Medical Commission" means the Pakistan Medical Commission constituted under the Pakistan Medical Commission Act, 2020 (XXXIII of 2020);

lvi. "Penalties" mean such Penalties as may be prescribed by the Authority from time to time under the provisions of the Act and regulations made therein;

lvii. "Prescribed" means prescribed by the rules and regulations made under the Act;

lviii. "Price" means the amount to be charged by a healthcare establishment, from the patient/beneficiary, for providing healthcare services including facilities ancillary thereto, as determined under these regulations;

lix. "Pricing Cell/Department" means the Pricing Cell/Department notified/established by the Authority pursuant to these regulations;

lx. "Principal Accounting Officer" means any official notified as the Principal Accounting Officer, that shall be responsible and accountable for the management of the Authority's funds and assets;

lxi. "Quality Assurance & Compliance Committee" means committee established by a healthcare establishment or healthcare service provider, as the case may be, and entrusted with the responsibility and capacity to ensure compliance with the governing law, standards, the instructions and /or corrective orders issued by the Authority from time to time in accordance with the Act and the Regulations;

lxii. "Record Keeper" means a person in charge of the Record Room;

lxiii. "Record Room" means a place where items, confiscated by the inspection teams, are kept by the Authority for the purposes of evidence and record;

lxiv. "Reference Manual" means such manuals as prepared by the Authority from time to time for achieving purposes of the Act, containing sets of guidelines for the Healthcare Establishments relating to implementation of the Standards for improved healthcare service delivery and system;

lxv. "Reference" means a matter which falls in the jurisdiction of the Authority referred to it by the Federal Government for further necessary actions;

lxvi. "Registration Board" means Registration Board of the Authority established under section 15 of the Act;

lxvii. "Regulations" means Regulations made under Islamabad Healthcare Regulation Act 2018;

lxviii. "Review Forum" means a forum to review the order of Complaint Hearing Committee or Complaint Management Officer, as the case may be;

lxix. "Rules" means rules made under the Act;

lxx. "Schedule" means any schedule annex with any part of the regulations;

lxxi. "Sentinel Event" means an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof that must be reported to the Authority within forty-eight hours of occurrence along with analysis report and action plan in a manner prescribed by the Authority from time to time;

lxxii. "Store" means a store room of the Authority where all the assets of the Authority can be stored with all necessary records;

lxxiii. "Standards" subject to the provisions of the Act, include but not limited to the IHRA Minimum Service Delivery Standards (MSDS) as notified by the Government; standards notified by the Authority for licensing of healthcare establishment;

(2) All other words and expressions used in these Regulations but not defined herein shall have the same meanings as are assigned to them in the Act, Standards, Reference Manual or guidelines for the healthcare establishment and /or such other instructions or orders including, but not limited to, any other directives relating to the improvement of healthcare services and/ or healthcare service delivery systems, as prepared and issued by the Authority, from time to time, for achieving the purposes of the Act.

Part-II

Management of the property of the Authority, its maintenance and Audit of its accounts

Chapter 1

Assets of the Authority and its Allocation

1. **Assets of the Authority includes.-** (1) Immovable
   a) Land purchased and transferred to the Authority for office building.
   b) Building declared as office of the Authority by the Federal Government.
   c) Building hired on rent for the office use of the Authority.
   d) Land or building purchased by the Authority, whether it is being used for office or not, including but not limited to hostels for its employees, rest houses, employees' housing colony.
   e) Assets/amenities managed by the Authority.

(2) Moveable

   a) Vehicles
   b) Computer Equipment including but not limited to printer, scanner, photostat machines, Fax, etc.
   c) Office Equipment (items used for office running).
   d) Furniture
   e) Fixtures in the building or land.
   f) Stock in store including but not limited to stationery, crockery, all kind of accessories for vehicles, furniture IT equipment and any other thing being used in office work.
   g) Material confiscated and removed from any land or building of the Authority including the office
   of the Authority.
   h) Software used in management system of the Authority.

2. **Issuance of assets for office use;-** (1) Following assets shall be issued for office use as per rank of

the officer;

a) Officers of M1

i.	Office table with glass and Flannel Cloth (3.25' X 6.25')	1
ii.	Revolving chair	1
iii.	Visitor chair	3
iv.	Laptop with Highest specification	1
v.	Seven Seaters Sofa Set with center table	1
vi.	Wooden hanger stand	1
vii.	Pakistan Flag (Table size)	1

viii.	Quaid-e-Azam's Photograph frame	1
ix.	Good Quality wall board with blazer (8' X 4')	1
x.	Officer's posting board (18' X 36')	1
xi.	Best quality marble table set with pen holder	1
xii.	Best quality Ball points pen	1
xiii.	Best quality Stapler Machine	1
xiv.	Foot scale (steel)	1
xv.	Pencil Sharpener (Machine)	1
xvi.	High lighter (set)	1
xvii.	Punch (single and double)	1
xviii.	Wall clock	1
xix.	Emergency light tube rod	1
xx.	Wall calendar	1
xxi.	Table diary	1
xxii.	Book shelf	1
xxiii.	File cabinet	1
xxiv.	Table lamp	1
xxv.	Dak Bags	2
xxvi.	Files rack	1
xxvii.	Best quality Printer	1
xxviii.	Fridge	1
xxix.	AC (invertor)	1
xxx.	Television (LED screen)	1
xxxi.	Towels biannual	1
xxxii.	Tissue papers (per month)	3
xxxiii.	Air Freshener (per month)	3
xxxiv.	Soap and hand sanitizer (as per need)	
xxxv.	Face Mask and gloves (as per need)	

b) Officers of M2-M4:

i.	Office table with glass and Flannel Cloth (3.25' X 6.25')	1
ii.	Revolving chair	1
iii.	Visitor chair	2
iv.	Laptop with best specification	1
v.	Five Seaters Sofa Set with center table	1
vi.	Quaid-e-Azam's Photograph frame	1
vii.	good quality marble table set with pen holder	1
viii.	Ball points pen	1
ix.	Stapler Machine	1
x.	Foot scale (steel)	1
xi.	Pencil Sharpener (Machine)	1
xii.	Two color High lighter	2
xiii.	Punch (single and double)	1
xiv.	Wall clock	1

xv.	Emergency light	1
xvi.	Table diary	1
xvii.	Book shelf	1
xviii.	File cabinet	1
xix.	Files rack	1
xx.	Good quality printer	1
xxi.	AC (invertor)	1
xxii.	Towels	1
xxiii.	Tissue papers (per month)	2
xxiv.	Air Freshener (per month)	1
xxv.	Soap and hand sanitizer (as per need)	
xxvi.	Face Mask and gloves (as per need)	

c) Officer of M5

i.	Office table with glass (3' X 5')	1
ii.	Revolving chair	1
iii.	Visitor chair	2
iv.	Laptop with standard specification	1
v.	Marble table set with pen holder	1
vi.	Digital standard printer	1
vii.	Stapler Machine	1
viii.	Foot scale (steel)	1
ix.	Pencil Sharpener (Machine)	1
x.	Two color High lighter	2
xi.	Punch (single and double)	1
xii.	Wall clock	1
xiii.	Table diary	1
xiv.	File cabinet	1
xv.	Files rack	1
xvi.	Tissue papers (per month)	2
xvii.	Soap and hand sanitizer (as per need)	
xviii.	Face Mask and gloves (as per need	

d) General Officers

i.	Office table with glass (3' X 5')	1
ii.	Revolving chair	1
iii.	Visitor chair	2
iv.	Laptop with standard specification	1
v.	Marble table set with pen holder	1
vi.	Digital standard printer	1
vii.	Stapler Machine	1
viii.	Foot scale (steel)	1
ix.	Two color High lighter	2
x.	Punch (single and double)	1
xi.	Wall clock	1

xii.	Table diary	1
xiii.	File cabinet	1
xiv.	Files rack	1

e) Other staff

i.	Office table (2.5 X 4')	1
ii.	Office chair	2
iii.	Ball point pen normal	2
iv.	Stapler	1
v.	Single punch machine	1
vi.	Foot scale (steel)	1

f) PS/PA/Stenos/Computer Operators

i.	Office table with computer	1
ii.	Revolving chair	1
iii.	Visitors chairs as per office space and requirement	
iv.	Other items with the approval of the competent Authority.	

(3) No section shall be allowed more than three visitor chairs.

(4) Any other item for office use shall be provided with the prior approval of competent Authority.

(5) Inventory list in every office section/room duly signed by Admin officer shall be maintained in every office for checking and handling/taking over purpose.

3. Crockery supply to offices.- (1) Officers of the Authority, can use the crockery of the Authority which may include;

a) CEO & Board Members of the Authority

i. Tea set with twelve cups & saucers.
ii. Water set with twelve glasses.
iii. Electric Tea Cattle.
iv. Tea Spoons Fourteen
v. China Plates six.
vi. Teacup mats twelve.

b) All others

i. Tea set with six cups & saucers.
ii. Water set with six glasses.
iii. Electric Tea Cattle.
iv. Tea Spoons eight,
v. China Plates three.

(2) The kitchen of the Authority shall have following crockery items for general use of the Authority;

i. Tea set with twelve cups & saucers.
ii. Water set with twelve glasses.
iii. Electric Tea Cattle.
iv. Tea Spoons Fourteen,
v. China Plates six.
vi. Teacup mats twelve.

Provided that the Kitchen of the Authority shall have a Refrigerator and a Microwave oven for the general use of the Authority.

4. Allocation of non-consumable assets on rent.- (1) The competent authority may allocate the spare and non-consumable assets of the Authority on rent to the employees/third party/private individuals through an agreement.

(2) The rental charges, excluding vehicles, building and land, shall be fixed by a committee, appointed by the CEO of the Authority, consisting of at-least three members who are equal to or above the rank of Deputy Director, with the approval of the CEO, keeping in view the condition and market rate of an asset.

Provided that in case of Vehicles, buildings or portion of a building, or land of the Authority, the Assessment of the rent shall be made by the above-mentioned committee and thereafter approval shall be sought from the CEO.

(3) The party to whom an asset is rented out shall be responsible for safety, security, repair and maintenance of assets during rental period.

(4) The party to whom an asset is rented out shall not sublet the asset of the Authority to any other person.

(5) In case of a building, land or any portion of building or land, advance rent of one year and in any other case advance rent of six months may be charged as security.

(6) Admin office shall inspect the assets rented out on quarterly basis. Any deficiency noticed shall be brought to the notice of CEO of the Authority immediately. In case of poor unkeep of the asset, the CEO may withdraw the same.

(7) Rent shall be paid within fifteen days of every month and non-compliance may be result in double rent or termination of rental agreement.

Chapter 2
Store Management

5. Store.- (1) There shall be a store of the Authority under the control and management of

the Director Operations/Deputy Director HR & Admin. The store shall be responsible for the following;

a) Inspection and acceptance of incoming assets.
b) Identification and temporary storage of assets.
c) Movement of assets where needed.
d) Inventory, accounting and records management of assets.
e) Packing and shipment of assets.

6. There shall be two types of store Assets.- (1) Consumable Assets: includes those assets issued to an employee for day-to-day office work and are being consumed and will not be returned to the store i.e., stationary, papers, lead pencil, ball points, stapler pins, tissue papers, soap, air freshener etc.

(2) Non-consumable: includes the assets allocated to an employee for day to day works but are not consumable and remain on the stock of store. These assets shall be on the charge of the employee concerned and shall be returnable to store. These assets shall be under proper charge and if custodian is not going to return the assets to store, he shall either pay the cost equal to reserve price (to be worked out) or after proper enquiry loss shall be written off with the approval of competent authority. It also includes dead stock assets.

7. There shall be following categories of store assets:

i. Category A

All assets having cost of more than rupees 01 million (per asset) and purchased through open tender. This category includes but not limited to;

a) All types of vehicles.
b) Any Machine
c) IT Equipment
d) Building
e) Land

ii. Category B

All assets having cost of more than rupees 0.1 million but less than 01 million (per asset) and purchased through open tender. This category includes but not limited to;

a) Computers/laptops
b) Fax Machine
c) Photocopier Machines
d) Electricity Generators.
e) Air Conditioners
f) Cyclostyle Machines/ printers
g) LED TV screen
h) Projectors
i) Telephone Exchange
j) Furniture

iii. Category C

All assets having cost of less than 0.1 million (per asset) and purchased through local purchase (LP) by registered venders of the Authority. This category includes but not limited to;

a) Stationery
b) Electricity accessories
c) Furniture
d) Fixtures
e) Equipment of daily use
f) Telephone exchange accessories
g) Any other thing having cost of less than 0.1 million per asset.

8. Safety and security of assets in store.- (1) The general control of the store shall vest in the Director Operations/deputy Director HR & Admin, who may appoint an employee as a store in-charge to take special care for arranging safe custody and proper space for stores, for keeping the store in good working condition and protecting them from loss, damage, or deterioration. Suitable accommodation shall be provided more particularly for valuable and combustible assets in store. Maintenance of accounts and inventories in accordance with the books of store shall also be ensured.

(2) Suitable security measures shall be taken for security and safety of the assets in store whenever deemed necessary.

(3) Every employee assigned with the duty of store shall safeguard the assets in the store by keeping in view the following guidelines: -

a. There must be a system of adequate safeguards to protect assets from fraud, waste and abuse.
b. Subsidiary records of fixed assets and stocks shall be kept up to date.
c. Periodic physical inventories of fixed assets and stock shall be prepared and maintained properly.
d. Valuable assets like vehicles are sufficiently covered by insurance policy with the approval of the competent authority.
e. Responsible officers make periodical inspections regularly and reports shall be submitted to the competent authority from time to time.

(4) Transfer of all assets having purchase cost of Rupees ten thousand or more from one department to the other department of the Authority shall be intimated to the store in-charge of the Authority, along with necessary details and approval of admin officer.

(5) On transfer, retirement, resignation or removal from service of an employee, the store in-charge shall ensure that all the returnable assets issued to such employee are received back to store.

Provided that; office of such an employee shall be locked and taken in possession by the HR & Admin office.

(6) A storekeeper on his transfer, retirement, resignation or removal from service shall not be relieved without proper handing over and taking over as well as getting clearance certificate from Director Operations/ Deputy Directors HR & Admin.

(7) Besides maintenance of record of purchase and disposal of assets in store of the Authority, all departments of the Authority shall also maintain record of the assets being controlled by them properly and keep ready for inspection at any time.

(8) All departments of the Authority shall provide information regarding assets used or replaced by it in annual performance report from 1st July to 30th June each year of the concerned department for maintenance of record.

(9) No stock taking or disposal or handing/taking over of an asset shall be carried out without the following; -

a) Date of purchase
b) Price of purchase
c) Ownership documents of the Authority
d) Reserve price of the asset

(10) The Director Operations/ Deputy Director HR & Admin, shall ensure safe and secure placement of the assets. The Admin office shall carry out physical inspections of stores at least once on quarterly basis and shall record his observations in inspection Register to be maintained by the store in-charge in the following form;-

a) date of inspection
b) name and designation of inspecting officer
c) observations to be recorded (if any)
d) signature of the inspection officer and store in-charge

(11) Store inventories shall be checked physically by the Director Operations/ Deputy Director HR & Admin and Director/ Deputy Director (M&E) half yearly and a certificate of the result of check shall be recorded. Reports shall be submitted to the CEO for perusal and necessary action if any, by 15th of July and December each year.

(12) In making physical checking of stores, the following instructions shall invariably be observed: -

a) Verification / checking shall be made in the presence of the store in-charge.
b) All discrepancies shall be brought to the notice of CEO.
c) Shortage and damages, as well as unserviceable store assets, shall be reported to the competent authority to write off the lose as prescribed under appliable regulations and rules.

(13) Balance of assets in store shall not be held in excess of the requirements of a reasonable period as experienced from time to time. assets remaining in the stock of the store for over a year may be declared surplus and auctioned unless there is any good reason to treat them otherwise.

9. Code numbers to assets.- (1) Each moveable asset of the Authority shall be allotted a Code Number as under:-

a. Register number

b. Page number of the register
c. Serial number in the page of the register

10. Entry of assets in the relevant register.- (1) All assets purchased shall be entered in the record register of the store at Director Operation/Deputy Director HR & Admin Office and managed properly by the Admin Officer, assigned with the duty of the store, under proper watch from purchase, to utilization and its final disposal. Store Section shall intimate the CEO about the purchases on monthly basis by 5th of each month in the prescribed form for maintenance of record of all assets. Each stock entry shall suffice with procurement officer's signature and date in the relevant stock register.

(2) While making a payment against any purchase, it shall be ensured by the accounts section that cash memos/invoices bills and vouchers are containing entry details of stock register duly certified by the Admin Officer assigned with the duty of the store.

(3) Purchase made through Imprest Accounts shall be reported to Admin Officer assigned with the duty of the Store. The Account officer can only make re-imbursement on receipt of entry in Store Section, on each bill liable to be taken on stock.

11. Consolidated record register of assets.- (1) A consolidated Register of the record of the following assets of the Authority shall be maintained at the office of Director Operations/Deputy Director HR & Admin asset-wise having following Parts in the prescribed form -

PART-I	Land & Building (s)
PART-II	Machinery/Equipment
PART-III	Vehicles
PART-IV	Office equipment (Item-wise)
PART-V	Furniture

12. Issuance of assets from store.- (1) Store assets already available in the stock or the assets declared surplus shall be issued on demand in prescribed form in triplicates, duly signed by the head of department to an officer/office staff with the approval of the Director Operations/Deputy Director HR & Admin.

(2) Demand for same asset shall be entertained once a week and thrice in a month. In case of special assignment, the approval of CEO with justification shall be obtained.

(3) The store in-charge shall maintain Issue Register for each section of the office separately with full details of asset issued.

(4) The store in-charge shall maintain section wise register in prescribed form about such assets which

are required to be returned to store either in case of replacement or transfer of an officer.

(5) Register of Assets shall be maintained for each category in store separately, given in regulation 13 of part II of these regulations.

Chapter 3
Purchase and Hiring of the Assets

13. Pre-requisite for procurement of assets.- (1) No asset shall be purchased without allocation/availability of funds against a respective head of account in the budget.

(2) Instructions contained in PPRA rules (as amended from time to time) about Tendering/pre-qualification and purchases Process shall strictly be followed while dealing with the store matters.

(3) Purchase of assets of the Authority, shall be made through Internal Procurement Committee.

14. Functions of Internal Procurement Committee.- (1) There shall be an Internal Procurement Committee which shall ensure that:-

a) Purchase shall be made in the most economical manner in accordance with the definite requirements of the Authority, keeping in view the price control imposed by the Government. Neither any asset shall be purchased in a small quantity nor it on undue higher side.
b) comparative statement is available on record, showing consumption of concerned asset during last six months to ascertain need of quantity of asset concerned. Fresh purchase shall be made strictly on indents/demands from the users and report about the available balance of store in the relevant stock Register.
c) Inventory accounting/costing shall be on LIFO (Last in First Out) or FIFO (First In First Out) basis.
d) Bin Card System shall be introduced in Store Department.
e) Before recommending purchase of an asset, the Internal Procurement Committee should see that: -
    i. Administrative or Technical sanction has been obtained from the competent authority.
    ii. Sanction of the competent authority for authorising expenditure has been obtained.
    iii. A properly detailed design and estimate has been approved.
    iv. The competent authority provides funds for purchase of such asset.
    v. Letters are issued to all firms given in clause-16(3) for invitation of quotations.

(2) As far as possible the purchase of an asset shall be ensured from government-based companies or authorized firms/dealers of the companies as per PPRA rules. Necessary proof on record shall be kept if such company or firm either not available on the station or not ready to provide required service.

(3) For purchase of an asset, letters shall be issued for calling quotations at least ten days before the date of opening of sealed quotations, to the Government based company, Authorized Dealers of a company and all Registered firms with the Authority/PPRA.

(4) A Director Operation/Deputy Director HR & Admin, dealing with purchases shall give a certificate to the Internal Procurement Committee that letters were issued to all the government-based companies, their authorized dealers, IHRA registered/ panel firms in time. Response so received up to due date is placed on file for consideration of the Internal Procurement Committee.

(5) The interested bidders shall be required to provide sample of item to be supplied with their bid/quotation. The Internal Procurement Committee shall check/ evaluate the quality of the

stores in question before recommending its purchase. The samples shall be matched with the stores actually received. Director Operation/ Deputy Director HR & Admin shall give a certificate on the back of each bill as under: -

> "The store item(s) mentioned in the bill is/are received and entered in the stock receipt register of Store. The item supplied is as per sample quoted in the bid"

15. Proposal for purchase of asset.- (1) The Director Operation/Deputy Director HR & Admin shall submit their proposals to the CEO in a format having following ingredients for purchase of a property/ asset: -

a) Name of item.
b) Cost (attach quotations/tender, as the case may be).
c) Number of item available in store.
d) Date and number of items purchased previously.
e) Whether item is country made or not.
f) If it is required to be imported or it is not available in the market and its cost is more than rupees o.1 million, under mentioned certificate duly signed by Director Operations/Deputy Director HR & Admin shall be given:

   "It is certified that I am satisfied that the article(s) included in the demand/indent for purchase, is/are not at present available in stock made in Pakistan and cannot be made available within the time. As such, these articles are required to be brought in to service by import from aboard".

g) Is required budget available?
h) If budget is not available, what will be the source of funds for purchase?
i) Detail of consumption of items previously purchased.
j) Recommendations and constitution of Internal Procurement Committee.
k) Justification for purchase of item in the interest of public works.
l) Comparative statement of rates offered by different firms.

(2) Following sections/offices shall initiate/process examine cases for purchase/repairs of items as shown against each: -

a) purchasing Land/Buildings	CEO of the Authority
b) Hiring/repairs of office Building and land	Procurement & Administration
c) Engineering Equipment/ Machinery	Procurement & Administration
d) Vehicles	Inspection and Procurement Department
e) Computers	IT and Procurement Department
f) Officer Furniture	Administration & Procurement Department
g) Other office use items	Store section
h) Any other item	Department Concerned

16. Purchase against Bill of Quantities (BOQ).- (1)All the purchases against Bill of Quantities of items shall be made through consultants/contractors and C.E.O of the Authority shall be kept informed so that a proper inventory of each project assets can be completed.

(2) Proper record, of all items purchased and used by the contractors/ consultants, shall be kept at the store of the authority and shall be verified and maintained by Admin Officer store.

(3) On completion of a project, a list of moveable items shall be presented to C.E.O office of the Authority to seek its demand, if any item is required to the Authority. The remaining items shall be duly declared surplus/condemned through Disposal committee of the Authority and thereafter, they shall be auctioned at site and only useable items will be shifted to the places where they are required.

17. Hiring of assets for the Authority's use.- (1) The CEO of the Authority is allowed to hire on lease private or government properties/assets, subject to any rules, regulations or instructions provided to the Authority from time to time.

(2) Subject to any instructions, rules or regulations of government if any, there shall be following pre-requisites for hiring of assets on lease;

a. Required asset is not available in the stock of the Authority.
b. It is required in the interest of official business of the Authority.
c. The said hiring is not specifically prohibited under the instructions of government/ Authority's rules.

(3) Rent of such assets shall be assessed keeping in view its condition, value and market rate in the vicinity concerned.

(4) Members of Internal Procurement Committee with the approval of CEO of the Authority shall Negotiate lease rent for hiring of assets for office purpose.

Chapter 4
Repair and maintenance of assets

18. Repair/Maintenance of assets.- (1) Repair and maintenance of the assets shall be made in the following manners: -

a. Steps for repair of an assets

Following steps shall be taken for repair of an asset of the Authority: -

i. Defect report by concerned officer to the office Deputy Director HR & Admin.
ii. Check the necessity of repair by the office Deputy Director HR & Admin.
iii. Recommendations/report of checking official with suitable proposal with rough cost estimate to the C.E.O of the Authority for administrative approval.
iv. After administrative approval Bids/quotations shall be called through press or from all Registered Firms (if major repair is required). Major repair means where

quotations/bids are required to be called for a work. In case of minor repair, registered firms will be involved to carryout the work.

v. After Opening and verification of bids/quotations and comparative statement by Internal Procurement Committee. Submission of case for financial approval to the C.E.O of the Authority through Deputy Director Finance.

vi. After approval, work order will be issued by dealing the office of Deputy Director to lowest bidder and action will be finalized as per these regulations or any other rules, regulations and instructions appliable to the Authority.

vii. As far as possible repairs be carried out through public sector, corporations/company or Authorized/Registered Dealers of the companies. Necessary proof on record shall be kept if such company or firm either is not in a position to provide required service or not available on the station.

Provided that; In case of purchase/repair of an asset through public sector, company/firm or authorized dealers of such companies, repair/purchase can be carried out on single quotation.

viii. On completion of work, the firm shall submit a bill within fifteen days. The bill shall be entered in respective books (stock, Logbook etc).
On the back of bill following certificate will be recorded by officer concerned i.e., whose asset is repaired: -

"The work has been completed as per approved specification/work order/rates. Entries have been made in the record concerned as per entry given on the face of bill. The payment is recommended to be released to M/S"

Signature:

Designation: Date:

b. Cash Payment:

i. Repair/maintenance of the assets of the Authority on cash payment shall be subject any rules, regulations or instructions made for the Authority. It shall normally be avoided. However, in case of emergency or urgency or when Authority's Panel Firms either are not available or they are not in a position to provide the required service on time,

OR

ii. When it appears that Authority's Panel firms are giving higher rates in quotation as compared to open market rates, repair on cash payment, with prior approval of the C.E.O of the Authority, by giving full justification for cash payment, shall be allowed by drawing advance amount (to be adjusted on completion of work). For cash payment at least two quotations out of panel firms will also be obtained and be kept on file with quotations of panel firms.

iii. Offer for repair/maintenance of an asset on cash payment will also be given to panel firms for competition.

c. Emergency repair/Maintenance:

In case of emergency repairs/maintenance, cases shall be submitted to the C.E.O of the Authority with full justification for approval, after carrying the required work, of re-imbursement of bills within 24 hours. The C.E.O may order inquiry for ascertaining factual position, if deem necessary.

d. Note in the Log Books:

Repair/maintenance and usage details of vehicles, Photocopier Machines and Computers/Laptops or any other such equipment as directed by the office of Deputy Director HR & Admin, will be noted in their Log Books.

19. Registration of Firms/workshops with the Authority.- (1) Registration of firms/workshops for supply and repair/maintenance may be made on three years basis after inviting applications through public notice in the press.

(2) On receipt of application from an interested firm/workshop for registration with the Authority, the application shall be referred to the Pre-qualification Committee appointed by the C.E.O of the Authority for the purposes of this clause.

(3) The Pre-qualification Committee under this clause shall consist of at-least three members who will be equal to or above the rank of a Deputy Director.

(4) The Pre-qualification Committee shall verify the followings requirements:

a. Status/capacity of the firm for stores.

b. Necessity in the Authority.

c. Registration with other government organisations.

d. Stock quality and quantity.

e. Statement of Financial position and its resources.

f. GST payer certificate.

g. Last year Income Tax Statement.

h. Any other detail as deemed necessary.

(5) Pre-qualification Committee shall conduct inspection of the firm/workshop of the applicant and its inspection report shall be shared with the Internal Procurement Committee, Finance & Audit Committee and CEO of the Authority.

(6) The firm/workshop after compliance with pre-qualification requirements and on payment of registration fee at the rate fixed by the Authority may be registered with the Authority.

(7) The firm/workshop's registration may be renewed with the approval of C.E.O of the Authority after every three years subject to satisfactory performance on payment of renewal fee at the half of the amount of the existing initial registration fee.

(8) Once a firm is depanelized, it will not be considered for registration till three years.

20. Categories of Firms/workshop for supply of store items.- (1) Firms/workshop required to be registered under clause 25 are categorised as follow:-

Category	Value Rank for Purchase of Stores.
I.	Over Rs.10.00 million.
II.	Over Rs.5.00 million and less than Rs.10.00 million.
III.	Over Rs.1.00 million and less than Rs.5.00 million.
IV.	Over Rs.0.5 million and less than Rs.1.00 million.
V.	Less than Rs.0.5 million

Chapter 5
Disposal of assets of the Authority

21. Committee for Disposal and Auction.- (1) The C.E.O of the Authority shall appoint a committee for disposal and auction of the properties/assets of the Authority.

(2) The Committee shall consist of at-least three members, equal to or above the rank of Deputy Directors.

(3) The C.E.O of the Authority shall appoint these members, from time to time, and shall appoint one of its members as a chairperson of the committee.

(4) The Committee for Disposal and Auction shall assess the assets of the Authority for t he following purposes:

a. Classification/conditioning of the assets.

b. Determine surplus assets.

c. Fixation of reserve price for condemnation, auction or disposal of the assets.

d. Disposal through Auction or otherwise.

e. Finalize the Auction bid.

Provided that; the committee shall carry out the classification/conditioning of the Assets as under;

i. Workable/useable Assets:

The Assets having good condition shall be placed in this class for issue wherever their need arises. These Assets shall be taken on running stock properly.

ii. Serviceable Assets:

The Assets, which need repairs with in a reasonable/acceptable, amount shall be counted in this class. After proper stock taking, these Assets shall be repaired and issued on demand when and where need arise.

iii. Surplus Assets:

The Assets either in good condition or need minor repairs but not useful for the Authority shall be declared surplus subject to the condition that, list of such Assets shall be circulated to all the offices of the Authority for their use. If no demand is received, the committee after inspection of Assets shall recommend as Surplus. These Assets shall be auctioned as soon as possible.

iv. Condemned Assets:

The Assets neither useful for the Authority nor disposed off through transfer/three continuous auctions or the Assets, which are not serviceable and have no value in the market, will be treated as Condemned Assets. The Assets classified as condemn shall be disposed off through open auction by calling lump sum offers at what so ever price is offered by the interested parties.

Provided further that; for transfer to Government Organizations, only Surplus/Condemned Assets shall be taken into consideration. Proposals in this regard along with detail of Assets shall be moved to the Media & Coordination department for inviting offers from Government Organizations.

(5) When Purchase/Market price of an asset is not available the Committee for Disposal and Auction shall workout the reserve price, keeping in view the following;

a) Historical cost

b) Life of asset

c) Condition

d) Salvage Value

e) Demand and price in the market in existing condition.

22. Disposal of Assets.- (1) Following are the pre-requisites to dispose of a property/asset of the Authority:-

a. It is declared surplus or condemned by the Committee for disposal and auction.
b. It is taken on stock.
c. Its historical cost, depreciation and reserve price is available.
   Provided that; In case of junk, price of which is not possible to be worked out item-wise, will be disposed of through open auction by calling offers on lump sum basis
d. It is an asset of IHRA with ownership documents.
e. It is not useful in IHRA anywhere.
f. The competent authority approves its disposal.

(2) Instructions given in this regulation or under any other rules shall be observed while disposing off the properties/assets of the Authority.

(3) A permanent Register of Disposal of properties/Assets will be maintained head wise.

23. Disposal of surplus or condemned Movable properties/Assets.- (1) A movable property/asset declared surplus/condemned by the (Assets Disposal Committee) committee should be offered first to the employees of Authority by adding 3 % more to the reserve price plus G.S.T. or calling rates from the employees on competitive basis.

24. Disposal of Vehicles to officers on retirement.- (1) On retirement with good service record, entitled officers may be allowed to purchase an official vehicle having five years or more life at the Written Down Book Value to be worked out by the Finance Department with the approval of competent authority of the Authority.

25. Use of surplus land or Building of the Authority.- (1) On availability of sufficient/suitable piece of surplus building or land, the competent authority with the approval of the Board may use that portion for a beneficial project i.e., colony or hostel for IHRA employees, guest house, office building or IHRA welfare works etc.

26. Disposal of property/Assets to Government/Semi Government/Autonomous Bodies.- Disposal of property/Assets to Government/Semi Government/Autonomous Bodies shall be transferred on payment of book value with the approval of the competent Authority.

27. Open Auction.- (1) Disposal of all surplus or condemned properties/assets shall be made through Open Auction conducted by Auction Committee.

(2) Notice for calling bids in respect of auction of assets of the Authority for publication in newspapers shall be given in the prescribed form.

Provided that; Detail instructions for bidders shall be given in bid documents.

(3) Reserve price of an asset (except land and building) for auction will be assessed on the basis of following formula: -

One of the reserve prices (which ever is higher worked out as per formula of government and method given in IHRA Financial Manual.	+	Current market value of the same make, model and condition asset.

Divided by two (2)

(4) Price of land and building (s) will be same as per existing market value but not less than the rate prescribed by land revenue authorities.

(5) After auction of a property/asset, pay orders/ bank Drafts of 1st, 2nd and 3rd position holder bidders shall be retained till finalisation of auction process and others will be released under the stamp and signature of chairperson of Auction Committee.

Provided that; An asset can be sold on single bid basis if the bid price is equal to or above the reserve price.

(6) On completion of auction, the Auction Committee will submit its proceedings to the Competent Authority for approval.

(7) After approval of competent authority, a letter of acceptance of bid of highest bid shall be issued by Director Operation of the Authority with necessary instructions.

(8) In case of land and vehicles, these assets will be handed over to the bidder after completion of process of transfer of ownership, by Revenue Authorities, in case of land and by E.T.O/registration authority in case of vehicles. Expenses incurred on account of transfer of asset shall be borne by the bidder. Following steps will be taken in this case: -

a. Bidder will be instructed to deposit full amount of bid along with Tax payable under the rules in IHRA non assignment account through Bank Draft.

b. On clearance of bank Draft in favour of the Authority a letter of N.O.C in the name of bidder will be issued to authority concerned for transfer of asset in the name of bidder.

c. On transfer of asset by the concerned quarters, the copy of transfer documents shall be kept on the record of the Authority and the asset will be handed over to the bidder.

(9) Amounts received through auction/sale of assets shall be deposited in "Receipt Account" of the Authority.

Provided that; When a surplus/condemned asset cannot be disposed of under normal procedure, following steps shall be taken for its disposal: -

a. Reduce the reserve price on each auction at the ratio of 5%, 10%, 20% after first auction in second, third and fourth auction.

b. Offer to the employees of the Authority to purchase an asset at the amount of 30% less than the reserve price.

OR

c. Any other person interested to purchase such asset at the amount of 25% less than the reserve price.

Provided further that; above steps shall be taken after proper certification and documentary proof by committee for disposal and Auction with the approval of the CEO of the Authority.

28. TRADING OF ASSETS.- (1) When an equipment/instrument is obsolete/out of order or is beyond economic repair and an interested party is ready to replace it with a new one with an additional nominal amount, the trade-off shall be allowed with the approval of C.E.O of the Authority, subject to the following conditions: -

a. Amount to be incurred on the repair is more than the reserve price of the item.
b. Guarantee period (if any) of the item is expired.
c. Amount of reserve price and extra amount to be paid to the supplier of new item is not higher than the market price of new item.

Chapter 6
Miscellaneous

29. Return and Internal Audit of purchases/ assets of Stores.- (1) A centrally controlled Register about the purchases of consumable Store Items will be maintained at the office of Director Operation/Deputy Director HR& Admin of the Authority and will send quarterly return of such 'purchases to C.E.O of the Authority in Prescribed form by the 5th of each March, June, September and December to maintain the record of master file (Purchase).

(2) The Director Operations/Deputy Director HR & Admin will submit a monthly return about Assets by 5th of each month in prescribed form being recommended surplus/B.E.R. in the office of C.E.O of the Authority.

(3) Annual assets report regarding properties/assets of the Authority, containing detail of purchases/disposal and present items in store during the last year shall be submitted to C.E.O of the Authority by 15th July of each year, as considering the fiscal year of the Authority from 1st July to 30th June, is stock taking cut off date.

(4) The Internal Audit will carry 100% inspection and physical verification of all stores/assets record at the Authority, with special emphasise upon "Stores/Assets Record Keeping".

30. Instructions, rules and law of Government shall strictly be followed.- (1) Subject to any IHR Act, 2018 and regulations made thereunder, all instructions, rules and law of Government shall strictly be followed while dealing with the matters of assets of the Authority under these Regulations: -

a. Tendering/Pre-qualification and Purchase Process.
b. Land Acquisition
c. Disposal of IHRA Property/Assets.
d. Procedures and Powers to Write off Losses.

Provided that; In case of any consultant(s) hired by Government of Pakistan as Member in Planning & purchase matters for certain fixed assets. Under such situation the same procedure should be followed as mentioned in para-30.

Provided further that; Instructions/orders passed by the Board of the Authority or Federal Government from time to time for corporate bodies in this regard shall be applicable to these regulations.

Provided further that; Record of losses written off regarding assets of the Authority shall be maintained in a register as a Permanent Record in the procurement office. All the losses written off shall be reported to all concerned by the C.E.O of the Authority.

31. Cancellation of an agreement.- (1) In case of cancellation of any agreement on the basis of any reason, Cost of any asset, whether Moveable or Immoveable or other will be re-imbursed to the Authority on submission of the IPCs.

Provided that; under such a situation the Director Operations/Deputy Director HR & Admin shall keep a record of the details of the agreement and inform the C.E.O of the Authority accordingly. The reimbursed amount will be submitted in the official account of the Authority against the said head of account from which it was drawn.

32. Ownership Documents of Assets of the Authority.- (1) The Authority shall have following documents in its record to prove its ownership of assets as a matter of right:

a. Land and Buildings.

i. All the Notifications and Awards passed under Land Acquisition Act, 1894.

ii. List/Record of owners who received compensation of land.

iii. Record of mutation of land.

iv. Assessment record of cost of land, by-land Revenue Authorities.

v. Registration document of building or land in the name of Authority.

vi. Lease Record

vii. Sale deed of building or land as the case may be.

b. Other Assets.

i. Newspapers published Notice (when required)

ii. Quotations (when required)

iii. Comparative statement of rates received through quotations.

iv. Approval of competent authority.

v. Sanction Memo

vi. Stock Register(s)

vii. Registration Book of vehicles

viii. Insurance/Token Tax Payment Papers of vehicles.

(2) Similarly, the Authority shall have following documents in its record to prove ownership of the assets disposed by it:

a. Stock Taking Report.

b. Surplus/Condemnation report of the Disposal Committee.

C. Circular to IHRA departments for calling demands.

d. Final list of items recommended for disposal.

e. Reserve Price Fixation report by Disposal Committee.

f. Published Notice/Bid/Tender Documents.

g. Bids/Tenders/offers received.

h. Comparative Statement.

i. Auction/Disposal Committee recommendations.

j. Approvals of competent authority.

33. Office Building of the Authority.- (1) Office Building of the Authority shall be maintained as per requirements of the authority with the approval of the C.E.O of the Authority, subject to the following terms and conditions:

a. A building to be hired/constructed for office use shall contain complete characteristics that should be reasonable in its area which at least accommodate all the concerned departments of the Authority and staff with moveable assets required for the functionaries of the Authority.
b. Repair/maintenance of the office building (s) will be the responsibility of Director Operations/Deputy Director HR & Admin or Regional Heads in case of establishing any regional office (s) by the Authority.
c. The locality of the office building shall preferably be central, secured and close to airport.
d. All utility services i.e., electricity, water, gas, telephone, internet, sewerage etc. shall be available.

34. Procedures for hiring of houses or Allotment of IHRA residences to the employees.- Pakistan Allocation Rules and instructions of Federal Government on the subject matter shall be applicable.

Note: "In case of change of nomenclature of posts mentioned in the Regulations due to re-organization, the newly created posts shall replace the old one and the officers so posted with new designations will exercise powers as are vested in existing posts of same status".

PART III

"Summoning and holding of meetings of the Board of the Authority and places where such meetings are to be held, the conduct of business thereof and the number of members necessary to constitute a quorum"

Chapter one

1. Convention and Chairperson of Board Meetings.- (1) Board meetings shall be held at-least once every quarter but may be held at any time in case of urgent circumstances on the call of chairperson himself or on the request of any member in writing for a reason to be specified therein.

(2) Board meetings shall be convened and presided over by the chairperson. However, the first meeting of every term of the newly elected members of the Board shall be convened and presided over by the member who has received the largest number of votes after such election.

(3) In case the chairperson of the Board is on leave or unable to exercise his powers for any cause, the chairman shall appoint a member to act on his behalf. In the absence of such an appointee, the members shall elect from amongst themselves one person to act on the behalf of the chairman.

2. Place and time of Board Meeting.- (1) Board meetings shall be held at the head office of the Authority or any other place suggested by the chairman, at a time convenient for the members of the Board to attend.

3. Designated Secretariat, meeting notices, and meeting Materials.- (1) The chief executive officer of the Authority shall act as the secretary to the Board. The secretary shall conduct the drafting of the meeting agendas and minutes, and handle other administrative matters related to Board meetings, and reports to the chairperson of the Board.

(2) The Board meetings shall be convened upon written notices sent to all members fourteen days prior to the date of the meeting, specifying the date and place of the meeting and attaching the meeting agenda and related material.

Provided that; Board meetings may be convened at any time without such prescribed notices in case of urgent circumstances and any member attending the meeting in person shall be deemed to have received such meeting notice.

(3) If any member considers meeting material to be insufficient, they may request the Board secretary to provide supplemental material in advance.

Provided that; if the members consider meeting material to be insufficient during the meeting, the meeting may be postponed upon a resolution of the Board.

4. Subject Matters of Board Meetings.- (1) The agenda of regular Board meeting shall be decided in consultation of chairman, who may seek suggestions from the members.

Provided that; subject to the generality of sub clause i, the agenda shall include the meeting minutes of the preceding meeting in the agenda;

5. Attendance signing Booklet and proxies.- (1) A signing booklet shall be provided at every Board Meeting for the attending members to sign in.

(2) The members shall attend Board Meetings in person.

Provided that; any member attending the meeting via video conference shall be deemed to have attended the meeting in person but shall sign an attendance card and send it to the secretary of the Board via facsimile in lieu of signing on the attendance signing booklet.

6. Convention of Board Meetings.- (1) If two-third of the total members are not yet present at the scheduled time for a Board Meeting, the chairperson may postpone the time of the meeting. The postponements shall be limited to twice at the most. If after two postponements no quorum can yet be constituted, the chairperson shall reconvene the meeting pursuant to the procedures under regulation 6 of part III regulations.

7. Other attendants.- (1) Depending on the subject matters of proposed resolutions, relevant managerial personnel may be invited to present at Board Meetings to assist the members in understanding the Authority's current conditions so that they can make appropriate resolutions. In addition, Certified Public Accountant (CPAs), Legal counsels, or other professional personnel may be invited to the meetings to provide professional opinions for the members of the Board, but shall excuse themselves and vacate the meeting when the proposed resolution will be discussed and resolved.

8. Discussion of Proposed Resolutions.- (1) In principle, the discussion of proposed resolutions at a Board Meeting shall proceed in accordance with the agenda attached to the meeting notice. however, if no objection is voiced by any member present at the meeting or with more than half of the attending member's consent, the chairperson may make changes. Unless otherwise resolved at the meeting, the chairperson cannot announce adjournment of the meeting before all the discussion items (including special motion) listed in the above agenda are resolved.

(2) In the process of a Board meeting, if the number of members present at the meeting become fewer than half of the members originally attending the meeting, the chairperson shall announce a temporary adjournment to the meeting upon a motion made either by himself or by any member present at the meeting, and provisions of regulation 9 of part III these regulations shall mutatis mutandis to such case.

(3) During a meeting, the chairperson may, at his discretion, set time for intermission or negotiation.

9. Voting. - (1) The chairperson may announce to end the discussion of any resolution and go into voting if the chairperson deems it appropriate for voting.

(2) Resolutions shall be deemed adopted if no objection is voiced by any of the attending members after solicitation by the chairperson. If objection is voiced after solicitation by the chairperson, such resolution shall be voted. A resolution shall be adopted by a majority of those members present at a meeting attended by two-third of all members.

Provided that; if there is an amendment to or substitute for a proposed resolution, the chairperson shall decide the sequence of voting for such proposed resolution and the amendment or substitute. If anyone of them has been adopted, the others shall be deemed vetoed and no further voting is required.

(3) The result of voting shall be announced at the meeting and placed on record.

(4) The method of the voting shall be one of the following as determined by the chairperson:

a. By showing of hands;

b. By voicing votes; or

c. By casting ballots. The chairman shall appoint a member to monitor the voting process and counting of ballots.

10. The recusal of Conflict-Interested Members.- (1) If a member has a personal interest in the matter under discussion at the meeting, the relevant member shall disclose the nature of such personal interest. If such interest may impair the interest of the Authority, the relevant member shall not join the discussion and voting of such matter, and shall recuse himself when the matter is being discussed and resolved.

11. Meeting items to recorded and signed.- (1) The resolution of every Board meeting shall be recorded in the meeting minutes. The meeting minutes shall accurately record the following items:

a. The term (or year), place, and time of the meeting;

b. The name of the Chairperson;

c. The attendance situation of the members, including the names and numbers of those who are present, on leave, and absent;

d. The names and titles of other attendants;

e. The name of the recorder;

f. Report items;

g. Discussion items: the voting method and the result of each proposed resolution; the summary of opinion by the members, experts, and other personnel; the names of the members that disclosed a conflict of interest under regulation 13 of this part, summary of the nature of the conflict of interest, the reasons for recusal or non-recusal, and the circumstances of recusal; any dissenting opinion or abstention with a written statement;

h. Special motions: the names of the persons proposing the special motions; the voting method and the result of each proposed resolution; the summary of opinion by the members, experts, and other personnel; any dissenting opinion or abstention with a written statement; and

i. Other items that shall be recorded.

(2) Meeting minutes shall be signed by the chairperson of the meeting and the recorder, distributed to each member within twenty days after the meeting, and carefully kept as the Authority's important file throughout the life of the Authority. The attendance signing booklet of a Board meeting shall be part of the meeting minutes and be permanently retained throughout the life of the Authority. The recording and distribution of the meeting minutes may be performed by means of electronic transmission.

Provided that; the chairperson shall have power to amend and delete anything from the meeting minutes and shall mention the reason for the same in writing.

12. Tape-recording of Board meeting process.- (1) The process of a Board meeting regarding the subject matters specified in regulation 7 of part III of these regulations shall be fully tape-recorded and retained for five years in a method that may be encrypted.

Provided that; if any litigation occurs regarding any matter resolved by the members of the Board before the above retention period expires, the relevant recording tapes shall continue to be retained until the litigation is concluded, and the above mentioned five-year rule shall not be applicable.

(2) If a Board meeting is held via video conference, the video and recording tapes shall be part of the meeting minutes and be permanently retained throughout the life of the Authority.

13. Cancellation of Board Meetings.- (1) In the case of special circumstances where a scheduled Board meeting of the Authority must be cancelled after meeting notices have been sent to the members, the meeting may be cancelled if the person with the convening right notifies the members in writing at least three days prior to the scheduled meeting date. In case of urgent circumstances where the scheduled Board meeting must be cancelled and it is impossible to notify the member prior to the time specified above, the meeting may be cancelled if the person with convening right notifies the members by telephone or other means at least three hours prior to the scheduled meeting time and confirms that each member has received such notice.

14. Delegation of the Board.- (1) The chairperson of the Board shall act on behalf of the Board pursuant to the Authority's objectives when the Board is not in session. In case the chairperson of the Board is unable to exercise his powers for any cause, any other member authorized by the chairperson or elected by the members shall act for him.

PART IV

POWERS AND DUTIES OF CHIEF EXECUTIVE OFFICER, 2022

Chapter 1

Appointment of Chief Executive Officer

1. Primary qualification and experience.- (1) The Board shall appoint a person to be chief executive officer of the Authority with a basic qualification of MBBS and having a minimum of fifteen years of experience in public health, public health administration, and of management and administration of national level health care programs.

(2) An adept health professional securing a Masters degree or equivalent in public health, or public health administration, and medicine.

2. Additional qualification and experience.- (1) Additional higher qualification in public health, Law, Management and/or clinical/medical subjects will be given further preference.

(2) Exhibits through understanding of Government procedures, policies, rules and regulations.

(3) Previous experience of working with international and UN organizations and field healthcare positions.

3. Primary Job responsibilities.- (1) subject to the Act, and power delegated by the Board, following shall be the primary job responsibilities of the CEO;

a. Responsible for management operations, and governance of the Authority under overall oversight of the Board of Directors;
b. Provide top level leadership vision and strategic directions to all aspects of the Authority's activities;
c. Manage the administration, operations and functions of the Authority
d. Act as the principal accounting officer responsible and accountable for the management of the Authority's funds and assets;
e. Assist Board in all elements of the Authority's work especially on matters related to strategic planning, implementation, monitoring and evaluation of the Authority's funds and assets;
f. Prepare and present to the Board with Strategic and operational plans for its review and appraisal;
g. Assist the Board in strategic thinking, planning and implementing its policies;
h. Protect the financial health of the Authority;
i. Acts as spokesperson of the Authority;
j. Provide Leadership to the senior management and directions to all staff;

k. The chief executive officer shall-also Act as the secretary to the Board; and
l. The chief executive officer shall subject to the supervision and control of the Board, administer the affairs of the Authority and may exercise such power as are delegated to him by the Board.

Chapter 2

Board-CEO linkages

4. Executive Constraints.- (1) The CEO shall operate IHRA in a manner which is lawful, prudent and in accordance with commonly accepted business practices and professional ethics.

(2) The Board's sole official connection to the operating organization, its achievement and conduct will be through the CEO.

(3) Only decisions of the Board acting as a body are binding on the CEO.

5. Accountability of CEO.- (1) The CEO is the Board's formal link to IHRA's operational achievement and conduct, so that all authority and accountability of staff as far as the Board is concerned, is considered the authority and accountability of the CEO.

6. Delegation to the CEO.- (1) The Board will instruct the CEO with written overall policies without interfering in operations or complaints Management.

(2) As long as the CEO uses any reasonable interpretation of the Board's ends and executive limitations policies, the CEO is authorized to establish all further policies, make all decisions, take all actions, establish all practices and develop all activities for the smooth functioning of the Authority.

(3) The CEO shall explore & enter into collaborated agreements & MOU's as long as they are reasonable and justifiable. Exercise financial control as PAO within limits of expenses as delineated by the Board.

7. Monitoring CEO Performance.- (1) The Board will provide systematic monitoring of CEO Job performance on annual basis.

(2) CEO monitoring will be based on expected CEO outcomes as expressed in the CEO Job description approved by the Board keeping in view the overall situation.

(3) The board will acquire monitoring data by any of the methods; i.e., Internal reports prepared by the CEO, and the Audit reports.

8. Communications and Support to the Board.- (1) The CEO shall communicate with the Board in a timely and sufficient manner to keep the Board informed and prepared for its work.

(2) The CEO shall submit monitoring information required by the Board in timely, accurate, and understandable fashion, directly addressing the Board policies being monitored

(3) The CEO shall report and prepare recommendations and suggest corrective action in a timely manner on actual or anticipated non-compliance with any policy of the Board allowing sufficient time for Board to consider corrective action

(4) The CEO shall keep the Board informed of relevant trends, anticipated adverse media coverage, media coverage, material external and internal changes, particularly changes in assumptions upon which any board policy has been or is being established.

9. Approval of presented requests to the Board.- (1) Any request to the Board, an individual Board Member or any Panel or a Committee of the Board, sent by the CEO office, and not responded to by the addressee in seven days shall be deemed automatically approved, insofar as it is related to minutes of a Board Meeting. Similar requests sent with regards to eliciting review/ approvals from the addressees, vide supra, shall stand approved after a period of 15 days automatically in case of nonresponse. If one member responds out of a two-member panel committee, and the other member does not in a 15 days' time, the decision shall be deemed to have been approved.

10. Appointment of IHRA staff.- (1) Subject to the Act, rules and other regulation regarding recruitment applicable to the authority, appointment shall be made as under;

a. Staff Recruitment, Compensation and Benefits:

i. With respect to employment, compensation and benefits to employees, consultants, contract workers and volunteers, the CEO shall have the authority and will operate IHRA in a manner which is legal, ethical and non-discriminatory and protects IHRA's public image, fiscal integrity and tax status.

ii. The compensation and benefits of the CEO may be changed in consultation with the Board.

iii. The CEO should not incur any compensation or benefit obligations over a longer term that cannot be supported over a longer period of time. If future revenue projections support expenses then those can be incurred and projected.

(2) Any Temporary appointments, consultancies shall be made by the CEO. All other appointments including fixed term employments/contracts, i.e., upto 20th grade or equivalent, shall be made by the CEO based on the recommendation from the internal HR committee (constituted by the CEO), to fulfill an emergency or exigency to be stated in writing. Scope of work and deliverables would be clearly spelled out.

11. Treatment of Staff and Volunteers.- (1) The CEO will draft, with legal advice and

maintain written policies that reflect the policies of board, clarify personal rules of staff, provide for effective handling of grievances and protect against wrongful conditions such as nepotism and grossly preferential treatment of personal reasons.

(2) The CEO shall not discriminate against any staff member for expressing an ethical dissent.

(3) Any employee who wished to engage in any paid activity in any field directly related to the work of the authority must have prior approval from the CEO.

(4) The CEO will assure that all staff and volunteers have been informed on their rights under this policy.

Chapter 3

Financial Conditions and Activities

12. General operations.- (1) The Principal Accounting Officers in the self-accounting entities shall themselves be responsible for ensuring that adequate controls and corporate governance exist over transactions within the entity. This shall be evidenced by the Principal Accounting Officer signing off each set of monthly summarised financial information.

(2) With respect to actual and ongoing financial condition and activities, the CEO will operate IHRA in a sound and prudent fiscal manner for short and long-term financial health, not deviating materially from board stated priorities,

a. Accordingly Total expenses shall not exceed available organizational resources

b. Unrestricted operating expenses shall not exceed unrestricted operating income

c. All other board policies are met

(3) The CEO will maintain internal financial reports sufficient to monitor the financial activity of IHRA in accordance with all other financial policies.

(4) The CEO will:

a. Prepare annual top line report as defined by Board

b. Prepare monthly balance and income statements compared to budget

c. Maintain internal controls as defined by existing standards to provide reasonable assurance on the reliability of financial reporting effectiveness and efficiency of the operations and compliance with applicable laws and regulations.

d. Maintain internal controls as defined in federal audit requirement

(5) The CEO will accurately prepare and file on a timely basis all reports, fees and documentation required by the federal and local government

(6) The CEO will settle payroll and other debts in a timely manner depending on the availability of funds.

(7) The CEO will aggressively pursue receivables after a reasonable grace period

(8) Financial conditions and activities policies will be monitored - (a) Internal top line report prepared by CEO on bi-annual basis and presented to Board quarterly.

13. Asset protection.- (1) The CEO will protect and adequately maintain all tangible and intangible assets of IHRA. Accordingly, CEO will:

a. Assure that only authorized personnel have access to material amounts of funds

b. Assure that the organization its Board or staff are not unnecessarily exposed to claims of liability

c. Assure that the intellectual property, information and files are protected from loss or significant damage

d. Protect IHRA's public image and credibility at all time

(2) Insurance of property owned or hired by the Government - For the insurance of property owned or hired by the department/entity, the Principal Accounting Officer shall follow rules and guidelines set by the MoF or by his/her department/entity. In accepting insurable risks on behalf of the Government the Principal Accounting Officer shall ensure that

a. the property is under effective government control and all safeguards are exercised against the occurrence of risks for which the Government is acting as insurer

b. there is a clear line of demarcation between property for which the Government accepts the risks and property for which it does not.

14. Grants and contracts.- (1) Grant funds must be used in prudent, lawful and ethical ways and in accordance with donor restrictions. In addition, the CEO shall:

a. Only enter into those grant arrangements in which IHRA has a reasonable expectation of delivering the promised activities and results

b. Any subcontractors must also be reasonably expected to deliver promised activities and results and to use funds in prudent, lawful and ethical ways. All subcontracts must conform to grant requirement

c. Not enter into grant or contract arrangements which place the financial solvency of IHRA at risk

d. Assure the temporarily restricted and permanently restricted assets are appropriately segregated to ensure compliance with donor restriction

e. Seek approval by the Board of Authority for any grant request

f. The CEO and staff Authority can exercise petty cash allowances & delegated authority within Board Approval.

15. Organisational Structure of the Accounting System.- (1) CEO shall act as the Principal Accounting Officer responsible and accountable for the management of the Authority's funds and assets.

(2) Responsibilities – Principal Accounting Officer (PAO) has the authority as delegated by MoF for the accounting functions and for preparing accounts for submission to the Accountant Generals. The PAO has the authority to control the financial management of the entity under him/her, within the limits prescribed by the Government. They also reconcile accounts with the AG/AGPR offices.

16. Preparation of budget.- (1) Preparation of non-development budget - The Principal Accounting Officers must approve and sign off the budgets relevant to their entities.

(2) Preparation of development budget - Once satisfied with the estimates, the Financial Consultant must obtain approval from the Principal Accounting Officer, who will sign off the budgets.

(3) Assignment Account – The Assignment account shall be under the supervision of the CEO, and any transactions shall be made with the approval of the CEO.

(4) Non-Assignment Account –Any transactions shall be made by the CEO and information will be shared with the Finance Committee of the Board.

(5) Consolidation of budget data - After budget estimates have been reviewed by the Financial Consultant and approved by the Principal Accounting Officer, the demands for grants pertaining to that ministry or department must be prepared and submitted, (along with the supporting Budget Orders and New Item Statements) to the Budget Wing of the Finance Division/Department.

(6) Communication - It is the responsibility of the Principal Accounting Officer to ensure the budgets applicable to his/her spending entity are properly communicated to the various delegated officers in that entity. The Principal Accounting Officer will maintain a record of such distributions.

a. The joint signatories shall be the CEO and the Director/Deputy Finance, IHRA to operate the Assignment account.

b. The CEO is duly empowered by the Board to spend from the IHRA Budget upto and including PKR 500,000/- without seeking the approval of Board. This is in pursuance of the proviso contained in PPRA Pubic Procurement Rules 2004, clause 42 (b) (i) as well.

17. Reporting and monitoring.- (1) The Principal Accounting Officer in each spending

entity, as part of his/her responsibility for monitoring expenditures, must submit a statement of excesses and surrenders to the Finance Division/Department at prescribed dates, and in a format set down by the Finance Division/Department.

(2) PAO shall have the powers to re-appropriate and re-allocate funds within the available budget codes (it is possible for the Principal Accounting Officer to reallocate funds, provided they are available from savings arising in the same grant). In this case the Principal Accounting Officer or his/her delegated officer is permitted to re-allocate funds between the individual allotments made to delegated officers or between detailed object heads of the same primary unit of appropriation within a particular grant.

Provided that;

a. re-allocation is not to or from the establishment (salaries and allowances) budget
b. delegated authority is also an authority competent to approve expenditure under these heads.
c. re-allocation is authorised before the expiry of the financial year to which the budget relates
d. amount re-allocated does not exceed any financial limits as determined by the Finance Division/ Department.
e. The Principal Accounting Officer is not permitted to re-allocate funds between major and minor function heads within the entity.

18. Issue of payment.- (1) No transaction exceeding the value of available funds can be passed for payment. However, if the claim is inevitably payable under legal contracts and insufficient funds exist, the demand for payment may be honoured. The authorising officer must report the matter to a delegated authority before approving the claim. In such circumstances the Principal Accounting Officer must take appropriate actions to find the extra funds for such payments.

19. Use of imprest account - for expenditures below the specified limit.- (1) The Ministry of Finance, in consultation with the Principal Accounting Officer (PAO) of the entity should set the limit of the imprest so that it requires reimbursement at least once a month, having due regard to the size of the department and the percentage of the imprest limit required to be spent before a reimbursement claim can be submitted.

PART V

"Mode of appointment of the Registration board and inspection committees, the summoning and holding of meetings thereof for conduct of business of such committees"

Chapter 1

1. Convention and Chairperson of Board Meetings.- (1) Registration Board's meetings shall be held at-least once in a month but may be held at any time in case of urgent circumstances on the call of chairperson himself or on the request of any member in writing for a reason to be specified therein.

(2) Registration Board's meetings shall be convened and presided over by the chairperson. However, the first meeting of every term of the newly elected members of the Board shall be convened and presided over by the member who has received the largest number of votes after such election.

(3) In case the chairperson of the Board is on leave or unable to exercise his powers for any cause, the chairman shall appoint a member to act on his behalf. In the absence of such an appointee, the members shall elect from amongst themselves one person to act on the behalf of the chairman.

2. Place and time of Board Meeting.- (1) Registration Board's meetings shall be held at the head office of the Authority or any other place suggested by the chairman, at a time convenient for the members of the Board to attend.

3. Designated Secretariat, meeting notices, and meeting Materials.- (1) The District Health Officer Islamabad shall act as the secretary to the Registration Board. The secretary shall conduct the drafting of the meeting agendas and minutes, and handle other administrative matters related to Registration Board's meetings, and reports to the chairperson of the Board.

(2) The Registration Board's meetings shall be convened upon written notices sent to all members fourteen days prior to the date of the meeting, specifying the date and place of the meeting and attaching the meeting agenda and related material.

Provided that; Registration Board's meetings may be convened at any time without such prescribed notices in case of urgent circumstances and any member attending the meeting in person shall be deemed to have received such meeting notice.

(3) If any member considers meeting material to be insufficient, they may request the Registration Board's secretary to provide supplemental material in advance.

Provided that; if the members consider meeting material to be insufficient during the meeting, the meeting may be postponed upon a resolution of the Registration Board.

4. Subject Matters of Registration Board's Meetings.- (1) Subject to the provisions of

the Act, the agenda of regular Registration Board's meeting shall be decided in consultation of chairman, who may seek suggestions from the members.

Provided that; subject to the generality of sub clause i, the agenda shall include the meeting minutes of the preceding meeting in the agenda;

5. Attendance signing Booklet and proxies.- (1) A signing booklet shall be provided at every Registration Board's Meeting for the attending members to sign in.

(2) The members shall attend Registration Board's Meetings in person.

Provided that; any member attending the meeting via video conference shall be deemed to have attended the meeting in person but shall sign an attendance card and send it to the secretary of the Registration Board via facsimile in lieu of signing on the attendance signing booklet.

6. Convention of Registration Board Meetings.- (1) If two-third of the total members are not yet present at the scheduled time for a Registration Board's Meeting, the chairperson may postpone the time of the meeting. The postponements shall be limited to twice at the most. If after two postponements no quorum can yet be constituted, the chairperson shall reconvene the meeting pursuant to the procedures under regulation 6 of part V of these regulations.

7. Other attendants.- (1) Depending on the subject matters of proposed resolutions, relevant managerial personnel may be invited to present at Registration Board's Meetings to assist the members in understanding the Authority's current conditions so that they can make appropriate resolutions. In addition, Certified Public Accountant (CPAs), Legal counsels, or other professional personnel may be invited to the meetings to provide professional opinions for the members of the Registration Board's, but shall excuse themselves and vacate the meeting when the proposed resolution will be discussed and resolved.

8. Discussion of Proposed Resolutions.- (1) In principle, the discussion of proposed resolutions at a Registration Board's Meeting shall proceed in accordance with the agenda attached to the meeting notice. however, if no objection is voiced by any member present at the meeting or with more than half of the attending member's consent, the chairperson may make changes. Unless otherwise resolved at the meeting, the chairperson cannot announce adjournment of the meeting before all the discussion items (including special motion) listed in the above agenda are resolved.

(2) In the process of a Registration Board's meeting, if the number of members present at the meeting become fewer than half of the members originally attending the meeting, the chairperson shall announce a temporary adjournment to the meeting upon a motion made either by himself or by any member present at the meeting, and provisions of regulation 9 of part V of these regulations shall mutatis mutandis to such case.

(3) During a meeting, the chairperson may, at his discretion, set time for intermission or negotiation.

9. Voting.- (1) The chairperson may announce to end the discussion of any resolution and

go into voting if the chairperson deems it appropriate for voting.

(2) Resolutions shall be deemed adopted if no objection is voiced by any of the attending members after solicitation by the chairperson. If objection is voiced after solicitation by the chairperson, such resolution shall be voted. A resolution shall be adopted by a majority of those members present at a meeting attended by two-third of all members.

Provided that; if there is an amendment to or substitute for a proposed resolution, the chairperson shall decide the sequence of voting for such proposed resolution and the amendment or substitute. If anyone of them has been adopted, the others shall be deemed vetoed and no further voting is required.

(3) The result of voting shall be announced at the meeting and placed on record.

(4) The method of the voting shall be one of the following as determined by the chairperson:

a. By showing of hands;
b. By voicing votes; or
c. By casting ballots. The chairman shall appoint a member to monitor the voting process and counting of ballots.

10. The recusal of Conflict-Interested Members.- (1) If a member has a personal interest in the matter under discussion at the meeting, the relevant member shall disclose the nature of such personal interest. If such interest may impair the interest of the Authority, the relevant member shall not join the discussion and voting of such matter, and shall recuse himself when the matter is being discussed and resolved.

11. Meeting items to be recorded and signed.- (1) The resolution of every Registration Board's meeting shall be recorded in the meeting minutes. The meeting minutes shall accurately record the following items:

a. The term (or year), place, and time of the meeting;

b. The name of the Chairperson;

c. The attendance situation of the members, including the names and numbers of those who are present, on leave, and absent;

d. The names and titles of other attendants;

e. The name of the recorder;

f. Report items;

g. Discussion items: the voting method and the result of each proposed resolution; the summary of opinion by the members, experts, and other personnel; the names of the members that disclosed a conflict of interest under regulation 13 of part V of these regulations, summary of the nature of the conflict of interest, the reasons for recusal or non-recusal, and the circumstances of recusal; any dissenting opinion or abstention with a written statement;

h. Special motions: the names of the persons proposing the special motions; the voting method and the result of each proposed resolution; the summary of opinion by the members, experts, and other personnel; any dissenting opinion or abstention with a written statement; and

i. Other items that shall be recorded.

(2) Meeting minutes shall be signed by the chairperson of the meeting and the recorder, distributed to each member within twenty days after the meeting, and carefully kept as the Authority's important file throughout the life of the Authority. The attendance signing booklet of a Registration Board's meeting shall be part of the meeting minutes and be permanently retained throughout the life of the Authority. The recording and distribution of the meeting minutes may be performed by means of electronic transmission.

Provided that; the chairperson shall have power to amend and delete anything from the meeting minutes and shall mention the reason for the same in writing.

12. Tape-recording of Registration Board's meeting process.- (1) The process of a Registration Board's meeting regarding the subject matters specified in regulation 7 of part V of these regulations shall be fully tape-recorded and retained for five years in a method that may be encrypted.

Provided that; if any litigation occurs regarding any matter resolved by the members of the Registration Board's before the above retention period expires, the relevant recording tapes shall continue to be retained until the litigation is concluded, and the above-mentioned five-year rule shall not be applicable.

(2) If a Registration Board's meeting is held via video conference, the video and recording tapes shall be part of the meeting minutes and be permanently retained throughout the life of the Authority.

13. Cancellation of Registration Board's Meetings.- (1) In the case of special circumstances where a scheduled Registration Board's meeting of the Authority must be cancelled after meeting notices have been sent to the members, the meeting may be cancelled if the person with the convening right notifies the members in writing at least three days prior to the scheduled meeting date. In case of urgent circumstances where the scheduled Registration Board's meeting must be cancelled and it is impossible to notify the member prior to the time specified above, the meeting may be cancelled if the person with convening right notifies the members by telephone or other means at least three hours prior to the scheduled meeting time and confirms that each member has received such notice.

14. Delegation of the Registration Board.- (1) The chairperson of the Registration Board's shall act on behalf of the Registration Board pursuant to the Authority's objectives when the Board is not in session. In case the chairperson of the Board is unable to exercise his powers for any cause, any other member authorized by the chairperson or elected by the members shall act for him.

15. Establishment of Inspection Committee.- (1) An inspection committee established by the Registration Board shall attend the meeting of the Registration Board on the notice of Registration Board as and when required by the Registration Board.

(2) An inspection committee shall report to the Registration Board regarding the tasks assigned to it under section 18 of the Act.

(3) An inspection committee may conduct its meeting twice in a month to ascertain the future work plan as per direction of the Registration Board, to prepare report on executed work plan as directed by the Registration Board or the Chief Executive Officer of the Authority.

Provided that; regulations mentioned in this part shall mutatis mutandis apply to the inspection committees for conducting its meetings as far as it does not contradict with the provisions of the Act or powers of the Registration Board.

(4) The meeting shall be conducted at the head office of the Authority on the date and time fixed by the Registration Board or as per convened by the head of the Inspection Committee as and when deemed necessary.

(5) The Inspection Committee may call any inspection team in its meeting to seek details of the inspection executed by the it.

PART VI

INSPECTION REGULATIONS

Chapter 1

Formation, Functions and Powers of the Directorate of Inspection

1. Formation of Directorate of Inspection.- (1) The Authority shall establish a directorate of inspection for the purpose of the all inspections.

(2) Directorate of inspection shall be sub ordinate to the Inspection committee and Chief Executive Officer of the Authority.

(3) Directorate of inspection shall consist of a Director, a Deputy Director, Inspection teams, and such other officers and staff as may be deemed necessary by the Authority, from time to time, to perform such functions and exercise such power as may be assigned to Directorate of Inspection by the Authority.

2. Functions of the Directorate.- (1) Subject to the provisions of the Act, the directorate shall be responsible to assist the Inspection committee or the Chief Executive Officer, as the case may be, in performance of the following functions;

a. Develop and implement a comprehensive system / mechanism of the inspection of all types of HCEs.
b. Prepare and implement quarterly / Yearly work plan of the directorate regarding inspections of HCEs, implementation of MSDS, and other tasks assigned to it by the Authority.
c. Notify the inspection teams to perform the functions and exercise the power of the authority in relation to inspection of HCEs under the IHR Act, 2018.
d. Impose and collect Penalties or fine on the HCEs in case of non-compliance of IHR Act, 2018 as per the list of Quantum of Penalties attached as Annex-C.
e. Issue guidelines, instructions and directives to the Healthcare establishments and healthcare Professionals.
f. Develop and implement the anti-quackery strategy and issue necessary directions to ban quackery in all its forms and manifestation.
g. Coordinate with all stake holders including Ministry of Health, DHO, ICT Administration and law enforcement agencies etc. for conduction of anti-quackery activities.
h. Inquire and investigate into malpractice, maladministration and failures in the provision of healthcare services.
i. Issue warnings / show-cause notices to the HCEs involved in malpractice, maladministration and failures in the provision of Healthcare services as per the standards and under the provisions of the Act, rules and regulations.

j. Sealing of HCEs involved in malpractice, maladministration and failures in the provision of Healthcare Services as per the standards and under the provisions of the Act, rules and regulations.

k. Issue suspension orders of HCEs involved in malpractice, maladministration and failures in the provision of Healthcare Services as per the standards and under the provisions of the Act, rules and regulations.

Chapter 2
Kinds of Inspection / Categories of Inspection

3. Kinds of Inspection.- (1) According to the Islamabad Healthcare Regulation Act, 2018 following are the different kinds of inspections which an Inspection team may made on the direction of the Authority, Inspection Committee or any other officer of the Authority duly authorized in this behalf by the Authority;

a. Inspection for grant, renewal, suspension or cancellation of Registration of a HealthCare Establishment (HCE)
b. Inspection for grant, renewal, suspension or cancellation of License for services of a HealthCare Establishment (HCE)
c. Surprise inspection to check compliance with MSDS and provisions of the Act.
d. Periodical Inspection
e. Inspection for inquiry or investigation of a case /complaint.
f. Inspection for any other purpose.

Chapter 3
Formation, Functions and power of Inspection Team

4. Formation of Inspection team.- (1) An inspection team shall consist of inspection officers of the Authority while two experts of the field, may be chosen from the pool of experts developed under section 19(2) of the Act.

Provided that; in the absence of Registration Board, The Authority may develop a pool of experts with the approval of the Board.

(2) Qualification and experience of the experts of an inspection team shall vary according to the different kind of inspections required to be made for different categories of HCEs.

(3) Authority shall ascertain the required qualification and experience of an expert for different categories of inspection and HCEs.

5. Functions of the inspection team.- (1) Subject to the act, an inspection team shall not

inspect a healthcare establishment without an order or direction in writing of the Authority, Director/Deputy Director inspections or any other authorized officer on behalf of CEO of the Authority.

(2) An inspection team may perform any of the inspections mentioned in chapter 2 of part VI of these regulations, subject to sub-clause 1.

(3) All inspections shall be carried out according to the Provisions of the IHR Act, 2018, rules and regulations prescribed thereunder.

(4) All inspection shall be made as per the checklists, made in the light of the Act, regulations or standards & notified practices approved by the Authority from time to time.

(5) An inspection team shall report to the Director/Deputy Director Inspections or such other officer of the directorate as may be appointed in this regard by the CEO of the Authority.

6. Power of an inspection team.- (1) An inspection team shall have following powers for any inspection made under chapter 2 of part VI of these regulations;

a. An application for grant of a registration or a License or its renewal pursuant to the Act, Rules and regulations made thereunder, would give power to an inspection team for complete acquiescence to any entry or inspection for which the grant or renewal of a registration or a license is sought in order to facilitate verification of the information submitted on, or in connection with, such an application.
b. The Authority or an inspection team or any duly designated representative shall have the power to enter upon and into premises of the Applicant or a Licensee, as the case may be, pursuant to the Act, Rules and regulations made thereunder at any time without threat of injury, verbal abuse, or harassment and in the spirit of mutual cooperation in order to determine the status of compliance with the Act, Rules, Regulations, Standards, Reference Manual, any other instructions or orders passed by the Authority. In case any person tries to interfere with the inspection process, the Authority may impose a fine as prescribed in annex C.
c. The Authority or its inspection team or any authorized person of the Authority shall have powers to have full access to all the relevant records, documents and reports at the said premises/HCE or in the possession of its Management, as required for the purpose of the Act, Rules and regulations made thereunder or other applicable law.
d. An Inspection team shall have power to copy any records, documents and reports found in HCE or in the possession of its Management either manually or by photocopy, unless otherwise protected by law, at no expense to the Authority.
e. An Inspection Team shall have power to inspect any apparatus, appliance, equipment, instrument, product, goods or item used or found in, or any practice or procedure being carried out at a Healthcare Establishment or by a Healthcare Service Provider.
f. Where, in the opinion of the Inspection Team, the use of any apparatus, appliance, equipment, instrument, product, goods or item; or the carrying out of any practice or procedure in a Healthcare Establishment, is dangerous or detrimental to any person therein or otherwise unsuitable for the purpose for which it is used or carried out, it may confiscate the said good or item or suspend the use of it and shall immediately report the

matter in writing to the Authority along with the necessary details. On receipt of report the Authority may act according to the provisions in the Act and these Rules.

Provided that; inspection team shall keep the confiscated good or items in the record room of the Authority for such time as may be necessary for the proceedings.

Provided further that; confiscated good or items shall be disposed of according to the law on the order in writing of the Director inspection.

g. An inspection team may pass an interim order of suspension of services or sealing of a HCE till further order of the hearing committee and shall record its reasons in writing for doing the same.
h. Except in the case of a prosecution for an offence under this Act, a member of the Inspection Team shall not be bound to give evidence in any proceedings in respect of, or to produce any document containing, any information which has been obtained from any Healthcare Service Provider or a Healthcare Establishment in the course of carrying out any investigation, inspection, enquiry or performing any duty or function under the Act and these Rules.
i. A member of the Inspection Team shall not disclose any information at any forum which is contained in the medical record, or which relates to the condition, treatment or diagnosis, of any person, as may have come to his knowledge in the course of carrying out any investigation, inspection, enquiry or performing any duty or function under the Act and these Rules unless allowed in writing by the Authority. In case the authorized officers undertake misconduct in his regard, they shall be processed against as prescribed in the Human Resource Management Rules and relevant policies of the Authority.

Chapter 4
Hearing proceedings

7. Hearing Committee.- (1) The Authority shall notify a Hearing Committee to conduct hearing of the HCE and the healthcare professional to whom a show cause notice, to appear before the hearing committee, is served.

8. Formation of Hearing Committee.- (1) The Authority shall appoint a hearing committee, which shall consist of the at-least three members to be appointed from the inspection directorate and must include a legal officer of the Authority, and shall appoint one of its members as chairman of the hearing committee.

Provided that; an expert, who has been part of the inspection team which inspected the HCE for violation of the IHR Act, rules and regulations made thereunder, shall not be member of the Hearing Committee.

Provided further that, until such time that Authority appoints regular employees of Inspection Directorate, Authority may appoint any suitable officers of the Authority as members of the Hearing Committee, under this regulation, to the achieve the purpose of the Act.

9. Hearing Opportunity.- (1) An adequate opportunity of hearing shall be provided to the Healthcare Establishments or healthcare professional, as the case may be, to whom show cause notice is served or whose services has been suspended or is sealed by the Inspection Team of IHRA, as the case may be.

10. Written response etc.- (1) The healthcare Establishment or healthcare professional, as the case may be, under regulation 16, may submit its written response along with other documents in its defense on or before the day fixed for hearing.

Provided that; on date of hearing, hearing committee shall firstly hear the inspection team which inspected the HCE and issued show-cause notice or order of suspension or sealing and thereafter, HCE will be heard in its defense.

11. Imposition of penalties etc.- (1) The hearing committee may impose penalties or fine, as the case may be, against the contravention, if any, of the provisions of Act, rules and regulations made thereunder according to the penalty fixed for each contravention in schedule-I annexed as annex c with these regulations.

Provided that; a fine imposed by the Authority shall be submitted by the HCE or healthcare professional within 7 days of the decision, in the prescribed bank account of the Authority.

12. Issuance of other direction.- (1) The hearing committee may also issue directions in its order to implement its plan of action, or take additional corrective actions as specified by the authority to cover the deficiencies mentioned in the show cause notice or order of suspension or sealing of the HCE.

Provided that; hearing committee may also issue a timeline to comply with the deficiencies mentioned in the show cause notice.

13. Time limit to decide the matter.- (1) The hearing committee shall dispose of the case/matter within 30 days from the date of issuance of show cause notice or order of suspension or sealing of HCE (Annex-A)

Provided that where a case/ matter is not decided with in the time mentioned in clause 1, any party may make an application to the CEO of the Authority for necessary direction as he deems fit.

14. Appeal.- (1) Any person, aggrieved from the order of the authority, may file an appeal against it before the Secretary Ministry of NHSR&C, within 30 days from the date of communication of the order under section 31 of the Act.

(2) The Secretary Ministry of NHSR&C shall hear the appeal against the decision of the hearing committee and shall decide the same within 60 days of its presentation.

15. Show Cause Notice.- (1) The Authority shall issue a show cause notice, (Annex-A) to the inspected HCE or healthcare professional, as the case may be, for violation of any provision of the Act, rules and regulations made thereunder, to appear before the hearing committee on such date and time as authority may deems reasonable to hear the HCE or the Healthcare professional. Statement of deficiencies shall clearly be stated in show cause notice, as a consequence of determination that a deficiency, omission, or violation of the Act, Rules, Standards, Reference Manual, any other instructions or orders, including but not limited to a plan of correction, passed by Authority has occurred. The show cause notice shall clearly state the name of the Healthcare establishment being inspected and healthcare services provider's name, father name, CNIC number, mobile number and postal address. It shall also bear a serial Number, date, official stamp, name and signature of the inspection officer of the Authority. It shall also state recovery memo if any. The Authority shall keep a duplicate of the show cause notice, duly signed by the person to whom the show cause notice has been served on behalf of HCE.

Provided that; a show cause notice / Observation form shall be served on the HCE or the healthcare professional for the minor contraventions.

Provided further that; inspection team may also serve, along with the show cause notice, an order for suspension of the services of the HCE or the healthcare professional as the case may be, for the minor contraventions.

Provided further that; the inspection team may seal the healthcare establishment if a HCE does not comply with the first show cause notice / observation form or decision of the hearing committee in the prescribed time period. (Annex-B)

(2) In the case of major contraventions, an inspection team may also serve, along with the show cause notice, an order for sealing of the HCE and seal the same.

16. Non-Compliance of the show cause notice.- (1) If a HCE or healthcare professional, as the case may be, to whom a show cause notice has been duly served, does not comply thereunder, within or on the date of hearing, ex-parte proceedings shall be initiated against it by the hearing committee.

Provided that; if on the date of hearing, a representative of the HCE or healthcare professional, as the case may be, whom a show cause notice has been served, appear before the hearing committee and seek for an adjournment, the hearing committee may, if it is satisfied that there is genuine reason for an adjournment, adjourn the hearing for some other day and time.

Chapter 5
Miscellaneous

17. Notice for Inspection.- (1) Surprise Inspection and Inspection for inquiry or investigation of a complaint or suspected violation of the Act, Rules, Standards, Reference Manual, any other instructions or orders passed by the Authority from time to time, shall be carried out without any prior notice to the Concerned Healthcare Establishment.

(2) The Authority will inform the HCE about the dates of the periodical inspection as well as pre-registration and pre-renewal inspection at least one week before the periodical Inspection.

18. Act done in good faith.- (1) No suit or other legal proceedings shall lie against the Authority, Board, technical advisory committee, chief executive officer, Directors, Deputy Directors, officers, inspection teams, advisors, consultants, or agents of the authority for anything done in good faith in the execution or purported execution of this Act, rules and regulations made thereunder.

19. Non-Cooperation by a HCE or healthcare service provider.- (1) A healthcare Establishment (HCE) or healthcare service provider, who fails to cooperate with the inspection team duly appointed by the Authority shall be dealt as under:

a. The Authority may impose a fine which may extend to fifty thousand rupees (Rs. 50,000/-) upon a Healthcare establishment or healthcare service provider who,-
   i. Refuses or fails, without reasonable cause, to furnish any information to the inspection team;
   ii. Gives any false or misleading information to the inspection team.
   iii. Obstructs the authorized person in conducting the inspection for the purposes of the Act, Rules and Regulations prescribed.

20. Assistance of a Legal Counsel.- (1) The Competent Authority may in its absolute discretion, for reasons to be recorded in writing, permit a party to be assisted through a legal counsel. An application in this regard may be submitted by a party so requesting, stating:

a. The name of the legal counsel and his specialities or experience in the relevant field of law along with supporting documents in this regard, if any; and
b. The reasons or issues due to which it may be necessary for the applicant to be so assisted.

PART VII

COMPLAINTS REGULATIONS

Chapter 1

Directorate of Complaints

1. Formation.- (1) The Authority shall establish a directorate of complaints for the purpose of disposal of complaints filed before it.

(2) Subject to the provisions of the Act, Directorate of complaints shall be headed by a director/deputy director who will be sub ordinate to the Chief Executive Officer of the Authority.

(3) Directorate of complaints shall consist of a Director, a Deputy Director, investigation/complaint officers, and such other officers and staff as may be deemed necessary by the Authority, from time to time, to perform such functions and exercise such power as may be assigned to Directorate of complaints by the Authority.

2. The IHRA Complaint Management System.- (1) The Authority shall establish an Complaint Management System under the directorate of complaints for receiving, managing, and resolving complaints, submitted to it or such matters as are taken up by the Authority on its own, through media/social media reports, Reference by the Federal Government, Motion by the Supreme Court or the Islamabad High Court, referral by other governments offices, general public or the aggrieved complainants as per provisions of the Act, for welfare of the public, with a view to protect public interest, improved healthcare services or the healthcare delivery systems.

(2) All Healthcare Establishments shall establish their own internal complaint management systems as prescribed by the Standards and Reference Manual or directions of the Authority which shall be coordinated with the IHRA Complaint Management Directorate through written report to Director Legal & Complaints. In the least there shall be a designated officer, in charge of complaints, in each healthcare establishment who shall maintain a register of Complaints and Remedies, and submit a monthly report to the Director Legal & Complaints or give direct access to their live online database to IHRA, as the case maybe, or both.

(3) The Authority may provide technical support to facilitate Healthcare Establishments in setting up their Complaint Management systems in the light of the Minimum Service Delivery Standards, notified practices and guidelines from time to time for which reasonable reimbursement for services etc. rendered may be charged.

(4) All Healthcare Establishments shall immediately implement the standards, MSDS, standing orders, reference manuals and any other guidelines issued by the Islamabad Healthcare Regulatory Authority (IHRA) at the peril of losing their registration, license, validation, suspension of services or penalty as the case may be in case of noncompliance.

(5) All Healthcare Establishments shall strictly follow the timelines accorded for responding to IHRA queries, letters, notices, summons or communications of all sorts or otherwise shall be liable for a penalty extended to (Rs.500,000) as set by the Authority.

Chapter 2
THE SCOPE OF COMPLAINTS

3. Scope.- (1) The Authority may accept, for the purposes of hearing and passing appropriate orders and or for taking such remedial steps as per law, a Complaint regarding medical negligence, maladministration, malpractice or failure in the provision of healthcare services or any other act or omission including but not limited to, any of the following, in order to determine if the same is against the accepted medical standards, norms, national or international or any regulations or standards:

a. Inordinate delay in provision of medical care,
b. Inadequate or incorrect communication of information about diagnostics, risks, or any other related subjects including non-communication of change of address;
c. Failure to follow standard medical procedures;
d. Failure to implement or comply with the Standards;
e. Failure to take informed consent unless extenuating circumstances exist;
f. Failure to maintain adequate services for clinical management including but not limited to assessment, diagnosis, treatment and follow up;
g. Undertaking the management of a patient without the availability of requisite competence, human resource, equipment or other facilities related thereto.
h. Inadequate clinical assessment and/or diagnosis;
i. Failure to keep, maintain or secure records including medical records, in accordance with the Standards and the Reference Manual etc;
j. Failure to implement and or follow recognized standards, safety or other, regarding infection control;
k. Failure to provide post-operative care according to the Standards;
l. Failure to foresee and take comprehensive precautionary measures against system failures and/or possible mishaps;
m. Inappropriate and unjustifiable costs of services or procedures;
n. Violation of rights provided in the Charters, and the Constitution of Pakistan;
o. Inadequate medical consultation or advice and/or treatment at the appropriate level;
p. Inadequate recordkeeping;
q. Failure to follow prescription procedures as per the Standards;
r. Failure to prevent unnecessary diagnosis and/or treatment;
s. Failure to install systems to prevent cases of sexual harassment, and/or improper conduct, such as unbecoming of a Healthcare Service Provider;
t. Failure to release patient records or true copy;
u. Failure to install systems to prevent substance abuse;
v. Misrepresentations of any sort relating to the healthcare of the patient
w. Billing or documentary fraud;
x. Flawed medical condition(s) or qualification(s) of the staff and other members of the Healthcare Establishment, whether rendering healthcare services or not, and including but not limited to, those having contractual relationship with the Healthcare Establishment or the Healthcare Service Provider, as the case may be;

y. Failure to ensure prevention of patient abandonment or neglect;
z. Failure to follow the relevant law;
aa. Quackery.
bb. Any other mistake or deficiency on the part of the health care establishment or professional that the Authority and its experts believe were medically and ethically incorrect and have caused sufferings for the patient and their families.

Chapter 3

THE REGISTRATION OF COMPLAINT

4. Making a Complaint.- (1) An Aggrieved Person may, firstly and preferably, make a Complaint to the concerned Healthcare Establishment in line with the Complaint Management System as established under sub-regulation (2) of regulation 3 of part VII of these regulation.

(2) Direct Complaint to IHRA: If the Complaint of the Aggrieved Person is not duly redressed by the concerned Healthcare Establishment within 14 days or the aggrieved person is not satisfied with the sincerity of healthcare establishment in resolving the complaint, then the Aggrieved Person may, make a complaint directly to the Authority, against a healthcare professional or healthcare establishment, within sixty days from the date of knowledge of the cause of action, by submitting an application in writing supported by an affidavit of the aggrieved person.

Provided that; the Authority may take notice of any instance or allegation of maladministration, malpractice, or failure in the provision of health care services, coming into its knowledge from any source whatsoever, regarding a health care matter, Healthcare Establishment, healthcare professional or related to it, as the case may be.

(3) Written Affidavit: Every Complaint shall be supported by a written affidavit, bearing the signature or thumb impression of the Complainant, as the case may be notarized or duly attested by an authorized member of the staff of the Authority.

Provided that; a complaint which is not supported by an affidavit shall not be proceeded by the complaint management Officer.

Provided further that; If a complaint is filed without an affidavit, the complaint management Officer shall grant an opportunity to the complainant to submit the affidavit within 14 days of the objection.

Provided further that; If the requisite Affidavit is not submitted in support of the Complaint within the stipulated time, the Complaint Management Officer may close the Complaint.

Notwithstanding anything in this clause, the Competent Authority may extend the time required in genuine cases, if justified.

(4) Content of Affidavit: The Affidavit, amongst other assertions, in support of the complaint must also contain the following:

a. That the allegations contained in the Complaint are true and correct to the best of the knowledge and belief of the Complainant;
b. That no suit, appeal, or any proceedings in connection with the subject matter of the complaint are pending before any court of competent jurisdiction;
c. That no allegation contained in the Complaint is without reasonable and justifiable ground(s) and that it is not being made simply with an intention to harass, defame, embarrass and/or to pressurize the healthcare establishment or healthcare professional, as the case may be, complained against;
d. That if the complaint, submitted either by an aggrieved person or a healthcare professional, is proved false, the Authority may impose penalty which may extend to two hundred thousand Rupees upon the complainant;
e. That the Complainant undertakes to keep the Authority informed of his/her address and contact details and shall regularly attend the hearings on the dates fixed by the Authority and fully understands that if he/she absents himself/herself, for no sufficient reasons despite duly served notice, or wilfully delays the proceedings of the Authority in its opinion, then he/she shall be liable to pay the costs as awarded by the Authority, decision of complaint shall be taken as ex-parte decree.
f. That a Complaint was made to the Healthcare Establishment and same was not addressed by it (if any);
g. That the Complainant has neither filed a Complaint on same subject matter previously before the Authority nor the same matter is already pending before the Authority and further that the subject matter has not already been decided by any forum.
h. That (In case of death of a Patient) where there is no Autopsy Report, the Complainant must give an undertaking to the effect that he/she is ready and willing to get the same through the process of exhumation and post-mortem and provide the same to the Authority at the earliest.

(5) Non-Admissible Complaints: A Complaint shall not be maintainable or admissible:

(a) If the Complaint is not duly signed or does not bear a thumb impression; or

(b) If the requisite Affidavit is not submitted by the Complainant within stipulated time; or

(c) If the Complaint is anonymous or pseudonymous; or

(d) The Complaint is time-barred under subsection (2) of Section 34 of the Act; or

(e) The subject matter of the Complaint is sub-judice before a court of competent jurisdiction on the date of receipt of the Complaint; or

(f) The subject matter of the Complaint does not fall within the purview of the Act.

(6) Accompanying Documents: Every Complaint shall be accompanied by the following documents:

(a) Attested copy of the Complainant's valid Computerized National identity Card or any other document depicting his identity and that of the patient;

(b) Valid Medical records; if any

(c) Receipts; if any

(d) Correspondence with the concerned Healthcare Establishment, Healthcare professional or other authorities, if any, as the case may be; and

(e) Other duly attested relevant documents in support of the Complaint.

Provided that; Scanned copies, photocopies and duplicates will suffice at the time of submission of the Complaint.

5. Receipt and Registration of Complaint.- (1) On the receipt of a Complaint, the person in-charge of the Complaint Registration Desk shall;

a. Enter information in the Complaint Management Register managed by the Directorate and allot a Complaint Registration Number.

b. Forward the Complaint to the Complaint Management Officer of the Directorate.

Provided that; Where the Complaint is made on a reference by the Federal Government or the National Assembly of Pakistan or on the motion of the Supreme Court of Pakistan or the Islamabad High Court, the date of receipt shall be taken as the date on which such reference or motion was made to the Authority; and if the matter involves an aggrieved party, then the date of receipt shall be taken as the date on which the said aggrieved party submits the affidavit in accordance with the sub-regulation (3) of regulation 5 of part VII of these regulations, In both the situations the Case or Complaint may be proceeded with and decided in the manner as if it has been made directly to the Authority, by a Complainant, or otherwise as directed by the Competent Authority.

6. Admission of Complaint.- (1) The Complaint Management Officer of the Directorate shall, after reviewing the Complaint, decide regarding its maintainability in accordance with the Act, Rules and Regulations. In case the Complaint is maintainable, the Complaint Management Officer shall instruct the Directorate to:

a. Issue acknowledgement receipt to the Complainant
b. Refer the complaint to the Complaint Hearing Committee for hearing;
c. Entrust the complaint to a complaint officer / investigation officer

Provided that; when a Complaint is filed by more than one person, the first person shall be taken as the Complainant for the purposes of correspondence and shall be informed accordingly.

(2) Rejection of Complaint: The Complaint Management Officer may reject the complaint in limine, if the same is not admissible and/or not maintainable under the Act, Regulations therein, under sub-regulation (5) of regulation 5, or does not require any investigation for any other reason in view of the Competent Authority;

Provided that; The Directorate shall record the reasons for rejection of the complaint in writing and a copy of the same shall be given to the complainant.

7. General Welfare of the Public or Safety.- (1) Where the Authority is of the view that it would be in the public interest to probe or look in to any instance or allegation, involving any of the Healthcare Establishment (s) or any such matter as provided for under the Act, or the Regulations which affects or relates to or may affect or relate to the general welfare of the public, or safety, as the case may be, it may itself, or direct any other Competent Authority to do the needful.

(2) The Authority shall in all such matters take the same as a Complaint and shall issue Notices to all the concerned parties directing them to submit their written response to the issue at hand.

(3) The Authority shall assign such Complaint to the Complaint Hearing Committee, to take such necessary steps as may be required under the Act, rules or regulations made therein.

Provided that; in cases where the allegations or the circumstances of a matter are of extremely serious nature or steps are required to be taken on a large scale, the Complaint Hearing Committee of IHRA at earliest submit its considerations and appropriate directions on the matter in hand or may, if deemed appropriate in view of the gravity of the situation, pass a summary order that shall be binding on the offender(s)/Parties involved for a stipulated period and not challengeable before any Court of Law.

Chapter 4

THE HANDLING OF COMPLAINTS

8. Complaint Hearing Committee.- (1) A maintainable complaint under regulation 6 sub-regulation 1, shall be referred to the Complaint Hearing Committee under regulation 6(1)(a).

(2) The Complaint Hearing Committee shall consist of three Members, consisting of Deputy Director Complaint, Complaint Officer and a Legal Officer, to be appointed by the Director/Dep Director Complaints.

Provided that; Deputy Director Complaint shall be appointed as chairperson of the Complaint Hearing Committee.

Provided further that, until such time that Authority appoints regular employees of complaint directorate, Authority may appoint any suitable officers of the Authority as members of the Complaint Hearing Committee to achieve the purpose of the Act.

(3) Quorum of the committee to conduct and give decision in a complaint shall be 2 members.

(4) The Complaint Hearing Committee shall have the power mentioned under section 4 (2) of the Act.

(5) The Complaint Hearing Committee shall have power to impose penalties under section 29 of the Act and rules and regulations made therein.

(6) Complaint Hearing Committee shall be the first level of hearing of Complaint as deputed and delegated by the Authority.

9. Entrustment of Complaints.- (1) For probing into a Complaint through its Complaint Management System, the Complaint Hearing Committee may do the same itself or entrust it to an Inquiry committee or investigation / complaint officer, as the case may be, that would take all necessary steps as may be required while exercising the powers including but not limited to, as specified under subsection (2) of Section 4 of the Act and for achieving the purposes of the Act.

10. Initial Meeting with Complainant.- (1) If necessary, the Complaint Hearing Committee or Inquiry Committee, or investigation / complaint officer as the case may be, may call for an initial meeting with the Complainant for clarity of facts and for the purposes of requiring him/her to provide any document or information in the possession or Knowledge of the Complainant.

(2) If after the initial meeting with the Complainant, the Complaint Hearing Committee or Inquiry committee or inspection / complaint officer, as the case may be, comes to the conclusion that in view of the facts and circumstances of the matter, or the evidence placed on record, there is some other issue which also needs to be looked into by the Authority, Complaint Hearing Committee, Inquiry committee or inspection / complaint officer may, by stating reasons for doing so, add the particulars of the allegations or the facts on which they are based.

Provided that; if the initial meeting with the complainant is conducted by an Inquiry committee or inspection / complaint officer, it may put up a separate note to the Complaint Hearing Committee in this regard, while stating the reasons for doing so and if approved by the said Complaint Hearing Committee, the particulars of the allegation or the facts on which they are based shall be added.

Provided further that; the Complaint Hearing Committee shall grant its approval only if it considers that the addition be made in the public interest to determine the real issues.

Provided further that; if any amendment or addition is being sought to be made subsequently, then a Notice shall be issued to the party complained against, and the Complaint Hearing Committee, shall hear the matter before making any order in this regard.

11. Response from Party (ies) complained against.- (1) In respect of every Complaint admitted under regulation 7, a notice shall be issued to the party complained against to submit its written response/reply supported by an affidavit, along with all the records and documents, relevant to the complaint, within ten (10) working days from the date of the Notice issued to them, in this regard.

(2) A Copy of the Complaint along with all its record, if any, shall also be sent with the Notice issued under sub clause (1).

(3) If a party complained against failed to submit its written response/reply within the time stipulated under sub clause (1) without any sufficient reason to the satisfaction of the Complaint Hearing Committee, right to submit written response shall be closed and the complaint Hearing Committee shall proceed in absence of written response/ reply.

(4) If a party complained against failed to submit its written response/reply within the time stipulated under sub clause (1) but the party complained against or its representative appears on the date of hearing before the complaint Hearing Committee, and show a sufficient reason for not complying with the notice, the Complaint Hearing Committee, may make an order of adjournment to afford him an opportunity to submit the same within 10 days of from the date of such order.

Provided that; no further adjournment shall be awarded in any case for submission of written response.

(5) A copy of the written response shall be sent to the complainant at the earliest.

12. Respondent's Affidavit.- (1) party complained against (respondent) shall file its written response/reply supported by an affidavit, which must include, amongst other assertions, in support of its response, where appropriate, the following information of the effect that:

a. The statements made in the response are true to the best of knowledge and belief of the said party;
b. If any suit, appeal, or any other proceedings in connection with the subject matter of the complaint are pending before any court of competent jurisdiction or not; and
c. The said party undertakes to keep the Authority informed of its address and contact details and shall regularly attend the dates fixed for Hearing by the Authority and fully understand that if it absents itself, for no sufficient reason despite duly served notice, or wilfully delays the proceedings of the Authority, then he/she shall be liable to pay the costs as awarded by the Authority and that the Authority shall decide the Complaint as per the governing law;

13. Joint Hearing.- (1) After submission of the written response by the respondent, Complaint Hearing Committee, shall issue notice to all the parties to appear before the Complaint Hearing Committee, on a day and time, so fixed in the notice, along with all the documents in their possession.

Provided that; Complaint Hearing Committee, may summon and enforce, attendance of any person, concern with the complaint, to examine him on oath, at any time, before the final order of the Complaint Hearing Committee.

(2) On the date and time of joint hearing, the Complaint Hearing Committee, shall firstly afford opportunity to the complainant to present its complaint, produces all relevant documents in his possession and present witnesses.

(3) Respondent shall be awarded opportunity of hearing, production of all the documents in its possession and to record statement of witnesses, after the complainant being heard.

Provided that; Complaint Hearing Committee, may order the production of any document relevant to the complaint in possession of any person.

(4) Before administering the oath, every witness shall be duly informed that the statement is to be recorded in writing and that it shall be read over to him in the language that he understands. On confirmation of the statement as recorded in writing, the witness shall put his signatures or thumb impression on the same, as the case may be.

(5) The evidence placed on record shall become the property of the Authority.

(6) Every party shall have a right to ask questions from the witness(es) of the other parties on oath.

(7) The Complaint Hearing Committee, or the Inquiry Committee or the investigation / complaint officer, or the review and appeal forums, as the case may be, may ask any question from any party or the witnesses or the Expert(s) for the purposes of deciding the issue involved in the matter.

(8) Subject to other provisions of part VII of these regulations, Complaint Hearing Committee, may if it seems necessary in the interest of justice, ask the Authority to appoint an inspection team for the purposes as are mentioned by the Complaint Hearing Committee.

(9) Subject to other provisions of part VII of these regulations; Complaint Hearing Committee, may, after hearing both the parties under sub clause 2 & 3, call the subject specialist for the expert opinion on the matter before Complaint Hearing Committee.

(10) Complaint officer / investigation officer shall assist the Complaint Hearing Committee on the facts of the complaint.

(11) The Complaint Hearing Committee, shall announce its decision on the bases of facts in issue proved and expert opinion, if any.

(12) The Complaint Hearing Committee, shall decide the matter within 90 days from the date of its presentation before the Complaint Hearing Committee.

14. Appeal.- (1) Subject to regulation 22 (5) of part VII, an appeal against an order of the Authority shall lie before the Secretary Ministry of NHSR&C and must be lodged within thirty (30) days of the Order of the Authority.

(2) An appeal against the order of Complaint Management Officer, rejecting a complaint under regulation 6 (2) of part VII, the Complainant may within thirty (30) days from the date of receipt of the decision of such officer shall lie before the Secretary Ministry of NHSR&C.

(3) An appeal shall be decided within 60 days from the date of its institution.

Chapter 5
Inspection and Expert Opinion

15. Inspection.- If the Complaint Hearing Committee, deems it necessary, an

inspection team duly approved by the CEO and notified by the Director/Deputy Director inspection may visit the Healthcare Establishment or the concerned area including but not limited to the healthcare establishment on the direction of Complaint Hearing Committee, for the following purposes:

a. collect evidence(s); or
b. inspect any apparatus, appliance, equipment, instrument, product, goods, or items used, found in, or any practice or procedure being carried out at the Healthcare Establishment; or
c. take sample(s) for further evaluation; and/or
d. make sketch(es) or take photographs
e. seal or de-seal the premises as the case may be.

(2) The Authority may order the inspection team, sealing or de-sealing of any Healthcare Establishment, or confiscation of records, equipment or devices etc, for reasons recorded in writing, with or without prior notice being given to the said Healthcare Establishment, on a report submitted to it by the Directorate of Complaints. Such a report shall be prepared by the said Directorate on the basis of the information and or the record before it and on considering the contents of the same, while keeping the seriousness of the matter in mind, it reaches a conclusion that:

a. In the light of facts and circumstances, it is necessary to preserve the evidence;
b. There are chances that the record/evidence, including but not limited to patient medical records and/or other relevant records may be changed, altered or destroyed.
c. Remove the evidence from within the jurisdiction of the Authority; or
d. It will be in the general public interest to inspect the said Healthcare Establishment.
e. Any one of the above.

Provided that the Authority may grant specific permission, in writing, in this regard after thoroughly taking into consideration the report and any other material placed before it.

Provided further that the materials confiscated would be dealt with according to law, an inventory compiled, and the items thus confiscated be given into the custody of the Record Keeper to keep them safe in record room.

(3) The Inspection Team shall carry out the inspection in accordance with the directions issued by the Authority, including the direction that any such inspection shall be carried out while ensuring the safety of the said team. The Authority may, if it deems appropriate, direct that any local authority, including but not limited to the police or the local administration, to assist the said team in carrying out the inspection. This arrangement shall continue till such time magisterial power delegations to the IHRA Officers/Officials are approved and operative.

16. Consultation with Expert(s).- Opinion of expert(s) may be obtained whenever considered necessary by the Complaint Hearing Committee.

(2) As many experts as may be considered necessary by the Authority may be engaged on such terms and conditions as deemed appropriate for carrying out the purposes of the Act.

(3) If the Complaint Hearing Committee deems it necessary or where a party specifically applies for obtaining an expert opinion, the Authority, if considered appropriate, may appoint expert(s) for the said purpose.

(4) The expert(s) so appointed shall disclose his conflict of interest, if any, to the Authority, as soon as he/she is so appointed. If there is any conflict of interest, the Authority, shall appoint any other expert(s) as the case may be, from the relevant field.

(5) The Authority may decline the request of any party for an expert opinion, if it concludes that the matter in dispute pertains to a factual dispute that does not require an expert opinion.

(6) The expert opinion submitted to the Complaint Hearing Committee shall be communicated to all the parties to the Complaint if deemed appropriate by the Complaint Hearing Committee.

(7) If any of the parties to Complaint is discontented with the expert opinion, it may either, submit his questions in writing to the Complaint Hearing Committee, for clarification by the same expert(s) whose opinion was obtained or apply to the Authority to present the matter to other expert(s) for a second opinion. In such a case, a list of the Expert(s) in the relevant field shall be provided to the said party, specifying the qualification (s) and experience of each expert, to choose an expert of his choice for the required second opinion.

(8) Where a party opts to submit written questions for clarification by the same expert(s) whose opinion was obtained by the Authority, may do so within ten (10) working days of service of the expert opinion and it must be only for the purposes of clarification of the earlier opinion.

Provided that such questions shall be presented once only and such a party shall not be allowed to seek a second opinion after receiving clarifications.

Provided further that; the Authority, after having gone through the clarifications provided by the Expert(s), for reasons recorded in writing, may seek a second opinion in such a case. If the Authority decides to obtain a second opinion in such a situation, then the party which opted to submit written questions for clarification by the expert(s), shall not be liable to pay for the second opinion from the Expert(s) so chosen by the Authority, in this regard.

(9) The answers of the Expert(s) to the questions put in the manner mentioned above, shall be treated as part of the expert opinion.

(10) It shall be the duty of the expert(s) to assist the Authority on a matter within his expertise.

(11) That at the end of the opinion of the expert(s), there must be a statement that:

a. the expert(s) understands his duty to the Authority; and
b. he/she/they have complied with that duty.

(12) Where a party applies for a second opinion, the Authority may at any stage direct that a joint meeting be held between the experts, in case there is a difference of opinion between them, for the purposes of requiring them to:

a. identify and discuss the expert issues involved in the proceedings; and
b. where possible, reach an agreed opinion on those issues.

(13) Following the discussion between the experts, they must submit a statement to the Authority showing:

a. those issues on which they agree; and
b. those issues on which they disagree and summary of their reasons for disagreement.

(14) In any case, the Authority may prefer the opinion of one expert over the other, but it shall record reasons in writing for doing so including but not limited to, his expertise in the relevant field and supporting material, if submitted by him.

(15) The Authority may appoint an expert or a panel of experts if it deems necessary in cases where the disagreement between the experts is of a serious nature, in order to resolve the controversy. The opinion of such an expert or panel of experts shall be final.

(16) The Authority may direct any of the parties to provide all the necessary information/record to the expert(s) through the Authority, as the case may be, required for the purposes of rendering the opinion.

(17) The expert(s) may request the Authority to issue directions for assistance in carrying out the assignment. In such a case, the Authority shall issue such directions as deemed appropriate.

(18) The opinion of the expert should be independent, objective and unbiased, and should be on the matters within his/her expertise. He/she should make it clear when a question or issue involved in the matter referred to him/her falls outside his/her expertise, or when he/she is not able to reach a definite opinion, for example, because he/she has insufficient information.

(19) Expert Opinion: - The opinion of the expert must be addressed to the Authority and must include:

a. details of his qualifications;
b. details of any literature or other material upon which he has relied for his expert opinion;
c. a statement setting out the substance of all facts and instructions, if any, given to him, which are relevant to the opinion given by him or upon which his opinion is based;
d. where possible, state who carried out any examination, measurement test or experiment which he has used for the report, give the qualifications of the person and also state whether or not the test or experiment has been carried out under his/her supervision;
e. a summary of the conclusions reached;
f. if he is not able to give his opinion without qualification, state the qualification;
g. where there are facts in dispute, the expert should not express a view in favour of one or the other disputed set of facts, unless because of his/her learning and experience, he perceives one set of facts as being improbable or less probable, in which case he may express that view, and should give reasons for same;
h. a statement that he/she understands his/her duties to the Competent Authority and that he has complied with and shall continue to comply with that duty.

(20) The expert must not be asked to, and must not amend, expand or alter, any part of the report in a manner which distorts his true opinion. However, he/she may be invited to expand or alter any part of the report in a manner to ensure accuracy and internal consistency, completeness, and relevance to the issues and clarity. Before disclosing his opinion, he should be given the opportunity to review, and if so necessary, to update the contents of his opinion.

(21) The expert(s) must at all times maintain complete confidentiality and discretion regarding the matters presented to him/her for expert opinion, and maintain not only the privileged information in strict confidentiality but also the privacy of the parties and the suit in question. Any such breach either deliberate or erroneous would lead to disbarment from any future such role and possible fine upon the expert(s) found in breach of confidentiality ruled upon by the Competent Authority in the IHRA.

(22) None of the parties shall be permitted to approach the expert(s) in any manner, whatsoever; under penalty of fine and adverse judgment if found in default.

Chapter 6
ALTERNATE DISPUTE RESOLUTION MECHANISM

17. Alternate Dispute Resolution Option.- (1) Notwithstanding anything in these Regulations, it shall be the choice of all parties concerned to request in writing to the Complaint Hearing Committee to hold proceedings in abeyance for a defined time, not exceeding 30 calendar days, to allow the parties to seek resolution through Alternate Dispute Resolution Mechanism, so provided and arranged for under the supervision of and by the IHRA.

(2) Trained Alternate Dispute Resolutions (ADR) Experts would be available for fee payable to the IHRA to resolve the issues amicably.

(3) The suitability of any request for ADR would be at the discretion of the Complaint Hearing Committee who shall give the reasons in writing for doing so.

(4) In case the ADR process is non-productive, the usual process of Complaint Mechanism shall resume under the IHRA Rules and Regulations.

(5) The ADR resolution shall be binding on the parties and form the basis for the final verdict once ratified and included in the Order of the Complaint Hearing Committee.

(6) Such ADR based decisions shall be binding on all parties and no further appeals shall lie or be entertained in any forum.

Chapter 7
THE POWERS TO PASS INTERIM ORDERS

18. Powers to pass Interim Orders.- (1) Wherein view of the allegations contained in the Complaint or after clarification of facts as provided under regulation 11 of part VII, the Complaint Hearing Committee may pass, by itself or through competent authority, including but not

limited to, any of the following: interim orders, ex-parte, etc. while recording the reasons thereof, in view of the facts and circumstances of the matter, in order to safeguard the public interest and for the achievement of the purposes and intent of the Act; -

a. Issue orders of restraint;
b. Issue orders of contempt;
c. Issue orders in circumstances requiring emergency and/or urgent determinations as well as Summary Decisions where required as per law;
d. Issue directions to the Federal/Islamabad City or Local Government whichever is relevant;
e. Issue directions to a Healthcare Establishment;
f. Pass any conditional orders relating to the manner in which healthcare services are being delivered or to improve the healthcare delivery system at any given Healthcare Establishment;
g. Issue any directions to any other Authority within the scope of the Act;
h. Issue such instructions as deemed necessary; and/or
i. Issue any such directions or orders as deemed appropriate for the purposes of regulation 17 of part VII of these regulations;
j. Communicate with the Pakistan Medical Commission (PMC), Council for Homeopathy, Council for Tibb, the Nursing Council, Veterinary Medicine Council or any other authority competent to handle the matter and to assist the Authority in deciding the matter(s) in the larger Public Interest. Where no such body exists, IHRA shall undertake to initiate their registration ab initio itself and regulate it in the national interest.

Provided that; the Complaint Management Committee may also further direct that any of the Interim Orders thus passed by it may be for a particular period/duration of time or that the same be implemented within a particular time frame and that a report be submitted before it regarding the compliance of the same.

(2) The Complaint Hearing Committee or the competent authority, as the case may be, shall have the powers to issue, amend, alter, affirm, or revoke any interim orders after hearing all the parties concerned in the matter, after due Notice.

Chapter 8

THE DISPOSAL OF COMPLAINTS/CASES

19. Disposal of Complaints/Cases.- The matter or the investigation of the Complaint/Case, as the case may be, shall on the orders of the Complaint Hearing Committee, be closed in any one or more situations as detailed below: -

a. the Complaint has no merit or substance in it and/or no further investigation is required;
b. the Complaint is proved to be false;
c. The Complainant fails to provide record and/or evidence, in his possession required, to decide the Complaint within stipulated period of time or extension thereof;
d. the Complainant fails to attend hearing(s) despite duly served notice, issued at the address as stated in the Complaint or any new address duly provided by him/her to the Authority.

e. adequate relief had already been provided to the Complainant by the Healthcare Establishment, before the Complaint was made to the IHRA and the Authority comes to the conclusion after hearing all the parties to the Complaint that no further action on its part is required;
f. the Complainant and the party (ies) complained against agree to a proposition consequent whereof grievance is redressed without any proof of negligence, maladministration, malpractice or failure in the provision of healthcare services at the Healthcare Establishment;
g. no maladministration or malpractice, failure in the provision of healthcare services at the Healthcare Establishment or any other act or omission, as detailed herein, has been found by the Authority;
h. the Complaint was found incompetent;
i. the Complaint is withdrawn by the Complainant during the course of investigation with the approval of the Competent Authority;

Provided that the Competent Authority may not grant the approval if, in view of the record, it considers that such withdrawal would not be in the public interest.

j. where the subject matter of the Complaint has already been adjudicated upon by a Court of competent jurisdiction and that there are no further steps required to be taken by the Authority under the Act;
k. where the Competent Authority comes to the conclusion that such steps have been directed to be taken, in view of the facts and circumstances of the matter at hand, by the Healthcare Establishment or the Healthcare Service Provider for compliance thereof and that no further action has is required on the part of the Authority, in the public interest.

20. Report by Inquiry Committee or investigation / complaint officer.- (1) In all matters where the Complaint/Case is proposed to be closed or where the investigation is completed, the Inquiry Committee or investigation / complaint officer shall present a comprehensive report to the Complaint Hearing Committee for any of the following:

a. to pass such orders as it may deem fit and appropriate in the facts and circumstances of the case; or
b. The Complaint Hearing Committee if so desires, may order a case to be re-investigated and may also summon and hear parties in a meeting.

21. Further Investigations.- (1) Where circumstances so require, further investigations may be conducted in any of the following manner by:

a. Compelling any person to produce any document;
b. Requiring either party to submit further comments or answers;
c. Revisiting and inspecting the concerned area; or
d. Summoning any person for hearing and recording evidence.
e. Any other act which may assist in deciding the issues at hand.

22. Decision.- (1) The Complaint Hearing Committee of the Authority shall announce its decision regarding award of penalties, suspension and/or revocation of license, or registration as the case may be.

(2) The Complaint Hearing Committee of the Authority shall decide all the matters after recording reasons in writing.

(3) All the decisions shall be duly signed by the chairperson of the Complaint Hearing Committee, Authority or the Secretary of Ministry of NHSR&C as the case may be.

(4) All decisions shall be communicated to the parties to the Complaint and such other persons as directed by the Director Legal and Complaints, who shall perform the duties of the Registrar for the IHRA complaints management system, in such form or manner as deemed appropriate by the Authority.

(5) Notwithstanding anything in the Rules, the Complaint Management Committee, Inquiry/Hearing committee is fully authorised to pass Summary Decisions in the interest of public safety, and in emergency and urgent situations and these shall not be challengeable in any Court. Non-compliance or opposition to orders shall be liable to imprisonment and fine as deemed relevant under the circumstances by the Competent Authority.

Chapter 09
Miscellaneous

23. Information to be kept Confidential.- (1) It shall be the duty of all involved in \ any proceedings pending before the Authority to keep all the information brought before the Authority, including but not limited to the details of the proceedings of the Authority, confidential.

(2) During the pendency of any proceedings before the Authority, no person shall do any act or cause it to be done in any manner that may embarrass or result in harassment to either the Healthcare Establishment or its staff or the Healthcare Provider or the Complainant, as the Case may be. The Authority may pass any interim order, in this regard, including but not limited to, restraining such a person to immediately take such steps to restore the honour/prestige of the person so affected and/or to take such steps which may mitigate the loss already caused. Contempt of Court laws apply to the hearings with regards to the dignity of all presiding officers at the various levels of hearing in the IHRA.

(3) In appropriate cases where the Authority has reasons to believe that any person is being unduly embarrassed or harassed, it may itself take or cause to be taken such mitigating measures as it deems necessary, in this regard.

24. Adjournment.- (1) Subject to these regulations, Any proceedings or hearing of a complaint may or may not be adjourned by the Complaint Hearing Committee or the Review and appeal forums, as the case may be, on its own motion or on the application of any of the parties, after recording reasons in writing and only in the interest of justice. Provided that no proceedings or hearings of a complaint shall be adjourned when the Complaint Hearing Committee or the Review

and Appeal Forums, as the case may be, come to the conclusion that the party seeking adjournment(s) is adopting delaying tactics which would seriously hamper the disposal of the case within period of Ninety (90) days and it shall not be in the public interest to further delay the matter. In such a situation and in other cases as envisaged herein such a party shall be proceeded against ex-parte after a clear written warning in this regard.

25. Legal Counsel.- (1) The Competent Authority may in its absolute discretion, for reasons to be recorded in writing, permit a party to be assisted through a legal counsel. An application in this regard may be submitted by a party so requesting, stating:

a. The name of the legal counsel and his specialities or experience in the relevant field of law along with supporting documents in this regard, if any; and
b. The reasons or issues due to which it may be necessary for the applicant to be so assisted.

26. Duty to Act with utmost Good Faith.- (1) It shall be the duty of all the persons appearing before the Authority, in any capacity whatsoever, to act with utmost good faith at all times and assist the Authority in performing its duties and also for achieving the purposes of the Act.

27. Notices and summons.- (1) Due Notice shall be given to all concerned for the purposes of the hearing by all the hearing forums, as the case may be.

(2) Summons: - Summoning orders may be issued to the Complainant and the party (ies) complained against along with their witness(es) by the Complaint Hearing Committee or the inquiry Committee or investigation / complaint officer under delegation of such power by the Authority.

28. Executive Authorities to aid the Authority.- (1) All executive authorities shall aid the Authority pursuant to the provisions of Section 44 of the Act, for:

a. Compliance of the decision or direction or any order issued by the Competent Authority;
b. Investigation and inspection in respect of any Complaint, and
c. Any other action required to be taken under Regulations or the Act.

29. Fines and Penalties.- (1) The Authority may impose a fine or penalty in respect of a Complaint in accordance with the provisions of the Act and rules and regulations made thereunder, (amended from time to time) unless specified otherwise in the Act or Regulations, as the case may be. In case of non-compliance of submission of fine or penalty, suspension of services, license and registration or sealing of HCE will be carried out by IHRA.

30. Compliance Reports.- (1) The Complaint Hearing Committee may seek compliance reports from any authority, person or Healthcare Service Provider and the Healthcare Establishment, regarding any matter pending or decided/disposed of by the Authority.

(2) The said report shall be placed before the Authority for its consideration and further necessary instructions, orders or directions, as deemed appropriate by the Authority.

(3) Non-Compliance in reference to the compliance report or responses elicited from HCEs and HCPs shall be penalized with fines specified in the Act or regulations made thereunder.

31. Savings.- (1)Every complaint filed or pending before the Authority, after coming into force of these regulations, shall be proceeded under these regulations from the stage of proceeding pending, before coming into force of these regulations.

(2) Nothing shall affect the validity of any decision or proceeding taken or done by the Authority, before coming into force of these regulations.

PART VIII

Registration and Licensing of a healthcare establishment and maintenance of their Record

Chapter 1

DIRECTORATE OF REGISTRATION, LICENSING AND ACCREDITATION

1 Registration, Licensing & Accreditation Management System.- (1) The Authority shall have an internal Registration, Licensing and Accreditation Management System under the Directorate of Registration, Licensing & Accreditation for receiving, managing applications for registration, grant of licenses and accreditation, issuance, suspension and /or revocation of registration, license, Accreditation and performing such other tasks for the purposes of ensuring that the healthcare services are rendered in accordance with the provisions of the Act, Regulations, Standards, Reference Manuals and corrective orders etc. as issued by the Authority from time to time.

2 Register of healthcare establishment and healthcare service provider.- (1) The Directorate shall maintain a register of all healthcare service providers and healthcare establishments providing healthcare services in the Islamabad Capital Territory, containing such details and information as considered necessary by the Authority.

3 Decisions by the Registration Board.- (1) All the decisions under this part regarding issuance, suspension and/or revocation of Registration, licenses and accreditation of healthcare establishment(s) shall be taken by the Registration Board.

Provided that till the time Registration Board is dormant, Deputy Director Registration and Licensing shall make these decisions.

Chapter 2

REGISTRATION AND ENFORCEMENT

4 Responsibility for compliance.- (1) It shall be the responsibility of every healthcare service provider, to apply to the Authority through the Directorate, for Registration, under the relevant category (Schedule I), in accordance with the provisions of section 21 of the Act.

5 Unregistered healthcare establishment or service provider.- (1) Proceeding shall be initiated against an unregistered healthcare establishment or service provider under section 30 of the Act.

Provided further that Authority may also impose a fine, which may extend to One Million Rupees on an unregistered healthcare establishment or service provider and / or order to stop provision of service(s) or seal the premises of a healthcare service provider who is found providing healthcare services without registration, as required under the Act.

(2) The Authority may recover the fines imposed and other dues recoverable under the Act and the Regulations in accordance with section 45 of the Act.

6 Application for Registration.- (1) A healthcare service provider, prior to the commencement of operations of his healthcare establishment, shall apply for registration with the Authority on the prescribed form, supported by such documents as may be prescribed by the Authority, from time to time. (Schedule-II)

(2) The applicant shall retain a copy of the application and its attachments as submitted to the Commission.

(3) The Authority shall issue a Certificate of Registration within 14 days of the receipt of the application, to the applicant who fulfills all the requirements and provide all such particulars and documents as notified by the Authority from time to time, particularly valid registration certificate(s) of the healthcare service provider(s) and/ or healthcare personnel, issued by the relevant federal council, i.e. Pakistan Medical Commission, Pakistan Nursing Council, National Council for Homeopathy and National Council for Tibb.

(4) A registration certificate issued under sub-clause (3) only amounts to enlistment of the healthcare service provider with the Authority and shall not be taken as compliance to the standards, required for issuance of License.

(5) An application for registration, grant of license or accreditation, not on the prescribed form, shall not be processed and shall be deemed to have been rejected.

(6) The parent lab registered with any provincial healthcare commission, will apply separately for the registration of all its collection centers as separate HCEs.

Notwithstanding what has been stated above, a parent laboratory shall be responsible for compliance of the relevant standards at its collection center(s).

(7) Before issuance of registration certificate, the Authority may carry out verification of information provided in the application by the applicant. In case the information provided by the applicant is not verified, the application may be rejected and action may be taken in accordance with the provisions of the Act.

(8) In case the Authority fails to issue Certificate of Registration to an applicant within fourteen working days, from the receipt of the application, the healthcare service provider shall be deemed to have been provisionally registered, provided that the application is complete in all respects.

(9) Notwithstanding what has been stated in sub-clause (3), it shall be the responsibility of the healthcare service provider to ensure that he and all his staff / employees, who may be required to be registered with any of the above noted federal councils, is / are so registered at all times and have valid registration from the relevant council.

(10) The Authority may reject such application for registration wherein the information provided is found to be incorrect or where despite issuance of notice by the Directorate, the healthcare service provider fails to provide the requisite information, supporting documents or other particulars required for registration, within the stipulated time.

(11) An applicant whose application has been rejected may re-apply for registration after complying with sub-clause (1) to (4).

(12) The Directorate shall maintain a register of all the healthcare establishments and healthcare services providers, providing healthcare services in the Islamabad Capital Territory containing such details and information as deemed necessary by the Authority.

7 Certificate of Registration not Transferable.- (1) A certificate of Registration issued under these Regulations shall neither be assignable nor transferable, unless a written permission is granted by the Authority, in accordance with these regulations.

8 Certificate of Registration to be posted.- (1) A certificate of Registration issued by the Authority shall be conspicuously posted in the healthcare establishment where it is visible to the Public.

CHAPTER 3

LICENSING AND ENFORCEMENT

9 Responsibility to apply for a license.- (1) Within thirty days of the issuance of the certificate of registration, or such other time as may be fixed by the Government, the healthcare service provider shall make an application for grant of license to his healthcare establishment on the prescribed form, supported by such documents and fee(s) as may be prescribed by the Authority from time to time. (Schedule -III)

(2) Application for Renewal;

(a) The applicant shall submit an application to the Authority for the renewal of existing license before its expiry.

(b) An application submitted in terms of clause (a) shall be on the prescribed form, supported with such documents and fee(s) as may be prescribed by the Authority from time to time.

(c) In case the application for renewal of a license is submitted before its expiry or within thirty days after the date of expiry, as the case may be, the healthcare establishment in respect of which such application is submitted shall be deemed to be provisionally licensed after the expiry of its existing license, till such time that the application is decided by the Authority.

(d) In case the application for renewal of a license is not submitted within thirty days from the date of expiry of the license, the healthcare establishment shall be considered as unlicensed and the name of the healthcare service provider may be removed from the register.

(e) In case the application for renewal of a license is submitted within thirty days from the date of expiry of the license, the applicant shall also be liable to pay a late fee at the rate of 2% of the prescribed license fee.

(f) Where an application for renewal of the license is submitted after thirty days from the date of expiry of the license, the applicant shall also be liable to pay a late fee at the rate of 5% of the prescribed license fee per month, starting from the date of expiry of the license.

(3) The applicant shall retain a copy of the application and its attachments as submitted to the Directorate.

(4) On receipt of an application, complete in all respects, the Authority shall issue a provisional license to the Applicant. Issuance of a provisional license to a healthcare establishment shall not be taken as compliance to the relevant standards by the said healthcare establishment.

(5) Notwithstanding what has been stated above, it shall be the sole responsibility of the healthcare service provider to ensure that he and all his staff/ employees, who may be required to be registered with any of the above noted councils, is/are so registered at all times and have valid registration from the relevant council.

(6) The Authority may reject an application for issuance of license or the renewal thereof, as the case may be, if the applicant has failed or refused to comply with the provisions of the Act and /or these regulations, as the case may be, or the application is not on the prescribed form, not accompanied by prescribed documents and/or fee(s) or information provided in the application is found to be incorrect, incomplete, or despite issuance of notice by the Directorate, the Applicant fails to provide the requisite information and/ or supporting documents required by the Directorate, within the stipulated time.

(7) Notwithstanding what has been stated in sub-clause (6), an applicant whose application has been rejected may re-apply after fulfilling all the requirements and providing all particulars, documents, fee(s) as notified by the Authority from time to time in this regard.

10 Unlicensed healthcare establishment.- (1) No person, including but not limited to association of persons, authority, body, company, corporation, firm, individual, partnership, proprietorship, any Government, Local Government or other entity, as the case may be, shall operate, conduct and/or maintain, in the ICT, any healthcare establishment for treatment or otherwise of

human beings without obtaining a license from the Authority in accordance with the criteria laid down by the Authority.

11 Actions on Non-compliance.- (1) The Authority may impose a fine which may extend to one million rupees and /or order to stop provision of service(s) or seal the healthcare establishment which is found to be operated without a valid license, as required under the Act.

12 Fee.-(1) The fee shall be as prescribed by the Authority from time to time, and shall be non-refundable.

(2) The prescribed fee for issuance of a license, renewal thereof and /or accreditation must be submitted along with the application and shall be for a period of five (05) years.

(3) The additional fee, as notified by the Authority from time to time, may be charged for, including but not limited to change(s) and/or amendment(s) to a registration certificate, license(s) and/or accreditation certificate.

13 Right of Entry.- (1) An application for registration, license or its renewal pursuant to the provisions of the Act and /or these regulations would constitute a permission and /or complete acquiescence on the part of the applicant or the licensee, as the case may be, to any entry or inspection by the Authority of the healthcare establishment for the verification of the information submitted on, or in connection with, such application.

(2) A duly authorized officer/ representative of the Commission shall have the right to enter upon the premises/ healthcare establishment of an applicant or a licensee, as the case may be, at any time without threat of injury, verbal abuse or harassment and in the spirit of mutual cooperation in order to determine the status of compliance of such healthcare establishment with the Act, Regulations, standards and /or any other instructions or orders passed by the Authority.

(3) Without prejudice to what has been stated in sub-regulation (2), a healthcare service provider shall provide full access to the designated officer(s)/ representative(s) of the Authority, to all relevant records, documents and reports at his healthcare establishment, as required for the purposes of these Regulations or other applicable laws. The said officer(s) representative(s) may obtain a copy of records documents and reports either manually or by photocopy, if deemed necessary, unless otherwise protected by law.

(4) The authority may impose a fine which may extend to fifty thousand rupees upon a healthcare service provider who refuses or fails, without reasonable cause, to furnish any information to the designated officer(s) / representative(s) or the inspection team of the Authority or gives any false or misleading information or obstructs, hinders or impedes such officer(s)/ representative(s) or the inspection team, as the case may be, in the performance of their functions or execution of their duties.

14 Verification by the Authority.- (1) Before issuing a Regular License, the Authority may verify or require verification of the following;

(a) Application is complete in all respects

(b) Full license fee is deposited.

(c) Compliance with the Act, Regulations, Standards and any instructions and/or corrective orders passed by the Authority or the Directorate, as the case may be, while processing the application keeping in view the survey and/ or the inspection report, as the case may be.

Chapter 4

INSPECTION AND ENFORCEMENT

15 Inspections.- (1) All inspections for grant of license shall be carried out as provided under the Act, and these regulations.

(2) Inspections shall be carried out without any notice to the concerned healthcare establishment in response to a complaint or suspected violation of the Act, Regulations, Standards, Reference Manual, and/ or any other instructions or orders passed by the Authority. The Authority may in circumstances requiring immediate action and /or emergency, get the inspection carried out through an inspection team or any other executive Authorities for violation of any other laws relating to buildings, fire etc. or for other purposes, including but not limited to the licensing process.

(3) Upon inspection, a statement of deficiencies shall be issued by the authorized officer or the inspection team, pertaining to any deficiency, omission or violation of the Act, Regulations, Standards, and any other instructions or orders, including but not limited to a plan of correction, issued by the Authority along with the timeline, if so required.

(4) The authorized officer or the inspection team may, in the event of default by the applicant or the licensee, as the case may be, issue directions to implement its plan of correction, or take additional corrective action if so required.

(5) If an applicant or the licensee disagrees with the statement of deficiencies issued by the inspection team, visiting team or the authorized officer, as the case may be, he may request for an informal conference to provide evidence to dispute the findings, within ten(10) working days from the receipt of such statement of deficiencies.

(6) It shall be responsibility of the applicant or a licensee to ensure compliance to the instruction, orders or plan or action, issued by the Authority, within stipulated time and submit the compliance report in the manner notified by the Authority.

(7) It shall be responsibility of the healthcare establishment to attend, at the place and time as specified by the inspection team or the authorized officer, for the purposes of assessment of compliance of the deficiencies identified at the time of inspection.

(8) In case a healthcare establishment fails to qualify for the grant of license after two inspections, the Authority may charge the cost of subsequent inspections at the rates notified by the Authority from time to time.

(9) In the event, a healthcare establishment fails to qualify for the grant of license even after the third inspection, the Authority may impose fine, order closure of service(s) and/ or reject the application for grant of license along with removal of the healthcare service provider's name from its register.

(10) In case a healthcare establishment fails to qualify for renewal of its license even after two inspections, the Authority may impose fine, order closure or service(s) and / or reject the application for renewal of license along with removal of the healthcare service providers name from its register.

(11) Within thirty (30) days from the date of approval of its application by the competent authority, the Authority shall issue a regular license to a healthcare establishment which fully complies with the provisions of the Act, Regulations, and the standards.

(12) Subject to the Act and inspection regulations, all licensed healthcare establishment shall be inspected / visited at least once every three (03) years, unless otherwise decided by the Authority.

16 License not transferable.- (1) A license issued under these Regulations shall neither be assignable nor transferable, unless a written permission is granted by the Authority, in accordance with these regulations.

17 License to be posted.- (1) A license issued by the Authority shall be conspicuously posted in the healthcare establishment where it is visible to the public.

18 Term of Licenses.- (1) The term of a regular license shall be for a period of five (05) years from the date of its issuance. The applicant, to whom a regular license has been issued, shall apply for its renewal prior to the expiry of the above term.

19 License to be premises specific.- (1) The license issued by the Authority shall only be in relation to the premises identified in the application.

20 Specifications of a License.- (1) A license must specify the following;

(a) Name of the healthcare establishment;

(b) Address of the healthcare establishment;

(c) Name of the owner;

(d) The total number of beds;

(e) The effective date, kind and term of the license;

(f) The identification of services being rendered at the healthcare establishment.

21 Distinct parts.- (1) A healthcare service provider operating healthcare establishment on different locations shall apply for their registration and license separately.

(2) Where an applicant has separate facilities located in physically separate buildings, on the same grounds, operated by the same ownership / administration, the Authority shall issue only one registration and license in respect of such facilities.

(3) The Authority may issue a regular license in respect of two or more buildings in the same premises if the applicant:-

a) Meets the requirements as listed in the sub-clause (2);

b) Operates the buildings as an integrated system with:-

(i) Administration by a single authority over all buildings portions of buildings;

(ii) Administration control of the medical staff for all healthcare establishment facilities under the same management; and

(iii) Application of same policies and procedures for all facilities and departments.

c) Provides for safe and appropriate transport of patients between all facilities and building.

(4) Healthcare establishments situated in the same premises but operated by different ownership / administration shall apply for separate registrations and licenses.

(5) Healthcare establishments situated in the same premises having same ownership / administration but providing different systems of treatment shall apply for separate registrations and licenses.

22 Changes in licensing information and / or capacity.- (1) No change in the capacity of the healthcare establishment as granted under the license, including but not limited to services being rendered at the said the healthcare establishment, shall be implemented/ enforced without prior written approval/ permission and /or the requisite license from the Authority, as the case may be.

(2) Any change in the building including but not limited to new construction, additions or alterations in any manner, as the case may be, must be approved by the relevant authority and reported to the Authority in a manner notified by the Authority from time to time in this regard.

Provided that sub-clause (2) shall not be applicable to minor alterations which do not affect the primary operations or the number of beds of the healthcare establishment, or to routine maintenance and repairs as the case may be.

(3) Any change of owner, manager, in charge, chief executive officer, administrator, other available human resource, equipment as updated from time to time, name and /or address of the healthcare establishment, as the case may be, shall be reported to the Authority in the manner as notified by the Authority, at the earliest however, in no case such period shall exceed a maximum of thirty (30) working days.

(4) Upon acceptance of the application in this regard, the Authority may issue amended registration and / or license, on such terms and conditions as deemed appropriate, including but not limited to the inspection, and payment of such additional fee(s) as notified by the Authority from time to time, for the said purpose.

(5) In the event a registration certificate and / or a license issued by the Authority, to a healthcare establishment is lost or damaged, the same shall be reported to the Authority as early as possible but not later than ten (10) working days from the date of such loss or damage. The Authority shall issue a duplicate registration certificate and / or license as the case may be on receipt of an affidavit on stamp paper in this regard and payment of such additional fee(s) as may be notified by the Authority, from time to time, for the said purpose.

(6) The Authority may remove the name of a healthcare service provider from its register, at any time if;

a. The registration certificate / license has been obtained by fraud or misrepresentation;

b. The closure of the healthcare establishment is reported or brought to the notice of the Authority by the applicant or through any other source;

c. The application for license is rejected;

d. The healthcare service provider is convicted under the provisions of the Act or the regulations made thereunder.

23 New services.- (1) In order for a license to extend to new service(s), a separate application, as prescribed by the Authority, may be submitted to the Authority for approval.

24 Rejecting, Amending, Modifying, or refusing to renew a license.- (1)The Authority may amend, modify or refuse to renew a license in conformity with the Act, Regulations, Standards, Reference Manual and instructions or directions issued by the Authority, as the case may be.

(2) If deemed appropriate, the Authority may, upon payment of such additional fee(s) as prescribed by the Authority, from time to time in this regard and after the required inspection, modify a license on the application of a healthcare establishment, where the ownership and / or the address of the healthcare establishment has been changed.

25 Grounds for suspension and/or revocation.- (1)The Authority may revoke and/or suspend a license in accordance with the provisions of the Act and these Regulations. In addition to the aforesaid suspension, the Authority may issue orders for immediate suspension of service(s),

facility(ies) or sealing of the healthcare establishment or part thereof and / or impose fine along with instructions to ensure compliance with the provisions of the Act, Regulations, standards, standing orders and instructions.

Provided that the license so suspended may be restored by the Authority upon successful compliance of the instructions issued by the Authority.

26 Immediate suspension of Service(s).- (1) Where during an inspection or visit by an authorized officer of the Authority, such conditions are found to exist at a healthcare establishment that may jeopardize the health and/or safety of the patients at the said healthcare establishment, or create an emergency, which in the estimation of the said officer may not be ably handled at the said healthcare establishment, keeping in view its capacity, the Authority may through its authorized officer(s) / representative(s) issue orders for immediate suspension of such service(s) or facility(ies) as deemed appropriate by the Authority.

27 Action in case of non-compliance.- (1) In case the healthcare establishment fails to demonstrate compliance with the provisions of the Act, Regulations, standards, standing orders and instructions with in the stipulated time, the Authority may impose penalty including but not limited to fine, closure of service(s), sealing of the premises or part thereof and /or removal of name of the healthcare service providers from its register.

28 Opportunity of Hearing before passing orders.- (1) Subject to the Act and these Regulations, the Authority shall provide adequate opportunity of hearing to a person before passing any order regarding the revocation of its regular license or imposition of fine.

29. Hearings.- (1) Where circumstances so require, the Authority may issue notice/summons, requiring any person(s) to appear before the Authority, on the date and time fixed for the purpose, to put forth his stance in the matter pending decision before the Authority.

(2) The person(s) so appearing before the Authority shall submit his stance in writing with supporting documents, if any, along with an affidavit duly verified by the Oath Commissioner.

(3) The Authority may require the person(s) appearing before it to produce any other documents deemed necessary for the just and proper disposal of the matter.

(4) While proceeding with a matter pending adjudication before it, the Authority may exercise all such powers as provided under section 4(2) of the Act.

(5) The Authority may, if deemed necessary, instruct the concerned officer of the commission to submit his views/comments in writing, on the stance/ response submitted before the Authority.

(6) If the Authority is satisfied that despite service of the notice/summon, the relevant person is not attending its proceedings, it may direct the local police or any other Executive Authority or law enforcement agency to produce such person or any other relevant person before it.

30. Power to pass orders.- (1) Without prejudice to what has been stated in artilce 29 above, the competent authority, may pass such orders, including but not limited to the following orders, while recording the reasons thereof, in view of the facts and circumstances of the matter, in order to safeguard the public interest and for achieving the purposes of the Act;-

a. Issue orders of restraint;

b. Issue directions to the Federal Government;

c. Issue directions to a Healthcare establishment;

d. Pass any conditional orders relating to the manner in which healthcare services are being delivered or to improve the healthcare delivery system at any given healthcare establishment;

e. Issue directions to any other authority within the scope of the Act;

f. Issue such instructions, directions or orders as deemed necessary, including but not limited to imposition of fine, closure of services or part thereof, and sealing of healthcare establishment;

g. Confirm the act/order of sealing of the premises/site or undo the same after hearing the owner, Manager, In-charge of the healthcare establishment or the proprietor, as the case may be;

h. Liaison and communicate with the Pakistan Medical Commission, council for Homeopathy, Council for Tib, Nursing Council or any other authority competent to handle the matter and to assist the Commission in deciding the matter, in the larger public interest.

Provided that the competent authority may also further direct that any of the orders so passed by it may be for a particular period/ duration of time or that the same be implemented within a particular time frame and that a compliance report be submitted before it.

(2) The competent authority shall have the power to issue, amend, alter, affirm or revoke any orders on hearing the concerned person(s) in the matter, after due Notice.

31 Appeals.- (1) Any person who is aggrieved of any decision of the Authority, may file an appeal in accordance with the provisions of Section 31 of the Act.

Chapter 5

MISCELLANEOUS

32 Quality Assurance & Compliance Committee.- (1) All healthcare establishments or healthcare service providers, as the case may be, shall establish their own Quality Assurance & Compliance Committee(s) for the purposes of interacting on their behalf with the Authority and shall be responsible for the compliance of process involved for obtaining the requisite license.

(2) The Quality Assurance & Compliance Committee(s) may consist of one or more members, as deemed appropriate by the healthcare establishment or the healthcare service provider, keeping in view its size and capacity. Such Committee(s) shall be duly authorized by the healthcare establishment or the healthcare service provider to undertake and/ or commit to the Authority / Directorate, as the case may be, and ensure compliance with the Act and these Regulations, on behalf of the said healthcare establishment or healthcare service provider.

33 Protection of Whistleblowers.- (1) Each healthcare establishment shall prominently and conspicuously post for display in a public area of the healthcare establishment that is readily visible to patients, residents, employees and visitors, a statement that non-employees, employees and staff are protected from discrimination or retaliation for reporting a violation of the governing laws including the Act, Regulations, standards, reference manual and any other orders or instructions passed by the Authority. The statement shall be in English and such other language(s) as it appropriate to the demographic makeup of the community being served.

(2) A healthcare establishment may not suspend or terminate the employment of, discipline, or otherwise discriminate against an employee for reporting in utmost good faith to the employee's supervisor, an administrator of the healthcare establishment, the regulatory agency, and / or the healthcare service provider, the Authority or any other law enforcing agency as the case may be, a violation of the governing law including the Act, Regulations, standards, reference manual and/ or any other orders or instructions passed by the Authority. For the purposes of forgoing sub-clause, a report shall be deemed to have not been made in utmost good faith if there is not a reasonable factual or legal basis for making the same.

(3) A healthcare establishment may not retaliate against a person who is not an employee for reporting a violation of the governing law including the Act, Regulations, Standards, reference manual and any other orders or instructions passed by the Authority.

PART IX

MINIMUM SERVICE DELIVERY STANDARDS

Chapter 1

1 Measurable criteria.- (1) For the purpose of measuring, monitoring and regulating the healthcare services' quality levels provided by the healthcare establishment or healthcare professional, all the healthcare establishments and healthcare professionals shall maintain the standards as prescribed in the schedules of part IX to these regulations.

(2) Authority shall take all measures to make compliance with the standards specified in the schedules to these regulations.

2 Penalty for contravention of the standards.- (1) Authority shall take action and impose penalties, according to provisions of the Act or rules and regulations made under the Act, against any healthcare establishment or healthcare professional, as the case may be, for non-compliance of the standards specified under these regulations.

4 Power to add, amend and omit the Schedules.- (1) the Authority is empowered to add any new schedule in this part, amend or omit any existing schedule from time to time for the purposes of the Act.

SCHEDULE

(i) Different standards have been made under these regulations for the different healthcare establishments providing different healthcare services, all these healthcare establishments shall be required to maintain standards as per relevant Schedule mentioned hereunder applicable to them:

Sr. No.	Category	Schedule
1.	Minimum Service Delivery Standards for Hospitals	Schedule-I
2.	IHRA Standards for Primary Health Care Facility	Schedule-II
3.	Minimum Service Delivery Standards For Clinical Labs	Schedule-III

4.	Minimum Service Delivery Standards For Dental Clinics	Schedule-IV
5.	Minimum Service Delivery Standards For Psychiatric & Addiction Treatment / Rehabilitation Facilities	Schedule-V
6.	Minimum Service Delivery Standards For Tibb	Schedule-VI

PART X

PRICING OF HEALTHCARE SERVICES

Chapter 1

1 Scope.- (1) These regulations shall apply to all healthcare establishments, including but not limited to public or private hospital, non-profit organizations, charitable hospital, trust hospital, semi-government and autonomous healthcare establishment.

(2) Notwithstanding anything contained in sub-clause (1) above, the prices of healthcare services being provided at public sector healthcare establishments shall be determined and notified by the relevant authorities, controlling and administering such healthcare establishments.

(3) Pricing mechanism as provided in chapter III of part X of these Regulations shall apply to healthcare establishments of Categories I, II and such healthcare establishments of Category III, as laid down in part VIII of these regulations, providing diagnostic/imaging services, day care surgeries and interventional procedures or such other healthcare services as notified by the Authority from time to time.

(4) Notwithstanding what has been stated in sub-clause (3), the prices for health care establishment other than as mentioned in sub-clause (3) shall be determined by the Authority in consultation with the relevant stake holders.

Chapter 2

Establishment of Pricing Cell/Department and Pricing Mechanism

2 Pricing Cell/Department.- (1) The Authority shall establish a Pricing Cell/Department for the purposes of carrying out functions under these Regulations.

3 Determination of Price(s).- (1) Each healthcare establishment shall undertake an activity based costing through a duly registered chartered accountancy/ cost accountancy firm, of all healthcare services being provided by it, including but not limited to commonly undertaken procedures, other procedures and ancillary facilities provided in connection with or with reference to the healthcare services, in such order as may be required/notified by the Authority.

(2) The Authority shall design and notify a framework for carrying out activity-based costing of healthcare services including but not limited to commonly undertaken procedures, other procedures and ancillary facilities provided in connection with or with reference to the healthcare

services being provided by any healthcare establishment, in such order as may be required/notified by the Authority.

(3) The framework notified by the Authority shall inter alia contain the features/requirements that every healthcare establishment would be required to follow and fulfil during determining the cost of their services and procedures.

(4) Upon completion of the costing exercise in accordance with the notified framework and adding profit margin not exceeding 25% of the actual cost, each healthcare establishment shall submit the same to the Authority along with complete record of the costing in the notified format, for further processing and formal approval.

(5) Subject to sub-clause (2), an existing healthcare establishment shall, within a period of ninety days of the coming into force of these Regulations, submit its proposed prices along with complete record in accordance with sub-clause (1) & (4).

Provided that all other healthcare establishment shall submit their proposed prices along with complete record of the activity-based costing, conducted in accordance with sub-clause (1) & (4) with their respective applications for Registration in accordance with section 21 of the Act.

(6) In case the Pricing Cell/Department finds or determines that the costing of any procedure(s) and/or services submitted by any healthcare establishment is inaccurate and/or exaggerated, it may verify/re-assess/validate the entire costing data or part thereof, submitted to the Authority through any means considered appropriate and shall intimate the rationalized price to be charged by the concerned healthcare establishment, provided that the cost of such exercise/activity, if any, shall be borne by the concerned healthcare establishment.

(7) If a healthcare establishment fulfils all requirement as contained in sub-clause (1), (3), (4) & (5) and subject to sub-clause (6), the Authority shall grant approval in accordance with sub-clause (4) within 30 days, otherwise the proposed prices submitted by the healthcare establishment shall be deemed to have been provisional approved by the Authority.

(8) The price(s) determined pursuant to these Regulations would constitute the maximum/ceiling for healthcare services and healthcare establishment(s) shall be at liberty to charge any price lower than that determined hereunder.

(9) Nothing contained in these Regulations shall prevent the Authority from determining the cost of any healthcare service(s), at any time, including but not limited to commonly undertaken procedures, other procedures and ancillary facilities provided in connection with or with reference to the healthcare services by any healthcare establishment on its own, using such means as it considers appropriate and notifying the price(s) to be charged for the same for a specified time period.

4 Updating and/or Review of Price.- (1) The Pricing Cell/Department may on its own accord or on an application submitted by a healthcare establishment in this regard, review and revise the prices from time to time.

(2) An application submitted by a healthcare establishment in accordance with sub-clause (1) shall be in writing and shall contain detailed reasons for the required review/revision of prices and

shall also be supported by evidence/activity-based costing in accordance with sub-clause (1), (3), (4) and (6) of regulation 4 of part X of these regulations .

(3) While revising/updating prices, the Pricing Cell/Department shall inter alia consider the rate of inflation as well as exchange rate as and when applicable.

Chapter 3

Enforcement

5 Enforcement.- (1) The Pricing Cell/ Department shall take whatever steps it deems necessary to ensure that all healthcare establishment, persons working at or employed therein fully comply with these Regulations. The Pricing Cell/Department shall be entitled to take action against any healthcare establishment and/or healthcare service provider, including but not limited to stoppage of services, sealing of the premises or part thereof or may pass any other appropriate direction as deemed necessary in the circumstances, on account of any violation of these Regulations either upon receipt of a complaint or on the basis of its own monitoring process.

6 Pricing Information.- (1) Every healthcare establishment shall ensure that prices of all healthcare services including commonly undertaken procedures as well as other procedures and consultation by any of its personnel as determined under these Regulations from time to time shall be made accessible to the public at large, by displaying the same at the main entrance and such other places as notified by the Authority.

7 Monitoring.- (1) The Pricing Cell/Department shall monitor all healthcare establishments to ensure compliance of these Regulations.

(2) Every healthcare establishment shall be under an obligation to comply with any instructions, reporting requirement and directions by the Pricing Cell/Department to provide any information and/or record deemed necessary to determine compliance of the Regulations from time to time.

(3) In order to ensure effective monitoring on an on-going basis, the Pricing Cell/Department shall be entitled to make use of information technology and may require healthcare establishment(s) to ensure installation and implementation of equipment and/or software at the premises of healthcare establishments taking into account their respective size etc.

(4) The Pricing Cell/Department may authorize such teams or persons as it may consider appropriate to visit any healthcare establishment(s) to monitor compliance with these Regulations from time to time. The Pricing Cell/Department may empower such teams or persons to take such actions/pass such interim orders as may be necessary in the public interest if any violation is determined/discovered during a visit. Such interim orders would be subject to final hearing of the matter by a committee to be constituted under sub-clause (5) of regulation 9 of part X below.

8 Complaints.- (1) An aggrieved person, upon discovering any violation of the Regulations may file a complaint before the Authority within 60 days of such discovery.

(2) Any complaint alleging violation of the Regulations shall be made in writing and shall be supported by a duly attested affidavit along with any documentary evidence and/or other material in support thereof. The complaint must contain complete information of the complainant including his name, father/husband name, current postal address, valid mobile number as well as a copy of his CNIC. The complaint must provide sufficient details regarding the healthcare establishment including its name and address along with the name of its owner/manager/in-charge/administrator.

(3) Notwithstanding anything contained in sub-clause (1) above, the Pricing Cell/Department may probe into and determine whether any violation of the Regulations was committed by any healthcare establishment in the interest of public at large and for fulfilment of the purposes of the Act.

(4) Upon receipt of a complaint or during enforcement of its mandate under these Regulations, the Pricing Cell/Department or any person/committee authorized by the Authority in this behalf shall send a copy of the complaint/Report to the healthcare establishment, in appropriate cases, against which it has been made and may direct it to appear before the said Cell/Department, person or the committee, as the case may be, on the specified date and time along with written response and any other information considered necessary on the facts of the case, failing which the Pricing Cell/Department or any person/committee authorized by the Authority in this behalf shall proceed for a hearing without waiting for any written response.

(5) The Authority may notify any person or constitute a committee(s) to hear upon complaint(s) or Report(s) submitted by the authorized officer(s)/team(s) or any violation of the provisions of these Regulations. The notified person(s) or committee(s) as the case may be, shall conduct the proceedings in accordance with the standard Operating Procedures as framed under these Regulations. In order to safeguard the public interest and for achieving the purposes of the Act and these Regulations, the notified person(s) or committee(s) may pass such interim orders while recording the reasons thereof, as deemed appropriate in the facts and circumstances of the matter. While proceeding with a matter pending adjudication before it, the notified person(s) or the committee(s) may exercise all such powers as provided under section 4(10) of the Act.

Provided that the notified person(s) or the committee(s) may also further direct that any of the orders so passed by it may be for a particular period/duration of time or that the same be implemented within a particular time frame and that a report be submitted before it.

(6) After hearing the parties and examining relevant documents/information, the notified person(s) or committee(s) shall present a comprehensive report along with its recommendations to the complaint management committee of the Authority for decision.

(7) All decisions shall be communicated to the parties and such other persons as directed by the complaint Management committee of the Authority, in such form or manner as deemed appropriate by the said committee.

(8) In case subject matter of a complaint filed under these Regulations inter alia also contains any such allegation(s) which fall within the scope of any other Regulations framed under the Act, the Pricing Department may refer/transfer such complaint to the concerned Directorate/Department of the Authority to process the same in accordance with the said Regulations.

Chapter 4

Representation to the Board

9 Representation.- (1) Any person aggrieved of the decision of the complaint management committee of the Authority may, within thirty (30) days from the date of receipt of such decision, file a representation to the Chief Executive Officer of the Authority challenging the same.

10 Actions taken in good faith.- (1) No suit, prosecution or other legal proceeding shall lie against the Islamabad Healthcare Regulatory Authority, Pricing cell/Department, Hearing committees, Enforcement Cell, officers, teams or other persons for anything which is done in good faith or intended to be done in good faith under these Regulations.

11 Removal of Difficulties.- (1) If any difficulty arises in giving effect to the provisions of these Regulations, the Board may make such order not inconsistent with the provisions of the Act and these Regulations as may appear to it to be necessary for the purpose of removing such difficulty.

12 Relaxation.- (1) The Board may, for reasons to be recorded in writing, relax any provision of this part, in an individual case, keeping in view the best interest of the Public at large.

Annex-A

(See regulation 15, Ch 4, part VI)

Area/Sector_____ Serial No_____

Dated_____/_____/_____

SHOW CAUSE NOTICE

To (Name and Father Name, CNIC No, Cell No, Designation and Complete Postal Address of the Healthcare Services Provider and Name of the Healthcare Establishment)

_____

_____

_____

_____

I, _____, authorized /notified under Sections 20(1) r/w sub-section (2) (3),

(Name of Inspection Officer)

of the section 20 of the Islamabad Healthcare Regulation Act 2018.

The undersigned under sections 4(i), 16(e), 20(1)(2)(3) of the Islamabad Healthcare Regulation Act 2018 has inspected your HCE. During inspection / search, the inspection team found that your Healthcare Establishment has been involved in the following contravention (s).

i._____

ii_____

iii_____

iv_____

Through this show cause notice served, you are provided with the hearing opportunity to explain your position in written for the above mentioned violations before the hearing committee on _____ at _____having all documentary evidences in support of your defence. If you could not appear on the above mentioned date & time of hearing, as asked by competent Authority, it will be assumed that you have no grounds/ justifications to offer in your defence and as a result, ex-parte proceedings shall be initiated against you and strict legal action shall be taken against you according to the law.

Received by _____ Name/sign and Stamp of Inspection Officer

(Heath Care Provider)

Annex-B

(See regulation 15, Ch 4, part VI)

Area/Sector_____ Serial No_____

Dated_____/_____/_____

SEALING ORDER

To (Name and Father Name, CNIC No, Cell No, Designation and Complete Postal Address of the Health Provider, His/ Her Designation and Name of the Healthcare Establishment)

_____

_____

_____

_____

I, _____, authorized /notified under Sections 20(1) r/w sub-section (2) (3),
(Name of Inspection Officers)

of the section 20 of the Islamabad Healthcare Regulation Act 2018.

WHEREAS I have reasons to believe that the above Healthcare Establishment (HCE) is involved in the Provision of Healthcare Services that contravene to the Provisions of IHR Act 2018 and Rules/ Regulations framed there under.

And Whereas you have been served with a show cause notice Serial No_____dated _____for compliance with the Act and rules but you failed to comply with.

Now therefore, I have sealed & Locked the HCE in whole or a part therein, for the violations mentioned below.

i. _____

ii _____

iii._____

iv _____

An opportunity of hearing shall be provided to you along with all documentary evidences in the office of IHRA. In case you did not appear or involved in the unauthorized de-sealing of the premises, FIR will be lodged against you.

Name, Father Name & Sig of the Healthcare Provider Name and Stamp of Inspection Officer

CNIC_____ Date _____

Ph. No_____

Recovery Memo showing Prescription pad (s), Laboratory Report (s), X-ray report (s), invoices, Medical Record of patient, articles, instruments, reagents, chemicals, registers, cash- memo, bills or any other things which the inspection officer has the reason to believe may furnish evidence against an offence, punishable under IHR Act 2018 and rules/ regulations.

DETAILS OF RECOVERY

1. _____
2. _____
3. _____

Name, Father Name Name and Stamp of Inspection Officer

& Signature of Healthcare Provider_____ Date_____

Certificate

The in-charge/manager/Healthcare provider shall be responsible to keep the seal/lock, building, properties, articles record, and other belongings safe & secure. The Inspection officer / IHRA shall not be held responsible for any mis-hap etc.

The HCE shall not be de-sealed/unlocked till decision of the IHRA or the court, as the case may be.

Sig: of the Healthcare Provider_____ Witness (s)

SCHEDULE I

FINE SCHEDULE OF THE ISLAMABAD HEALTHCARE REGULATORY AUTHORITY

(See regulation 11, Ch. 4, Part VI)

S.No	Mal-Practice	Approved Proposed Action	1st Time	2nd Time	De-Sealing Appeal Fee
1	Quacks	Non bailable and cognizable Offence, 7 years Imprisonment or fine up to two millions Rupees, or with both			Permanent seal
02	Misleading information/Misrepresentation (Section 20-4)		Upto Rs.50,000/-	Rs.50,000/-	N/A
3	Obstruction with inspection team		Upto Rs.50,000/-	Rs.60,000/-	N/A
4	GP Represents himself as a specialist of prescription pad and sign board etc.		Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
5	GP doctor using multiple pads practicing with different names mix clinical pas i.e. Neuro, eye specialist, orthopedics etc.		Upto Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
6	MD doctor practicing as a full doctor those who are not registered with PM&DC		Upto Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
7	Qualified Hakeem/Homeopath/allopathic doctor not registered with Healthcare Authority		Rs.15,000/-	Rs.30,000/-	Rs. 10,000/-
8	Hakim/Homeopath/Allopath practicing other system of medicine		Upto Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
9	Qualified registered/unregistered practitioners (All including specialist) prescribing unregistered drugs and food supplements etc.		Rs.15,000/-	Rs.30,000/-	Rs. 10,000/-

10	Blood Bank having no test / Screening /cross matching facility found and involved in providing/selling unscreened blood		Upto Rs.125,000/-	Rs.250,000/-	Rs. 10,000/-

Note: **All fines are non-refundable**

11	Blood bank found with expire blood and blood products	Complaint and investigation found guilty	Upto Rs.125,000/-	Rs.250,000/-	Rs. 10,000/-
12	Wrong/fake/substandard reports	Complaint and investigation found guilty	Rs.50,000/-	Rs.15,000/- can lead to suspension /cancellation of registration/PMDC certificate can be forward for cancelation to PMDC for disciplinary action	Rs. 10,000/-
13	Non-compliance of the provision in the Act, Rules, Regulations, Standards, Policies i.e. (Islamabad Healthcare Regulation Act 2018, laws add rules/ regulations adopted by the Healthcare Authority, minimum service delivery standards (Hospitals etc.)		Upto Rs.200,000/-	Upto Rs.1000,000/-	Rs. 10,000/-
14	Non-compliance of the provision the Act, Rules, Regulations, Standards, Policies i.e. (Islamabad Healthcare Regulation Act 2018, Laws add rules/ Regulations adopted by the Healthcare Authority, minimum service delivery standards (Treatment / Diagnostic Clinics etc.)		Upto Rs.100,000/-	Upto Rs.700,000/-	Rs. 10,000/-
15	Non Compliance of PMDC Code of ethics		Rs.10,000/-	Rs.30,000/-	Rs. 10,000/-
16	Non availability of Rate list		Rs.10,000/-	Rs.30,000/-	Rs. 10,000/-
17	Referral of Patients from Govt. hospital to Private hospital (illegally)		Rs.30,000/-	Rs.50,000/-	Rs. 10,000/-
18	Paramedics/Nurses/LHV etc. practicing as doctor		Upto Rs.25,000/-	Rs. 50,000/-	Rs. 10,000/-
19	Non-registration of diagnostics (CT, X-Ray, MRI etc.)		Upto Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
20	False Complaint		Upto Rs.100,000/-	Upto Rs.200,000/-	Rs. 10,000/-

21	Any other violation not included in the above list		Rs.10,000/- to Rs.100,000/-	Rs.500,000/-	Rs. 10,000/-
22	Unnecessary tests refers by doctor		Rs.30,000	Rs.60,000/-	Rs. 10,000/-
23	Unwanted/Unnecessary surgery		Rs.200,000/-	Rs.500,000/-	Rs. 10,000/-
24	Use veterinary drugs/ prescribe		Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
25	Expire Reagents, Drugs etc.		Rs.30,000/-	Rs.60,000/-	Rs. 10,000/-
26	Blood bank involves in selling / provision of substandard blood.		Rs.150,000/-	Rs.300,000/-	Rs. 10,000/-
27	Institute /person involved in smuggling/transaction of illegal unscientific transportation of blood Transaction		Rs.50,000/-	Rs.300,000/-	Rs. 10,000/-
28	Casualty from parental/ injectable duo to irrational use		10,00,000/- Complaint		Rs. 10,000/-
29	Mortality duo to over dosage of anesthesia (Loading dose/maintenance dose)		10,00,000/- Complaint		Rs. 10,000/-
30	Irreversible damage due to irrational administration of injectable		Rs.200,000/-	Rs.500,000/-	Rs. 10,000/-
31	False Complaint against the Authority, Board, Chief Executive Officer, Directors & Deputy Directors, Officers, Inspection teams, Advisers, Consultants of the Authority IHRA		Rs. 200,000/-		
32	Defamation of Authority, Board, Chief Executive Officer, Directors & Deputy Directors, Officers, Inspection teams, Advisers, Consultants of the Authority IHRA		Proceeding will be carried out under Defamation Ordinance, 2002		
33	Harassment of the Authority, Board, Chief Executive Officer, Directors & Deputy Directors, Officers, Inspection teams, Advisers, Consultants of the Authority IHRA		Proceeding will be initiated as per Pakistan Penal Code 1860		

Schedule-II

(See regulation 4, Ch.2, Part VIII)

Categorization of HCEs

HCEs has been categorized as follows;

Sr.No	Category	Criteria
1.	Category-I	HCEs having 50 or more beds
2.	Category-II (i) Category II-A (ii) Category II-B (iii) Category II-C	HCEs having up to 49 beds HCEs having 31 to 49 beds HCEs having 16 to 30 beds HCEs having up to 15 beds
3.	Category-III	HCEs providing only Outpatients services

Schedule III

(See regulation 6, Ch.2, Part VIII)

Forms For Registration

Form No: REG/IHRA/2021/_____

APPLICATION FOR REGISTRATION HAVING "INDOOR FACILITY"

Healthcare Establishments are required to complete this form as per requirements of the provision under Section 21 of the Islamabad Healthcare Regulations Act, 2018.

A. HEALTHCARE ESTABLISHMENT	
Name of the Healthcare Establishment:	Date of establishment at present location: D D - M M - Y Y Y Y
Previous Name (if any):	
Mailing Address:	Longitude: _____ Latitude:
Landline:	Mobile:
Email address:	

B. TYPE OF HEALTHCARE ESTABLISHMENT (please tick the relevant box)

- ☐ **Teaching**
- ☐ **Non-Teaching**
- ☐ **Single Speciality (please Specify): _____**
- ☐ **Multiple Speciality: _____**
- ☐ **Others: _____**

C. BED STRENGTH

- ☐ **Number of Beds: _____**

D. TYPE OF OWNERSHIP

☐ **Sole Proprietorship** ☐ **Partnership** ☐ **Corporation** ☐ **Trust**	☐ **Voluntary Non-Profit** ☐ **Association** ☐ **Limited Liability Company (Pvt)** ☐ **Limited Liability Company (Public)** ☐ **Others_____**

E. APPLICANT DETAILS

Name:														
Designation: Status: Owner ☐ Manager ☐ In-charge ☐														
Qualification:														
PMC/PNC/NCH/NCT Registration No:														
CNIC No:														
					-								-	
Mailing Address:														

Landline:	Mobile
Email:	

Required Documents:

- Copy of CNIC of applicant
- Declaration attached to this application (Page # 3) should be signed and stamped.
- Affidavit by the Healthcare Service Provider on Stamp Paper of Rs 50/- issued in his/her name if the Healthcare Service Provider is not the owner.
- Appendixes A, B and C to be completed
- Fee Deposited Receipt (Refer to Appendix-D)

Instructions:

- Fee to be deposited in Islamabad Healthcare Regulatory Authority (IHRA) Current Account No. **1150420000481** in Askari Bank Limited, Kamran Center Branch, Islamabad
- Each page shall be signed and stamped by the applicant
- Incomplete Form will not be entertained
- Provision of incorrect information/documents will result in rejection of application.

- Return the completed Form to:

Director Registration, PRCS-DMLC Building (2nd Floor)
Sufi Tabassum Road, H-8/2, Islamabad.

(For queries regarding completion of the application, please contact IHRA **Ph: 051-9250383** 9:00 am to 5:00 pm working days only)

DECLARATION BY HEALTHCARE ESTABLISHMENT

I, undersigned, do hereby solemnly affirm and declare that the HCE (Name of HCE)

_____

provides services as above, and that the information provided above is true and correct to the best of my knowledge and belief and that nothing has been concealed therefrom. I also state that if any false or incorrect information is provided to the Authority, it may result in the rejection of my application for registration and I may also be found liable to pay fine to the Authority.

Signature:	Name of Applicant:
Date Signed:	Designation:

Appendix A: Information of Full Time Doctors/Staff

Name	Designation	Registration NO (PMC/PNC/NCH/ NCT/PMF)	Contact Information

Appendix B: Information of Part Time Doctors/Staff

Name	Designation	Registration NO (PMC/PNC/NCH /NCT/PMF)	Contact Information

Appendix C: List of Machinery & Equipment

Sr. No	Name of Equipment	Type	Model	Functional/ Non-Functional

Form No: REG/IHRA/2021/_____

APPLICATION FOR REGISTRATION HAVING "NO INDOOR FACILITY"

Healthcare Establishments are required to complete this form as per requirements of the provision under Section 21 of the Islamabad Healthcare Regulations Act, 2018.

A. HEALTHCARE ESTABLISHMENT	
Name of the Healthcare Establishment:	Date of establishment at present location: D D - M M - Y Y Y
Previous Name (if any):	
Mailing Address:	Longitude: _____ Latitude:
Landline:	Mobile:
Email address:	

B. TYPE OF HEALTHCARE ESTABLISHMENT		
☐ GP Clinic	☐ Advance Imagining Lab	☐ Homeopath
☐ Single speciality	☐ Imaging Lab	☐ Hakeem
☐ Poly Clinic	☐ Collection Center	☐ Acupuncturist
☐ Laser Clinic	☐ Dental Clinic	☐ Physiotherapist
☐ Cosmetic Surgery Clinic	☐ Maternity Home	☐ Others _____
☐ Pathology Lab	☐ Nursing Home	
☐ Rehabilitation Center	☐ Sliming Center	

C. TYPE OF OWNERSHIP	
☐ **Sole Proprietorship**	☐ **Voluntary Non-Profit**
☐ **Partnership**	☐ **Association**
☐ **Corporation**	☐ **Limited Liability Company (Pvt)**

☐ **Trust**	☐ **Limited Liability Company (Public)** ☐ **Others_____**

D. APPLICANT DETAILS														
Name:														
Designation: Status: Owner ☐ Manager ☐ In-charge ☐														
Qualification:														
PMC/PNC/NCH/NCT Registration No:														
CNIC No:														
					-								-	
Mailing Address:														
Landline:								Mobile						
Email:														

Required Documents:

- Copy of CNIC of applicant
- Declaration attached to this application (Page # 3) should be signed and stamped.
- Affidavit by the Healthcare Service Provider on Stamp Paper of Rs. 50/- issued in his/her name if the Healthcare Service Provider is not the owner.
- Appendixes A, B and C to be completed
- Fee Deposited Receipt (Refer to Appendix-D)

Instructions:

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I, undersigned, do hereby solemnly affirm and declare that the HCE (Name of HCE)

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provides services as above, and that the information provided above is true and correct to the best of my knowledge and belief and that nothing has been concealed therefrom. I also state that if any false or incorrect information is provided to the Authority, it may result in the rejection of my application for registration and I may also be found liable to pay fine to the Authority.

Signature:	Name of Applicant:
Date Signed:	Designation:

Appendix A: Information of Full Time Doctors/Staff

Name	Designation	Registration NO (PMC/PNC/NCH/ NCT/PMF)	Contact Information

Appendix B: Information of Part Time Doctors/Staff

Name	Designation	Registration NO (PMC/PNC/NCH /NCT/PMF)	Contact Information

Appendix C: List of Machinery & Equipment

Sr. No	Name of Equipment	Type	Model	Functional/ Non-Functional

Schedule IV

(See regulation 4, Ch.2, Part VIII)

Forms for License of Services

Form No: LIC/IHRA/20 /_____

APPLICATION FOR LICENSING HAVING "INDOOR FACILITY"

Healthcare Establishments are required to complete this form as per requirements of the provision under Section 22 (I) of the Islamabad Healthcare Regulations Act, 2018.

E. HEALTHCARE ESTABLISHMENT	
Name of the Healthcare Establishment:	Date of establishment at present location: D D - M M - Y Y Y Y
Previous Name (if any):	
Mailing Address:	Longitude: _____ Latitude:
Landline:	Mobile:
Email address:	

F. TYPE OF HEALTHCARE ESTABLISHMENT (please tick the relevant box)
☐ **Teaching**
☐ **Non-Teaching**
☐ **Single Speciality (please Specify): _____**
☐ **Multiple Speciality: _____**
☐ **Others: _____**
G. BED STRENGTH
☐ **Number of Beds: _____**

H. TYPE OF OWNERSHIP

☐ **Sole Proprietorship**	☐ **Voluntary Non-Profit**
☐ **Partnership**	☐ **Association**
☐ **Corporation**	☐ **Limited Liability Company (Pvt)**
☐ **Trust**	☐ **Limited Liability Company (Public)**
	☐ **Others_____**

I. APPLICANT DETAILS

Name:

Designation:

Status: Owner ☐ Manager ☐ In-charge ☐

Qualification:

PMC/PNC/NCH/NCT Registration No:

CNIC No:

					-								-	

Mailing Address:

Landline:	Mobile
Email:	

J. OWNERSHIP DETAILS

Name:

CNIC No:

					-								-	

Mailing Address:

Landline:	Mobile

K. EXTERNAL VALIDATION
List all applicable external certificates, License, Accreditation, Awards
Agency: _____ License/Certificate/Award:_____
Agency: _____ License/Certificate/Award:_____
Agency: _____ License/Certificate/Award:_____

L. BED CAPACITY			
Number of Beds	Male	Female	Total
1. Medical			
2. Surgical			
3. Intensive Care			
4. Neonatal			
5. Operating Room			
6. Emergency Room			
7. Others (Please specify)			
Total			

M. SERVICES			
Check if Provided	**Service**	**Check if Provided**	**Service**
☐	Burns	☐	Day surgery
☐	Cardiology	☐	ENT
☐	Communicable Diseases	☐	Facio-Maxillary
☐	Dermatology	☐	Gynae
☐	Endocrinology	☐	Head and Neck
☐	Gastrointestinal	☐	Joint Replacement
☐	General	☐	Neurosurgery
☐	Genetics	☐	Obstetric
☐	Genitourinary	☐	Ophthalmological
☐	Geriatrics	☐	Orthopedic
☐	Hematology	☐	Pediatric surgery
☐	Hepatologv	☐	Plastic and Reconstructive
☐	Neonatology	☐	Thoracic
☐	Neurology	☐	Transplant
☐	Oncology	☐	Urology

☐	Ophthalmology	☐	Vascular
☐	Pediatric	☐	Additional Specialized Areas
☐	Pain Management	☐	Blood Bank Services
☐	Palliative Care	☐	Chiropody
☐	Pulmonary	☐	Chiropractic
☐	Renal	☐	Clinical Psychology
☐	Renal dialysis	☐	Nutrition
☐	Rheumatology	☐	Drugs and Alcohol Rehabilitation
☐	Reproductive	☐	General Dental
☐	Ambulance	☐	Inpatient Pharmacy
☐	Community/Home Based	☐	Laboratory - Biochemical
☐	Emergency	☐	Laboratory - Biochemical
☐	Hospice	☐	Laboratory - Microbiology
☐	Long Term Care Unit	☐	Limbs and Prosthetics
☐	Maternity	☐	Orthogenetic
☐	Poly Trauma	☐	Outpatient Pharmacy
☐	Primary Care	☐	Periodontal
☐	Self-Care Unit/Independent	☐	Physical Therapy Rehabilitation
☐	Psychiatry	☐	Prosthetic Dental
☐	Homeopathy	☐	Radiology/Imaging (Diagnostic)
☐	Tibb	☐	Radiology (Therapeutic/intervention)
☐	Allied Health	☐	Others
☐	Speech therapy		
☐	Surgical		
☐	Cardiac		

N. STAFFING

Indicate number of full time (FT) and part time (PT) employees. Attach additional pages if necessary.

	FT	PT
1. Board Membership(if applicable)		
2. Management		
3. Medical/Surgical Services		
a. Consultants		
b. Medical Officers		
c. House Officers		
4. Nursing		
5. Post Graduate Students/Residents		
6. Support Services		
7. Allied Health		
a. LHV		
b. Technicians		
c. Midwives		
d. Physiotherapy Assistant		
e. Health aide		
f. Receptionist		
8. Pharmacy		
9. Therapists		
a. Physiotherapist		
b. Occupational therapist		
c. Speech therapist		
10. Others		
Total Fulltime Staff:		
Total Part Time Staff:		

O. MANAGEMENT

A. CHIEF EXECUTIVE OFFICER (CEO)/IN-CHARGE/CHIEF OPERATING OFFICER (COO)		
Name:		
Title:		
Male ☐ Female ☐	Date Joining: / /	Status: Interim ☐ Acting ☐ Permanent ☐
Email:	Phone Landline:	Mobile:
Is the CEO/In-charge of more than one Facility? ☐ Yes ☐ NO		
If Yes, Name of facility, name and address:		
Professional and Educational Qualification of CEO/IC/COO		
B. PERSON IN-CHARGE IN ABSENCE OF CEO/IC/COO (SUBSTITUTE ADMINISTRATION)		
Name:		
Title:		
Contact Details:	Telephone:	Fax:
Professional and Education Qualification:		
C. MEDICAL DIRECTOR/ MEDICAL SUPERINTENDENT		
Name:	Male ☐ Female ☐	Date Joining _/ /
Title:	Status: ☐ Interim ☐ Acting ☐ Permanent	
Fax:	Landline:	Mobile:
Is the Medical Director in-charge more than one Facility? ☐ Yes ☐ No		
Email:		
Name of Facility, Address and City:		

Professional and Education Qualification:		
D. NURSE ADMINISTRATOR (DIRECTOR OF NURSING):		
Name:	Date Joining : _____/_____/_____	
Email:	Landline:	Mobile:
Professional and Education Qualification:		
E. PHARMACY INCHARGE		
Name:	Date Joining: ____/_____/_____	
Email:	Landline:	Mobile:
Professional and Education Qualification:		
F. LABORATORY INCHARGE		
Name:	Date Joining: ____/_____/_____	
Email:	Landline:	Mobile:
Professional and Education Qualification:		

Required Documents:

- Copy of CNIC of applicant
- Declaration attached to this application (Page # 7) should be signed and stamped.
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- Appendixes A, B and C to be completed
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Sr. No	Name of Equipment	Type	Model	Functional/ Non-Functional

Form No: LIC/IHRA/2021/_____

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Previous Name (if any):	
Mailing Address:	Longitude: _____ Latitude:
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Q. TYPE OF HEALTHCARE ESTABLISHMENT		
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☐ Poly Clinic	☐ Collection Center	☐ Acupuncturist
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☐ Cosmetic Surgery Clinic	☐ Maternity Home	☐ Others _____
☐ Pathology Lab	☐ Nursing Home	
☐ Rehabilitation Center	☐ Sliming Center	

R. TYPE OF OWNERSHIP	
☐ **Sole Proprietorship**	☐ **Voluntary Non-Profit**
☐ **Partnership**	☐ **Association**

☐ **Corporation** ☐ **Trust**	☐ **Limited Liability Company (Pvt)** ☐ **Limited Liability Company (Public)** ☐ **Others_____**

S. APPLICANT DETAILS														
Name:														
Designation: Status: Owner ☐ Manager ☐ In-charge ☐														
Qualification:														
PMC/PNC/NCH/NCT Registration No:														
CNIC No:														
					-								-	
Mailing Address:														
Landline:							Mobile							
Email:														

T. OWNERSHIP DETAILS														
Name:														
CNIC No:														
					-								-	
Mailing Address:														
Landline:							Mobile							

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Name	Designation	Registration NO (PMC/PNC/NCH/ NCT/PMF)	Contact Information

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Name	Designation	Registration NO (PMC/PNC/NCH /NCT/PMF)	Contact Information

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Sr. No	Name of Equipment	Type	Model	Functional/ Non-Functional

SCHEDULE-V

(See regulation 1, Ch.1, Part IX)

IHRA Standards for Hospitals

1 Management of Hospital

1.1 Mission and Strategic Planning

Standard 1: The hospital is directed and managed effectively and efficiently in accordance with its objectives and mission statement.

Indicator 1: Mission statement is available.

Indicator 2: The mission and values are available and disseminated to the staff and general public in languages and forms appropriate to the local population and their needs.

Indicator 3: Goals and objectives of the services are reflected in the strategic plan.

Indicator 4: Policies and annual plans are in line with strategic plans.

1.2 General Management

Standard 2: Responsibilities for operating the organization, managing its resources and for complying with applicable laws and regulations, which are clearly documented.

Indicator 5: There is a Governing Board for the hospital.

Indicator 6: Governing Board must be responsible for establishing and reviewing of mission goal, setting quality culture, resources, legislation and monitoring and evaluation of achievement of strategic and annual plans.

Indicator 7: Hospital In-charge has appropriate qualification and requisite experience.

Indicator 8: Job descriptions clearly defines accountability and responsibility of the in-charge.

Indicator 9: Current Organizational Chart identifies the chain of communication.

Indicator 10: Organizational chart are reviewed and communicated to the relevant staff.

Indicator 11: Mechanisms are defined within hospital for internal and external services.

Indicator 12: Staff follows the policies of confidentiality and release of information.

Indicator 13: Scope, roles and functions of each clinical services/unit/department are stated.

Indicator 14: Each service in the hospital is led by an identified manager with appropriate qualification and experience.

Indicator 15: Duty rosters are published at least two weeks in advance.

1.3 Risk and Quality Management

Standard 3: The hospital prevents and manages risks, identifies opportunities to continuously improve its processes and services, makes improvements and evaluates their effectiveness.

Indicator 16: Risk management plan for safe healthcare delivery is available.

Indicator 17: Incidents, accidents, near misses and adverse events/reactions are reported and recorded.

Indicator 18: Body for Continuous Quality Improvement (CQI) meets on regular basis.

Indicator 19: Quality group develop plan for CQI with defined roles and responsibilities.

Indicator 20: Performance indicators for priority diseases and key processes are available.

Indicator 21: Regular assessment is conducted of patient satisfaction on key process.

Indicator 22: Policy and procedures are developed with inputs of the staff.

Indicator 23: Staff follows documented policies and procedures.

Indicator 24: Appropriate and evidence based clinical guidelines are available.

Indicator 25: Staff is trained to follow the guidelines.

Indicator 26: Clinical audit and its process is agreed between management and clinical staff.

Indicator 27: The effectiveness of the improvement plan is evaluated.

Indicator 28: Sufficient financial resources are allocated for CQI.

1.4 Financial Management

Standard 4: Financial resources are managed efficiently and effectively in order to optimize services that can be provided and results can be achieved.

Indicator 29: A qualified Financial Manager is responsible for developing rules and procedures for financial management

Indicator 30: In-charge (Medical Superintendent, CEO, Director or COO) and departmental heads are involved for setting annual targets for the budgets of the financial years

Indicator 31: Accounting system is in placed to indicate revenues and expenditures

Indicator 32: Internal control audit system is in place.

Indicator 33: External financial audit is undertaken on annual basis.

Indicator 34: A mechanism is used to safeguard of assets in accordance with financial rules and regulation.

1.5 Human Resources Management

Standard 5: Staff are appointed, trained, evaluated and promoted in accordance with documented procedures, job descriptions and service needs.

Indicator 35: The hospital develops and implements policies and procedures for the management of staff, which includes appointment, selection, training, appraisal, promotion, and retention of appropriately qualified staff to meet the service objectives of the organisation.

Indicator 36: Staff availability and skill mix are consistent with the on-going role and functions of each unit.

Indicator 37: Records are available which show:

- Staff levels and skill mix
- Workload and complexity
- Sickness and absence
- Training

Indicator 38: Staff appointments are made in line with the required qualification and experience for the job.

Indicator 39: Staff is treated in accordance with an equal opportunities policy and as per Government rules.

Indicator 40: Current job descriptions and responsibilities for all staff are available and all staff has a copy of their job description.

Indicator 41: All new staff has their professional registration papers checked on appointment and regularly thereafter to ensure employees have a current valid registration with the relevant professional accreditation body.

Indicator 42: All staff is oriented to the hospital and their specific positions through a documented induction program.

Indicator 43: The induction programme includes:

- The hospital's mission, values, goals and relevant planned actions for the year
- Services provided
- Roles and responsibilities
- Relevant policies and procedures, including confidentiality
- Use of equipment
- Safety
- Emergency preparedness
- Quality improvement

Indicator 44: Every staff member in the hospital can be identified by appropriate mechanisms, E.g., uniforms, name tags, hats.

Indicator 45: Staff performance is evaluated annually with the staff member against their job description and agreed targets and is used to identify strengths, areas for improvement and training needs.

Indicator 46: The hospital identifies staff authorised as competent to undertake admissions, carry out assessments, provide treatment in different services and maintain and manage waiting lists.

Indicator 47: Student nurses, doctors or other health professionals are supervised by a qualified nurse, doctor or other health professional as appropriate.

Indicator 48: There are appropriate facilities for staff representatives including access to a meeting room.

Indicator 49: A training needs assessment exercise is conducted every two years with the objective of developing training plans for all staff groups in order to meet the development needs of individual health professionals and the service needs of the organisation.

Indicator 50: A continuing education programme is accessible to all staff. Participation is encouraged and monitored by the hospital.

Indicator 51: There is a training budget, which is calculated to allow appropriate training to take place.

Indicator 52: Accurate and complete personnel records, including records of training, are kept in a secure location and treated as confidential.

Indicator 53: Key indicators such as absenteeism and staff turnover are measured and the results analysed and used for improvement.

2 PATIENT RIGHTS

2.1 Information for Patients

Standard 6: Patients have the right to receive all information relevant to their care management to enable them to make informed decisions.

Indicator 54: Patient right and responsibility charter is developed and displayed in patient area.

Indicator 55: There is documented process to inform about patient rights.

Indicator 56: Guidance and advice is provided at the registration point.

Indicator 57: There is display of information in reception area and wards about the rights of the patients, services and facilities available in the hospital, cost of services, and feedback and complaints pathways.

Indicator 58: Information on hospital areas is displayed at prominent places through appropriate signage.

Indicator 59: Patient and their families are informed about the status of their health and clinical conditions.

Indicator 60: Information is provided about the treatment and its cost, effects, side effects and alternatives.

Indicator 61: Written consents are obtained about the invasive procedures.

Indicator 62: Up to date evidence-based information is provided for disease prevention and health promotion.

Indicator 63: Relevant health messages are displayed at prominent places.

Indicator 64: Patients have informed choices and preferences.

Indicator 65: Precautions and information about the hospital's responsibility of personal belongings.

Indicator 66: An interpreter is available at the hospital.

2.2 Patient Feedback on Services

Standard 7: Patients have the right to complain about the services and treatment and their complaints are investigated in a fair and timely manner.

Indicator 67: Patients are informed about their right to express their concerns or complains verbally or written.

Indicator 68: Patients are provided with mechanisms for submission of complaints.

Indicator 69: The progress of the complaint investigation must be shared with patient.

Indicator 70: Documented process of complaint handling and the patients are informed about the progress.

Indicator 71: The results of the complaints investigation are submitted on monthly basis and used for quality improvement.

2.3 Privacy and Dignity of Patients

Standard 8: Patients' privacy and dignity are respected throughout the entire care process.

Indicator 72: Patient has right of individual bed.

Indicator 73: Consultation, treatment room and washing facilities allow privacy.

Indicator 74: In-patient changing facilities are appropriate and allow privacy.

Indicator 75: No procedure is carried out in presence of unconcerned person.

Indicator 76: Processes are in place to identify and respect of values and beliefs of patients.

Indicator 77: The patients are relieved of pain and suffering according to current knowledge.

Indicator 78: The needs of end-of-life care is assessed and documented.

Indicator 79: Staff is made aware of the needs of end-of-life care.

SERVICE DELIVERY

3 CARE CONTINUUM

3.1 Access to Health Services

Standard 9: Services are continuously available and the hospital minimizes physical, economic, social, cultural, organizational or linguistic barriers to access.

Indicator 80: Access ways and passageways are kept clear at all times.

Indicator 81: Functional, clean and disinfected wheel chairs and stretchers are available at the gate/reception for patients who are unable to walk.

Indicator 82: Hospital should avoid cross infections of patients while ensuring infection prevention practices at all places

Indicator 83: All patient areas of the hospital are easily accessible by wheelchair.

Indicator 84: Multi-storey buildings have ramps or functional lifts with an operator.

Indicator 85: The hospital and its departments are clearly signposted and a site plan is displayed at a central place for orientation of staff and patients.

Indicator 86: A reception with a male and female receptionist to guide the patients is open during operating hours.

Indicator 87: The hospital specifies visiting hours and communicates these to the public.

Indicator 88: Rules for numbers and kind of visitors and attendees are clearly defined and visibly posted and facilities to enable relatives to sit at the bedside and to stay overnight if needed.

Indicator 89: Documented policies and procedures for prioritizing the patient examination and treatment, bed availability, referrals, waiting time and support to special persons

Indicator 90: On admission to hospital, patients are introduced to the nurse on duty and given an orientation to the unit to which they are admitted including the location of toilets, pantry and other facilities and services.

Indicator 91: Patients admitted to the hospital have access to an allotted bed with fresh linen and do not have to double up with other patients.

Indicator 92: Elective admissions, including waiting list management and cancellations are managed in accordance with documented policies and procedures and based on patient need.

3.2 Continuity of Care

Standard 10: Patients have the right to continuity of care, including cooperation between all health care providers and/or establishments which may be involved in their diagnosis, treatment and care.

Indicator 93: Every patient is registered and issued the appropriate form for recording various details of symptoms, diagnosis, treatment and services being provided.

Indicator 94: All patients and visitors to the hospital receive courteous and prompt attention from the staff at reception and in ward or department.

Indicator 95: The doctor on duty has primary responsibility for the clinical care of any patient until a specialist takes over.

Indicator 96: The nurse on duty is responsible for patient assessment, care planning and evaluation of care in coordination with other care providers and services.

Indicator 97: A stock of essential drugs is available at all times in each treatment area

Indicator 98: Doctors, qualified nurses and appropriate support staff are available on-site 24 hours per day.

Indicator 99: There should be clear processes for nurses to summon urgent medical help if required.

Indicator 100: Regular meetings of different care providers are held to share information on patients' progress and patient care is formally handed over with the transfer of all relevant information when staff changes duties.

Indicator 101: The patient's record is available to all care providers.

Indicator 102: Planning for discharge or end of service begins at admission and involves the patients and their family and potential providers of follow-up services.

3.3 Assessment

Standard 11: All patients have their health care needs identified through an established assessment process.

Indicator 103: Assessments are carried out by qualified professionals identified by the hospital as competent to do assessments.

Indicator 104: Criteria to prioritise emergency patients exist and are implemented.

Indicator 105: Patients' choice regarding examination by a male or female is respected as far as possible.

Indicator 106: A nurse/chaperon is available when patients are being examined by members of the opposite sex.

Indicator 107: An assessment of the patient's needs is systematically completed on an agreed form including, for example, medical, psychological, social, physical, environmental, educational, spiritual and cultural needs.

Indicator 108: The initial assessment includes the recording of vital signs, weight, height and significant findings.

Indicator 109: The patient's relatives and carers are included in the assessment by providing information wherever possible.

Indicator 110: A history and full medical examination is entered in the patient records by a member of the medical staff as soon as possible but within maximum 6 hours of admission. All patient assessments should preferably be reviewed and approved by the attending consultant within 24 hours of admission.

Indicator 111: After examining the patient, the doctor legibly endorses the assessment findings, records the provisional diagnosis and the course of action on the OPD card or the patient record and dates and signs it.

Indicator 112: Except in an emergency, admission notes are completed prior to any surgical procedure.

Indicator 113: Following examination, written as well as verbal information is provided for patients regarding future visits, treatment and medication.

Indicator 114: Patients are re-assessed at certain intervals to determine their response to treatment and to plan for continued treatment or discharge and re-assessment results are documented in the patient's record.

3.4 Care Planning, Monitoring and Evaluation

Standard 12: Health Care Providers develop and implement a written, up-to-date plan of care/service for each patient and monitor the care provided against this plan.

Indicator 115: A written care plan for each patient is prepared in collaboration with the patient, carers/relatives and other appropriate health professionals.

Indicator 116: Care plans identify the goals of care and treatment and reflect the patient's assessed needs, perceptions and priorities, agreed philosophy of care, current practice guidelines and evidence-based practice.

Indicator 117: The care plan includes how the patient's individual choices and preferences are to be addressed.

Indicator 118: The care plan is evaluated and updated in accordance with the findings of re-assessment and progress in meeting identified goals.

Indicator 119: The care plan is used by doctors, nurses and other health professionals to facilitate continuity of care and on-going appropriate treatment.

Indicator 120: Outcome indicators, e.g. hospital acquired infections, bedsores, leg ulcers, LOS, falls, errors and patient complaints, are systematically monitored, recorded, analysed and used to improve care.

3.5 Treatment

Standard 13: The organization delivers services to the patients that meet their individual assessed needs, reflect current best practice and are coordinated to minimize potential risks and interruptions in provision.

Indicator 121: Clinical guidelines/treatment protocols are used to guide patient care processes.

Indicator 122: Policies and procedures guide the care of high-risk patients, such as:

- emergency patients
- those who are comatose or on life support
- those with communicable diseases or who are immune suppressed
- patients on dialysis
- vulnerable elderly and children
- Seriously ill patients

Indicator 123: Written procedures to ensure that the right medication is administered to the right patient. These must include:

- Identification of the patient before medications are administered
- Verification of the medication and the dosage amount with the prescription
- Verification of the routes of administration
- Verification of the time of administration

Indicator 124: Medication effects (including adverse effects) and medication errors are monitored, reported and analysed.

Indicator 125: Parental medication must be given under strict aseptic conditions, observing hand hygiene

Indicator 126: Appropriate and sufficient manpower, equipment and support services are available to allow nursing staff to meet the care needs of patients, with at least one nurse present round the clock.

Indicator 127: Patients are not disturbed unnecessarily except for medical reason.

3.6 Documentation of Care

Standard 14: The patient record contains sufficient information to identify the patient, support the diagnosis, justify the treatment and care, document the course and results of the treatment and care, and promote continuity of care among health care providers.

Indicator 128: A clinical record is initiated for every patient admitted to the hospital and wherever possible there is only one set of case notes for each patient.

Indicator 129: Patient records are maintained through the use of a unique number or other form of identification unique to the patient.

Indicator 130: Entries in the patient records are legible, dated, signed and identifiable.

Indicator 131: The use of symbols and abbreviations is kept to a minimum in accordance with an agreed list of abbreviations within the hospital.

Indicator 132: There is an agreed format for filing of information within the patient record.

Indicator 133: The hospital respects information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind as confidential, even after death. Confidential information is only disclosed if the patient gives explicit consent or if the law expressly provides for this.

Indicator 134: The patients' record can be used for research purposes only if the patient has given a written consent and/or if there is an approval by the Ethics Committee.

Indicator 135: The original patient record may not be removed from the hospital premises, except by court order. Policies and procedures are in place to prevent the loss and/or misuse of patient records.

Indicator 136: The patient record is sufficiently detailed to enable the patient to receive effective coordinated treatment and care and includes:

- Details of admission, date and time of arrival
- Patient assessment and medical examination
- Sheet containing history pertinent to the condition being treated including details of present and past history and family history
- Diagnosis by a registered health professional for each entry to the hospital
- Details of the patient care or treatment plan and follow-up plans
- Diagnostic test orders and results of these tests
- Progress notes written by medical, nursing and allied health staff to record all significant events such as alterations in the patient's condition and responses to treatment and care
- Record of any near misses, incidents or adverse events
- Medication sheet recording each dose given
- Treatment record
- Observation charts, E.g., temperature chart, input and output chart, head injury chart, diabetic chart
- Specialist consultation reports
- Mode of discharge, E.g., left against medical advice or discharged on request
- In case of death, details of circumstances leading to the death of patients

Indicator 137: For surgical patients, the clinical record additionally includes anaesthetic notes, operation record and consent form.

Indicator 138: Where referrals have been made, the patient record includes the referral letter and indications for referral.

Indicator 139: An 'alert' notation for conditions such as allergic responses to medications or food, adverse drug reactions, radioactive hazards and infection risks is prominently displayed in the record.

Indicator 140: A completed discharge summary signed by the doctor (full name) who authorized the discharge is submitted to the records department within 72 hours of the patient's discharge.

Indicator 141: All diagnoses/procedures are coded using international standards and a yearly summary report is prepared and used for planning.

Indicator 142: Patient records (hard copies) are retained for a minimum of 7 years and disposed of according to existing rules and legislation.

Indicator 143: All patient records should preferably be saved in a computer system and be available for perpetuity.

Indicator 144: Appropriate policies and procedures are in place to govern access to and storage of patient records.

Indicator 145: There is a clear policy which allows patients access to their records.

Indicator 146: All patient records are filed in a central medical record filing / computer system.
Indicator 147: There is a provision of a separate storage area for keeping medico-legal case records.

Indicator 148: There is a system for easy retrieval of records.

Indicator 149: The storage area for patient records is protected against fire, flooding and damage by insects consistent with the Govt. of Pakistan norms.

Indicator 150: A tracking system monitors the removal, movement and replacement of patient records between internal users and the Medical Records Department.

3.7 Discharge, Transfer and Referral

Standard 15: Safe and appropriate discharge, transfer or referral of patients is based on the patient's health status and need for continuing care.

Indicator 151: A written and dated procedure including criteria to determine readiness for discharge, transfer or referral of patients is used and specifies who is authorised to do it.

Indicator 152: Reasonable time, preferably 12 hours, of notice of discharge or transfer is given to patients and carers.

Indicator 153: Follow up arrangements, agreed with the patient and/or the family, and are noted in the patient record prior to discharge.

Indicator 154: On discharge, the attending doctor summarises in the patient record the primary (and secondary) diagnosis, any complications, any operative procedures undertaken and any follow up arrangements agreed with the patient/family.

Indicator 155: A discharge card/slip containing relevant information such as reason for admission, findings, diagnosis, treatment, medication, condition at discharge, date of discharge and name of attending practitioner is signed and given to the patient and/or his family prior to discharge, with a copy retained in the patient record.

Indicator 156: The patient and/or the appropriate carer or attendant is advised on any necessary skills for care after discharge such as moving and handling techniques or catheter care.

Indicator 157: If patients are transferred to another hospital or doctor, copies of their clinical notes and the discharge slip accompany them to provide sufficient information for continuity of care and feedback

Indicator 158: Patients being transferred to other facilities are provided with necessary resources such as transport, walking aids and documentation.

Indicator 159: Before transfer the facility to which the patient is being transferred is informed about receiving the patient, their status and the time of arrival and afterwards the hospital checks with the facility that the transfer has been safely made.

4 OPERATION THEATRE DEPARTMENT

4.1 Service Management

Standard 16: Operation Theatres provide safe, hygienic and appropriate services for patients and are coordinated with other services of the hospital to provide continuity of care.

Indicator 160: The operation theatre(s) and/or department are managed by a suitably qualified, registered and experienced nurse, doctor or senior operating department assistant.

Indicator 161: A list of hospital-approved surgical procedures, equipment and other inputs and processes is communicated to staff.

Indicator 162: Anaesthetic services are provided by qualified, registered and experienced anaesthetists.

Indicator 163: An anaesthetist is present / available for all surgical procedures 24 hours a day.

Indicator 164: A designated, suitably trained member of staff (Operating Theatre Assistant, anaesthesia technician) is available to assist the anaesthetist at all times.

Indicator 165: A visiting consultant surgeon or assistant provide surgery, assistance and advice through a signed agreement specifying the limits of their consultation.

Indicator 166: Regular documented audits of the operating theatre are carried out and the information is used by relevant management, safety and/or quality improvement committees.

Indicator 167: Any changes required to practice, provision or organisation as a result of the audits are discussed with all staff concerned before implementation.

Indicator 168: Coded data available to OT staff from audits includes:

- Admissions and discharges by speciality
- Diagnosis-specific bed utilisation
- Procedure-specific operating rates
- Post-operative infections
- Post-operative deaths
- Unplanned return to theatre
- Post-operative pulmonary embolism
- Post-operative CVA
- Post-operative cardiac myocardial infarction
- Unplanned re-admission within 28 days of discharge
- Unplanned transfer to ICU
- Unplanned transfer to another unit
- Unplanned second operation within 6 weeks of surgery
- Damaged organs following surgical procedure

Indicator 169: Mechanism/process of patients' safety is in place and followed, including:

- Identification of the right surgical site
- Swab and instruments counting before incision and stitching

4.2 Policies, Procedures and Records

Standard 17: Operational policies and procedures clearly describe the key processes of the Operation Theatre and/or department, the responsibility of the staff and expected results, and records provide accurate information for analysis and evaluation.

Indicator 170: Written up-to-date procedures are available, followed by staff and include but are not limited to the following:

- Signage of OT as a restricted area and identification of persons allowed in the OT
- Sterilisation and identification of sterilised OT equipment
- Separation and transport of dirty linen
- Pre-operative assessment and instructions
- Routine equipment checks and preparation
- Annual review of functioning equipment in line with the services offered by the OT
- Sending for and the transportation of patients from ward to OT
- Admission to the operating department

- Identification of patients
- Identification of operation site
- Recovery
- Inoculation injury
- Staff protection against exhaust from anaesthetic gases
- Post-operative care
- Handover procedures for pre-operative and post-operative patients
- Diathermy use
- Tourniquet use
- X-ray use
- Laser use
- Swab, needle and instrument count
- Infected patients

Indicator 171: The following formal documentation/records are available in the department:

- Theatre register (anaesthesia register and surgeons' register)
- Prosthesis register
- Electro medical equipment register
- Record of correct swab/instrument count
- Controlled drugs
- Specimens register
- Record of weekly/monthly analyses of surgeries (including the ICD 10 code)
- Next-day schedule for operations
- Maintenance of stock levels of drugs and consumables
- Duty roster

Indicator 172: Specific safety rules and instructions are displayed and followed by staff for the following:

- Storage and use of hazardous chemicals, E.g., glutaraldehyde, formalin
- Storage and use of compressed gases
- Appropriate shielding and protective clothing, E.g., for image intensification
- Emergency electrical power supply (UPS, inverters, generators and emergency electric lights)

Indicator 173: Surgical patients are managed by surgeons, anaesthetists and nurses with appropriate qualifications and experience.

Indicator 174: Children have (the right of) access to a parent prior to and during induction of anaesthesia, and during recovery.

Indicator: All patients undergoing surgery are identified by a bracelet or other unique identification method secured to the patient.

Indicator 175: Full, non-abbreviated preoperative notes are kept for all patients and include but are not limited to:

- Signed evidence that informed consent to surgery has been obtained by a doctor for critical surgery and by the nurse for routine surgery
- Signed evidence that the correct procedure was followed when obtaining consent for children under the age of 18 years
- Details of the site and side of an operative procedure

Indicator 176: There has a separate fully functioning and equipped recovery room.

Indicator 177: A trained recovery nurse is present for each anaesthetic session and remains in the recovery area until the last patient has been discharged back to the ward.

Indicator 178: Sufficient, qualified and experienced staff monitoring patients in the recovery room to ensure individual patient supervision at all times.

Indicator 179: Documented discharge criteria are used to assess patients' readiness to leave the recovery room.

Indicator 180: The anaesthetist is available in the hospital until the patient has recovered from anaesthetic.

Indicator 181: The anaesthetist provides the final authorization for the patient to leave the recovery area.

Indicator 182: There are clear, formal instructions on how to contact a doctor in an emergency.

Indicator 183: A documented visit is made to each in-patient at least once by the surgeon, anaesthetist or doctor between the first post-operative day and discharge.

Indicator 184: A record of the operation for the patient record is made immediately following surgery and a copy is retained in the OT. The record includes the following:

- Date and duration of operation
- Anatomical site/place where surgery is undertaken
- The name of the operating surgeon(s), operating assistants including scrub nurse and the name of the consultant responsible
- The coded diagnosis made and the procedure performed
- Description of the findings
- Details and serial numbers of prosthetics used
- Details of the sutures used
- Swab and equipment count
- Immediate post-operative instructions
- The surgeon's and scrub nurse's signatures

Indicator 185: Anaesthetic records contain:

- Date and duration of anaesthesia
- Name of surgical operation performed
- The name of the anaesthetist, anaesthesia assistant and, where relevant, the name of the consultant anaesthetist responsible
- Pre-operative assessment by the anaesthetist
- Drugs and doses given during anaesthesia and route of administration
- Monitoring data
- Intravenous fluid therapy
- Post-anaesthetic instructions
- Any complications or incidents during anaesthesia
- Signatures of anaesthetist and anaesthesia assistant

4.3 Facilities and Equipment

Standard 18: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients undergoing procedures in the operating theatre(s).

Indicator 186: Arrangements are made so that hospitals OTs are situated separately from areas accessible to the general public.

Indicator 187: Hazard and/or warning notices are clearly displayed before restricted and high-risk areas.

Indicator 188: Changing facilities are provided for theatre staff to enable those entering the theatre to not cross "dirty" areas.

Indicator 189: Separate male and female changing and rest rooms are available.

Indicator 190: There is a clear separation of 'dirty' areas in OT(s) and only persons wearing theatre dress enter the OT(s).

Indicator 191: Staff uses a separate space for maintaining records and other office activities.

Indicator 192: The anaesthetic induction area/room and operating theatre are equipped with safe and well-maintained equipment specific for OT activities including but not restricted to the following:

- Anaesthetic machine and ventilator
- Laryngoscopes
- Endotracheal tubes/laryngeal masks
- Airways
- Nasal tubes
- Suction apparatus and connectors
- Oxygen
- Drugs and IVs required for planned anaesthesia

- Drugs for emergency situations
- Monitoring equipment including ECG, ETCO2, temperature monitoring, pulse oximeters and blood pressure
- Accessible defibrillator
- Anaesthetic gas scavenger system
- Tipping/tilting trolleys/beds
- Multi positioned table with radiolucent tops
- Suction machine
- Instrument cleaning/decontamination facilities
- Temperature and humidity control
- IV Cannulas and CV lines in different sizes
- Blood warmer
- Adequate light sources
- Special equipment for particular age groups, E.g., neonate resuscitation table

Indicator 193: A list of additional items needed for special procedures and surgeries carried out by the OT is available in the theatre.

Indicator 194: The recovery area is well lit and adjacent to the operating theatre.

Indicator 195: Resuscitation equipment and drugs are immediately accessible in the recovery area.

Indicator 196: A list of functioning equipment available in the recovery room includes:

- Airways (Ambu bags) and other intubation material and equipment
- Suction
- Oximeter
- ECG
- Tipping/tilting trolleys/beds
- Blood pressure measurement apparatus
- Defibrillator
- Anaesthesia machine
- Oxygen concentrator
- Emergency ventilator

5 EMERGENCY SERVICES / CASUALTY DEPARTMENT

5.1 Service Management

Standard 19: The Casualty Department provides safe, timely and efficient live-saving emergency care and minor treatment and surgery for patients.

Indicator 197: The casualty department is managed at all times by a suitably qualified and experienced nurse, doctor or senior casualty department assistant.

Indicator 198: Deputising arrangements for suitably qualified and experienced deputies are documented and used.

Indicator 199: A signed agreement and close professional links with other emergency units offering more comprehensive services enables the provision of necessary emergency services.

Indicator 200: Data and outcome indicators are systematically recorded and aggregated for analysis. These include a documented review of volume of activity, source and appropriateness of referrals and adverse events.

Indicator 201: Data available for clinical review includes:

- Number of attendances
- Repeat visits
- Patients who died in the casualty department

5.2 Policies, Procedures and Records

Standard 20: Operational policies and procedures clearly describe the key processes of the casualty department, the responsibility of the staff and expected results. Records provide accurate information for analysis and evaluation.

Indicator 202: Written procedures and guidelines are used consistent with the policy for:

- Identifying which patients should be seen immediately by a doctor in the department
- How medical help is summoned in emergency
- Dealing with life threatening emergencies before medical help arrives
- The transfer of patients
- The transfer of records
- The use of Tele-medical techniques

Indicator 203: The hospital disaster plan clearly identifies the role, procedures and individual staff responsibilities within the casualty department in the event of a nearby major incident or disaster.

Indicator 204: All patients are seen within fifteen minutes of arrival for initial assessment and treatment prioritisation.

Indicator 205: Each patient is informed of the approximate waiting time after the need for treatment has been assessed.

Indicator 206: A process is used to monitor patient waiting times.

Indicator 207: Patients are examined in privacy by a doctor of the same sex as the patient (if available), or have the service of a chaperone if desired.

Indicator 208: Relatives are kept informed of the patient's condition with the agreement of the patient where they are able to give such consent.

Indicator 209: Locally agreed policies and procedures, consistent with local and/or national guidelines, are used for:

- All major acute emergencies commonly falling in the scope of hospital.
- Road traffic accidents
- Major incidents
- Assault
- Domestic violence
- Child protection
- Rape
- Psychiatric emergencies
- Drug abuse
- Suspected criminals
- Suspected victims of crime
- Police enquiries
- X-ray requests
- Requests for reports
- Tetanus immunisation
- Death in the unit

Indicator 210: An individual record of attendance is completed which contains:

- Name
- Address
- Age/Date of birth
- Next of kin
- Occupation/School
- Case number
- Telephone number
- Date and time of arrival
- Time of examination
- Diagnoses
- Treatment
- Minor surgery carried out
- Specimens taken
- Instructions for follow up
- Doctor's or nurse's names and signatures
- Medication given to/or taken away
- Advice given on discharge

Indicator 211: A departmental register identifies all attendances, reason for attendance, diagnostic tests, treatment given and any referrals.

Indicator 212: A formal mechanism (roster) known to all staff is used for identifying medical staff on duty and on call and is prominently displayed in the emergency care area.

Indicator 213: A procedure exists for referral for specialist care if necessary.

Indicator 214: An agreed policy is followed which defines under what circumstances, if any, nurses may issue or administer specific drugs (including tetanus toxoid) without a specific doctor's order.

Indicator 215: The type and extent of minor surgery to be undertaken is defined and is consistent with the facilities, equipment and skills available on site.

Indicator 216: A written, dated, signed policy on the referral, selection and treatment of patients for minor surgery is followed.

5.3 Facilities and Equipment

Standard 21: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients attending the emergency services /casualty department.

Indicator 217: A mechanism exists for regular review of the design and appropriateness of the treatment facilities and medical and surgical supplies to assess whether they are sufficient for the work undertaken in the unit.

Indicator 218: The casualty entrance is clearly signposted from outside the hospital.

Indicator 219: A call bell is available if the entrance to the unit is locked.

Indicator 220: Parking is available for patients, including designated space for the disabled.

Indicator 221: There is a canopy over the casualty entrance used by ambulances.

Indicator 222: The doorways and access are suitable for wheelchairs and trolleys.

Indicator 223: Emergency alarms are strategically sited within the unit to summon help.

Indicator 224: Contemporary basic clinical textbooks and information are available for staff.

Indicator 225: There is appropriate equipment for:

- Resuscitation
- Monitoring
- Minor operations
- Sterilisation
- X-rays and other imaging (either locally or by referral)

Indicator 226: Hallways, clinical and public areas are clear of equipment, beds or other obstructions.

Indicator 227: Treatment areas afford the patients' privacy.

Indicator 228: A private area/room is available for interview and examination.

Indicator 229: The waiting area:

- Has drinking water facility
- Has comfortable and adequate seating
- Is clean and secure

Indicator 230: There are toilet facilities suitable and available for males, females and disabled.

Indicator 231: A public telephone is available for the use of patients and relatives.

6 INTENSIVE CARE UNIT

6.1 Service Management

Standard 22: The Intensive Care Unit is managed by suitably qualified staff and organized to provide safe and efficient care for seriously ill patients who need to be continuously monitored.

Indicator 232: A qualified professional with relevant training in intensive care is responsible for overall co-ordination of the unit and is accessible for specialist advice.

Indicator 233: A designated deputy is responsible for the management of the ICU in the absence of the manager.

Indicator 234: An appropriately qualified, registered and experienced nurse is responsible for the day-to-day management of nursing care in the unit.

Indicator 235: Staff is allocated on the basis of a systematic analysis of patient dependency and number of patients.

Indicator 236: All staff working in the unit are appropriately qualified and experienced for the work they do and have attended specialist high dependency care courses and continuous medical education for updating their skills.

Indicator 237: Registered nurses in the unit have completed formal in-service training or a recognised course in intensive care and at least one is present on all shifts.

Indicator 238: A suitably experienced doctor is immediately available at all times.

Indicator 239: The Unit has a person who leads on infection control issues.

Indicator 240: Relevant current texts are available for all staff for reference on the unit.

Indicator 241: The expenditure/cost of procedures in the ICU is clearly defined, and available.

6.2 Policies and Procedures

Standard 23: Operational policies and procedures which clearly describe the key processes of the ICU, the responsibility of the staff and expected results are followed by staff.

Indicator 242: Specific policies and procedures include emergency admission to ICU from:

- Theatres
- Wards
- Other departments
- Outside

Indicator 243: Management policies and/or procedures are available and followed by staff for the following:

- Airway management
- Conscious Sedation
- Ventilators/respirators
- Central oxygen supply and oxygen cylinders
- CVP readings (central venous pressure)
- Infusion pump management
- Pulse oximeters
- Cardiac monitors
- Arterial lines
- X-ray and other imaging investigations
- Epidural care
- Recovery facilities for all surgical cases where there is no dedicated recovery unit
- Recovery care of major surgical cases

Indicator 244: Specific emergency procedures are available and followed for:

- Apnoea/respiratory arrest
- Cardiac arrest
- Laryngeal spasm/stridor

Indicator 245: There are written criteria defining who is authorised to perform the following emergency clinical activities:

- Intubation
- Tracheotomy
- Insertion of central lines

- Defibrillation

Indicator 246: There are written policies and procedures agreed and followed for the following:

- Clothing of staff and visitors
- Filtering of patients' respired air
- Changing of catheters, humidifiers and ventilator tubing
- Isolation of at-risk or infected patients
- Cleaning of the unit

Indicator 247: Regular meetings take place to review cases and patient management, both within the unit and in conjunction with other departments.

Indicator 248: The Unit discourages open visiting.

6.3 Facilities and Equipment

Standard 24: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients in the ICU.

Indicator 249: There is sufficient space for storing disposable and consumable items.

Indicator 250: A functional resuscitation trolley and defibrillator are available on the unit

Indicator 251: Within the Unit, a designated member of staff is responsible for checking and recording daily and after each use.

- Resuscitation equipment
- Stockholding and date of resuscitation drugs

Indicator 252: Each bed has a central line facility for:

- Oxygen
- Suction
- Compressed air
- Central ECG monitoring

Indicator 253: Beds in the unit are arranged to allow ready access for routine and emergency procedures and are within direct vision of supervising staff at all times.

Indicator 254: Adequate (at least three) numbers of power sockets are available for each bed.

Indicator 255: Facilities in the unit include:

- CVP monitoring
- Pulse oximetry
- Blood pressure monitoring (automatic)

- Urometry
- Ambient and patient temperature monitoring
- Arterial blood gases
- Glucometer
- Electrolyte machine

7 RESUSCITATION

7.1 Service Management

Standard 25: All professional staff is trained in resuscitation at least to basic life support levels. Those working in higher risk areas, E.g., casualty department, operation theatres and ICU are trained in advanced life support.

Indicator 256: There is a written, agreed description of the scope and operation of resuscitation services provided within the Hospital.

Indicator 257: A resuscitation training team exists within the Hospital and is responsible for the co-ordination of procedures, equipment and training of health staff both in the hospital and in the community.

Indicator 258: The provision of resuscitation conforms to the recommendations of the Health Department and/or international guidelines.

Indicator 259: There is a formal mechanism for obtaining specialist clinical advice on resuscitation issues.

Indicator 260: There is a programme for regular in-service training of clinical staff in handling equipment and procedures for resuscitation throughout the hospital.

Indicator 261: Records on training status are maintained for individual staff members.

Indicator 262: All medical staff has received advanced resuscitation training at least every three years, by a trainer who has undertaken a recognised course and documentation is provided to show evidence of this.

7.2 Policies and Procedures

Standard 26: Policies and procedures related to resuscitation exist and are known to the staff.

Indicator 263: Policies and procedures are reviewed as necessary but at least once year.

Indicator 264: An agreed, defined clinical procedure for resuscitation of adults (and children, if appropriate) exists and is followed by the staff.

Indicator 265: An agreed, defined policy for when to use a defibrillator exists and is followed.

Indicator 266: There is an agreed and written policy on the training of staff in the use of a defibrillator.

Indicator 267: There is a policy for providing paramedic and medical assistance for resuscitation to the community.

7.3 Facilities and Equipment

Standard 27: The Hospital provides adequate and functioning equipment for resuscitation in emergencies.

Indicator 268: Within the hospital, a designated member of staff is responsible for the checking and recording daily and after each use:

- Resuscitation equipment
- Stockholding and date of resuscitation drugs

Indicator 269: Facilities available for resuscitation include:

Mechanical

- Resuscitation trolley containing equipment and medication for advanced life support
- Defibrillator
- Laryngoscopes (including for children, if appropriate)
- Suction apparatus
- Manual ventilation equipment E.g., bag, valve-mask, pocket mask
- ECG monitor and leads

Supplies (including for children if relevant)

- Intravenous infusion sets
- Endotracheal tubes and/or laryngeal masks
- Oral airways
- IV Cannula

Medications

1. Oxygen

- Intravenous fluid
- Resuscitation drugs.

Indicator 270: All equipment is checked on a daily basis and after each use by suitably qualified staff. Records of the checks are kept with the equipment and monitored.

Indicator 271: Endotracheal Intubation, cricothyroidotomy set and chest drainage equipment is only used by those experienced and trained in their use.

Indicator 272: Facilities (equipment) are conveniently located within the hospital to be accessible to highest risk patients.

8 MATERNITY SERVICES

8.1 Service Management

Standard 28: Maternity services provide safe, timely and efficient maternity care for patients.

Indicator 273: The maternity department is managed by a suitably qualified, registered and experienced.

Indicator 274: Deputising arrangements for suitably qualified and experienced deputies are documented and used.

Indicator 275: A signed agreement and close professional links with a referral hospital offering more comprehensive services ensures provision of necessary emergency maternity services not available in the hospital.

Indicator 276: The maternity department has 24 hour on-site cover from qualified medical doctors and an anaesthetist.

Indicator 277: Consultant obstetricians provide assistance and advice through a signed agreement.

Indicator 278: Data for clinical audits and reviews is collected, analyzed and used for quality improvement activities and includes:

- Relevant quality indicator.
- Number of women in ante-natal clinics
- Number of women with medical or surgical disorders in ante-natal clinics
- Number of women transferred to higher-level care during pregnancy
- Number of deliveries
- Number of live and still births
- Perinatal mortality figures
- Maternal mortality figures
- Number of transfers to specialist care during labour
- Number of still births
- Birth Registration records
- Number of Caesarean sections
- No. of difficult labour cases

8.2 Policies, Procedures and Records

Standard 29: Operational policies and procedures clearly describe the key processes of the maternity unit, the responsibility of the staff and expected results. Records provide accurate information for analysis and evaluate

Indicator 279: Written procedures and guidelines are used consistent with the hospital policies and functions for:

- Ante natal care and booking/registration
- Post-natal care
- Perinatal care
- Counselling for parenthood (e.g. family planning, genetic referral)
- Identifying high risk pregnancy
- Admission to labour room/ward
- Planning, treatment and mode of delivery
- Plan for managed pain during labour and delivery
- Delivery monitoring process
- Referral
- Discharge including discharge summary
- Birth record and certificate
- Labour register
- Immunization for mother and baby
- Infection control
- Disposal of placentas

Indicator 280: A paediatrician is involved in the team developing and reviewing policies and procedures.

Indicator 281: Each woman accessing the maternity department is cared for by a suitably qualified, registered and experienced nurse, doctor or senior midwife who she can contact for advice and help throughout her pregnancy.

Indicator 282: Anaesthetists with relevant qualifications and experience available for mothers with epidural, C Section, emergency breech and instrumental deliveries, emergency resuscitation and women with eclampsia.

Indicator 283: A trained mid-wife/nurse is present at every birth.

Indicator 284: A record of regular training in maternal and neonatal resuscitation is kept in the department for medical and nursing staff attending deliveries

Indicator 285: A guideline on requesting medical assistance at any time during labour is used by nurses and midwives

Indicator 286: A roster indicates 24-hour arrangements for on-site availability of a suitably qualified and experienced doctor and an anaesthesiologist in case of an emergency.

Indicator 287: Separate records are initiated and used for each baby.

Indicator 288: Records kept after discharge, include the combined:

- Maternity notes (including care plans)
- Birth registration(s)
- Labour register
- Admission register
- Neonatal and perinatal morbidity
- Neonatal and perinatal mortality
- Maternal morbidity and mortality

8.3 Facilities and Equipment

Standard 30: Facilities and equipment are safe and adequate in design and number for the purpose and quantity of patients attending/in the maternity department.

Indicator 289: The delivery room is equipped with functioning, safe and well maintained equipment specific for deliveries including but not restricted to the following:

- Fetoscope
- Ultrasound machine
- Delivery table which can be turned to the trendelenburg position
- An anaesthetics machine with emergency oxygen supplies
- Endotracheal tubes, laryngoscope
- An incubator, with temperature adjustable for infants in need
- Separate oxygen supply to the incubator
- Resuscitation equipment and drugs for infants and for adults
- Intravenous crystalloid and plasma expanders
- Weighing machine for the baby

Indicator 290: Privacy for mothers is possible, e.g. when breast-feeding.

Indicator 291: A separate room for seriously ill or intensive patients, e.g. eclampsia, is available.

Indicator 292: The area for labour provides for:

- Space for the woman and a female companion
- Alternative birthing methods
- Ambulation throughout labour
- Washing and toilet facilities for the comfort of the mother and companion

Indicator 293: Lighting is versatile enough to provide a restful environment and allow birthing procedures to be performed.

Indicator 294: The post-natal ward provides sufficient room for babies to room-in with mothers.

Indicator 295: Nursery facilities with an even temperature and humidity are available, and are adequate in size with appropriate supplies and equipment for teaching mothers about caring for their babies.

AUXILARY SERVICES

9 LABORATORY SERVICES

9.1 Service Management

Standard 31: The medical testing laboratory is managed and organised to provide efficient and effective laboratory care to patients and support services to clinicians.

Indicator 296: The medical testing laboratory is managed by a suitably qualified and registered pathologist, experienced medical technologist or other suitably qualified and registered laboratory scientist.

Indicator 297: A suitably qualified deputy is designated in the temporary absence of the laboratory manager.

Indicator 298: Sufficient and appropriately qualified staff is available to fulfil the job descriptions of the defined service.

Indicator 299: Laboratory staff participates in the health and safety committee, hospital quality committee and other relevant committees.

Indicator: Departmental staff attends meetings of appropriate advisory /consultative bodies and have input into decisions affecting the laboratory.

Indicator 300: A pamphlet outlines the list and prices of services offered the types of specimen's required and approximate reporting time for tests.

Indicator 301: Laboratory staff inform in writing the designated hospital infection control committee of any infection identified in in-patient samples that could provide a risk to the hospital staff or patients.

Indicator 302: The service has a continuing education programme for staff development enabling staff to meet the needs of the hospital, the department, the individual and the patients.

Indicator 303: Staff follows written policies and procedures for collection, transport and controlling, storing, reporting and disposing of all samples and tests in compliance with legal requirements.

Indicator 304: Staff is involved on a regular basis in a quality management programme to monitor and improve the laboratory quality

Indicator 305: Any outstation laboratory equipment is subject to the same quality control procedures as in the main laboratory.

Indicator 306: The department has planned and systematic activities for the monitoring and evaluation of its services.

9.2 Samples and Tests

Standard 32: Laboratory samples and tests are managed to maximize accuracy of testing and minimise risks to patients and staff.

Indicator 307: A requisition form is used and includes the following:

- Patient information
- Patient location
- Investigations required
- Type of sample
- Clinical
- Probable diagnosis
- Requesting physician
- Sample collection time
- Name of phlebotomist

Indicator 308: Staff follows and communicates to patients, verbally and in writing, procedures for the patients' preparation for tests.

Indicator 309: Samples collected are labelled with the patient's name, registration number, date and time of collection.

Indicator 310: Separate labels are used for high-risk samples.

Indicator 311: Specimen trays are designed to enable safe transport.

Indicator 312: The sample reception area receives, records, and verifies the samples or specimens.

Indicator 313: A laboratory registers records:

- Patient name, location
- Identification of sample source(s)
- Full name of the investigation(s)
- Number of investigations
- Investigation results

Indicator 314: Samples are safely and accurately distributed to the respective sections of the laboratory.

Indicator 315: Results are recorded in the laboratory register and on the reporting/result form.

Indicator 316: Patient Results Registers are readily accessible to staff.

Indicator 317: Results are made available to the main reception of the laboratory to enable picking up by OPD, wards or patients.

Indicator 318: Signed and dated SOPs for each test and patient preparation for each test are readily available to staff in the laboratory.

Indicator 319: Staff follows written, dated and signed procedures for:

- Patient preparation for tests
- Completion of test request forms
- Reporting of test results
- Reporting results verbally
- Dealing with out-of-hours test requests
- Investigating transfusion reactions
- Emergency and urgent requests
- Storage of specimens and blood on the wards and in other departments
- Dispatch of samples to other laboratories
- Posting of samples
- Acceptable parameters for response to test requests and reporting times

Indicator 320: Staff follows written procedures for samples:

- Sample collection
- Handling
- Labelling
- Transportation
- Retention
- Storage
- Disposal of samples, including blood and body fluids

Indicator 321: The service is able to give expert advice on:

- The appropriateness of tests
- The samples required
- The interpretation of results
- Further recommended tests

Indicator 322: Instructions are clearly displayed describing the safe disposal of clinical, toxic and radioactive waste.

Indicator 323: Clearly labelled, separate containers are used for disposal of hazardous and infectious waste.

Indicator 324: A written agreement exists, and staffs follows this agreement, between the hospital and external laboratory covering all aspects of tests including time scales for reporting results.

Indicator 325: A written policies/ procedures Critical or unexpected findings are discussed with the referring doctor.

9.3 Safety

Standard 33: All persons are protected from potential hazards in the laboratory.

Indicator 326: A mechanism is in place to restrict access to the laboratory to authorised personnel only.

Indicator 327: Health and safety policies, current relevant hazard notices and safety action bulletins are displayed as required or are readily available to staff, including but not limited to:

- Safety regulations
- Fire precautions
- AIDS/HIV/
- Hepatitis

Indicator 328: Appropriate equipment is used for the safe handling of hazardous materials.

Indicator 329: Action to be taken in the event of an infection emergency is known to all staff and is clearly stated in writing.

Indicator 330: Staff is offered immunisations relevant to their type of work and emergency immunisations based on written policies.

9.4 Facilities and Equipment

Standard 34: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients served by the laboratory.

Indicator 331: Laboratory and office space are sufficient to enable staff to carry out their jobs safely.

Indicator 332: The laboratory environment is well lit ventilated.

Indicator 333: Staff has access to sufficient laboratory equipment to carry out their jobs safely.

Indicator 334: Storage facilities for specimens and reagents are sufficient to enable staff easy access.

Indicator 335: Refrigerated storage facilities are used for specified samples, specimens, and blood samples.

Indicator 336: Functioning emergency electrical supply for refrigerators is available and there is a procedure in place to regularly assess its readiness.

Indicator 337: Inspection, calibration and maintenance schedules are completed and used for all laboratory equipment.

Indicator 338: Staff facilities include:

- Locker space
- Toilet and washing/shower facilities
- Staff rest room
- Overnight accommodation for on call staff

10 RADIOLOGY

10.1 Service Management

Standard 35: Radiology services are managed and organised to provide safe and efficient care for patients and support to clinical specialties.
Note: Radiology services cover all services provided by a radiology department.

Indicator 339: A radiologist is responsible for the clinical direction of the department and the safety of the patients.

Indicator 340: Radiology services are administered by an identified qualified, registered radiologist or radiographer with clearly defined responsibility for all non-clinical aspects of the department.

Indicator 341: Trained, qualified radiographers, or in some cases radiologists, are the only staffs who may take images.

Indicator 342: There are on-call staffs for mobile radiography and other imaging at all times.

Indicator 343: Radiation protection is supervised by the radiologist and monitored by the Hospital in-charge and the Nuclear Regulatory Authority.

Indicator 344: Staff follows written policies and procedures for all aspects of radiology services, including:

- Reception and registration of the patient
- Preparation of the patient for imaging
- Processing and interpreting the film or scan
- Reporting on the film or scan
- Documentation and despatch

Indicator 345: Up to date reference manuals, radiation regulations and guidelines, radiation safety reports, are available within the department.

Indicator 346: The department participates in the Hospital's quality improvement system and monitors the quality of its services using an internal quality control programme which includes:

- Equipment utilisation review
- Performance checks on equipment, including processors
- A record of maintenance checks for all items of equipment
- Film and scan reject rates
- Clinical audit
- Turnaround times for the reporting of films and scans

Indicator 347: Radiology Department takes action on the results of its quality control programme, in a radiology quality committee and participate in the hospital health and safety committee and other relevant committees.

10.2 Service Provision

Standard 36: Patients are systematically registered, receive radiological services in line with written requests and have their x-rays reported promptly and accurately.

Indicator 348: Patients are registered, assigned a registration number and given special instructions in a systematic way.

Indicator 349: Request Forms are of a standard format and contain:

- Patient's name
- Identification number
- Date of birth (if not available, age)
- Examination requested
- Previous examinations
- Clinical diagnosis/indications/relevant history
- Information relating to the pregnancy rule in women of childbearing age
- Identity of requesting physician
- History of allergy
- For medico legal cases mark of identification of the patient and name of police official bringing the patient

Indicator 350: Diagnostic imaging is performed only upon a signed written request from a qualified medical practitioner.

Indicator 351: Arrangements are in place for dealing with out of hours or emergency requests.

Indicator 352: A written policy agreed with the radiologist defines the terms under which pregnant women may be subjected to radiological examination

Indicator 353: All films are read by a radiologist and the written radiologists' reports are received by the hospital within a defined time after examination.

Indicator 354: Required reporting times are based on the urgency of the situation, e.g. films or scans for emergency patients are reported within one hour and routine reports are reported within 24 hours.

Indicator 355: If a radiologist is unable to report on the film in a timely manner a written, signed interpretation of the radiograph is made by an appropriate clinician whose skills are relevant to the area radio graphed, E.g., chest radiography by a chest physician or bone/joint radiography by an orthopaedic surgeon.

Indicator 356: Critical or unexpected findings are discussed with the referring doctor.

Indicator 357: Radiology reports or copies of the reports are placed in patients' medical files in the wards.

10.3 Safety

Standard 37: Radiological services are provided in accordance with current radiation rules and regulations, risks are minimised and the safety of patients and staff are protected.

Indicator 358: Signs warning women of childbearing age of the dangers of radiation in pregnancy are prominently displayed.

Indicator 359: All examinations using ionising radiation are performed by suitably trained personnel.

Indicator 360: Staff provides services in accordance with current ionising radiation regulations and statutory requirements.

Indicator 361: Emergency drugs and equipment including all resuscitation equipment are functioning, are readily accessible and are monitored.

Indicator 362: All staff working in radiology services attend update courses on resuscitation, current radiology trends and evidence-based practice.

Indicator 363: Protective clothing is provided and used where biohazards or radiographic equipment is present.

Indicator 364: The radiologist in charge is responsible for ensuring that compliance with national guidelines is monitored:

- Staff working with radiological equipment wear radiation monitoring devices

- These devices are assessed and maintained in accordance with statutory regulations
- Records of these tests are kept for the working lifetime of staff employed by the service

10.4 Facilities and Equipment

Standard 38: Facilities and equipment are provided and maintained to maximise patient comfort and safety.

Indicator 365: A separate registration area for patients is provided and a toilet with washing facilities for special investigations is located adjacent to the examination room.

Indicator 366: A separate waiting area for males and females with adequate seating and separate male and female toilets and washing facilities are provided for the comfort of patients waiting for services and for their families.

Indicator 367: The appropriate hospital advisory committee (or its equivalent) with representation of radiology staff is consulted before any diagnostic equipment is installed.

Indicator 368: All equipment is subject to tests on installation to ensure the equipment meets with contract specifications and confirms mechanical, electrical and radiation safety.

Indicator 369: Records of these tests are kept in the department for reference.

Indicator 370: The workload of each piece of diagnostic equipment and staff is defined and used for determining the resources needed for the department.

Indicator 371: Radiology equipment is stable, functioning and installed only in properly lead protected rooms.

Indicator 373: A planned preventative maintenance programme is followed to keep equipment in sound working order.

Indicator 374: The radiation safety of essential equipment is regularly monitored and reported.

11 PHARMECY SERVICES

11.1 Management

Standard 39: The pharmaceutical service is managed and organised to provide efficient and effective pharmaceutical services through rational use of drugs within the hospital.

Indicator 375: The pharmaceutical service is managed by a qualified, graduate and registered pharmacist.

Indicator 376: A suitably qualified deputy with specified duties and responsibilities is designated in the absence of the pharmacist.

Indicator 377: Sufficient and appropriately qualified staff is available to fulfil the job descriptions and the defined services.

Indicator 378: A qualified pharmacist or designated deputy is on duty or on call outside normal working hours to provide a pharmaceutical service.

Indicator 379: Staff follows written policies and procedures for ordering and purchasing, controlling, storing, dispensing and disposing of all medicines within the hospital in compliance with legal requirements.

Indicator 380: The department monitors the quality of its services using an internal quality control program and staffs participate in the Hospital's quality improvement system.

Indicator 381: The pharmacy service provides a regular prescription monitoring service, locally, to ensure the safe, effective and economic use of medicines. This includes:

- Identifying inappropriate medication
- Monitoring adverse reactions
- Monitoring dispensing errors
- Checking adequacy of labelling of drugs and information on package inserts
- Physical examination of drugs to assess their quality and expiry dates
- A mechanism to encourage prescription of cost-effective and economical drugs

Indicator 382: The pharmacist is a member of the purchase committee.

11.2 Selection, Ordering and Purchasing of Medication

Standard 40: Selection and procurement of medication is appropriate to the scope of service, patient needs, and cost-effectiveness.

Indicator 383: The hospital formulary is prepared in a collaborative process considering patient needs, services provided in the hospital, cost-effectiveness and evidence-based criteria.

Indicator 384: The hospital formulary is in accordance with existing provincial/national guidelines, e.g. National Essential Drugs List (NEDL).

Indicator 385: Written policies and procedures exist and are implemented for the following processes:

- Tendering
- Evaluation of tenders
- Selection
- Ordering
- Reception and physical examination of delivered drugs

Indicator 386: Evaluation of tenders and selection of the provider occurs through a transparent process based on specific criteria including quality and cost.

Indicator: 387: The quality, quantity and expiry date of purchased medicines are checked upon receipt.

Indicator 388: Samples of delivered drugs sent to the Drugs Testing Laboratory for quality check.

Indicator 389: The list of medications available in the hospital pharmacy is available to all units

Indicator 390: A process exists to obtain required medications not stocked or normally available in the hospital pharmacy.

11.3 Storage and Stock Management

Standard 41: Stock is stored and managed to ensure that medications are current, kept safe and are continuously available to meet the needs of clinical staff and patients.

Indicator 391: Medicines are stored on shelves enabling:

- Protection from the adverse effects of light, dampness and temperature extremes
- Freedom from vermin and insects
- Adequate ventilation

Indicator 392: Medicines for emergency use are stored in sealed tamper evident containers in all patient areas.

Indicator 393: Adequate and secure storage facilities provided include:

- A suitable cupboard or container for the storage of flammable and/or hazardous material
- A functioning pharmacy refrigerator

Indicator 394: Controlled drugs are stored separately in a cupboard, securely fixed to the wall or floor, to comply with drugs regulations.

Indicator 395: Stocks of controlled medicines are ordered by an authorized

Indicator 396: A formal stock control system is used by the department and for the hospital.

Indicator 397: There is a stock list with agreed par levels for all wards and departments.

Indicator 398: Medicines required in an emergency are available and replaced promptly after use.

Indicator 399: All expired or recalled medicines, including unwanted medicines returned by patients and unused controlled medicines, are safely disposed of in accordance with a written procedure.

Indicator 400: A formal, written procedure is followed to action hazard warnings and medicine recalls.

Indicator 401: A formal, written procedure is followed for retention of order forms, copy of delivery notes, stores receipt, and issue vouchers, and book of records (controlled drugs book/prescription drugs book) on the premises as provided for in the relevant laws.

11.4 Prescribing, Administration and Dispensing of Medicines

Standard 42: Prescribing, dispensing and administration of medications are safe, efficient and effective and promote best possible treatment outcome.

Indicator 402: A system is in place to ensure that:

- Prescriptions are only issued by authorized prescribers
- Administration of medicine is done by, or under the supervision of, competent health personnel

Indicator 402: All prescriptions are legible and duly signed by a doctor, including the following:

- Name and additional identifier
- Age, Sex and weight (where applicable)
- Diagnosis
- Name of Medication, dose, route, frequency and duration
- Clear identification of prescriber

Indicator 403: Staff follows a written policy for the verbal ordering of medicines in emergencies which has been agreed by medical, nursing and pharmacy staff.

Indicator 404: Medicines are dispensed by, or under the supervision of, a pharmacist in accordance with a written prescription from a qualified registered medical practitioner.

Indicator 405: The patient is provided with written and verbal information on the prescribed medicine including:

- The costs
- The potential benefits and adverse effects
- How to use medicine safely and properly
- Risks of ignoring instructions

Indicator 406: There is an approved hospital prescription/medication chart on which all medicines for an individual patient are prescribed and their administration recorded.

Indicator 407: A pharmacy registers records:

- Patient name and registration number
- Date
- Diagnosis
- Medicine dispensed
- Name of the pharmacist

Indicator 408: Staff follows written, dated and signed procedures on the following:

- What medicines may be administered without a prescription and under what circumstances
- Self-medication
- Use of antibiotics
- Administration of IV drugs, narcotics, psychotropic substances and cytotoxic
- Obtaining medicines after hours from hospital pharmacy
- Obtaining medicines that are not available within the hospital pharmacy
- Dealing with patients' own medicines.

Indicator 409: Medical practitioners follow policies for antibiotic prescribing which include:

- Restricting the use of broad-spectrum agents to minimise the development of resistant viruses and bacteria
- Using prophylactic antibiotics only where their efficacy has been established

Indicator 410: Current editions of reference books, including pharmacopoeia, the copy of the National Essential Drugs List (NEDL)/hospital own formulary, standard treatment guidelines and other information booklets are available.

11.5 Facilities

Standard 43: Facilities and equipment are safe and adequate for the purpose and the number of patients attending the pharmacy.

Indicator 411: All doors, windows and hatches within the pharmacy can be locked.

Indicator 412: There is a designated area for:

- The receipt and unpacking of goods in wards
- Segregation of expired and recalled drugs
- Dispensing of medicines

Indicator 413: The pharmacy has a administrative area

Indicator 414: There is a specific drug information/reference area for use by hospital staff.

Indicator 415: There is a designated waiting area for patients.

Indicator 416: A box or trolley containing those medicines which may be urgently required in the event of a cardiac arrest is available.

Indicator 417: Where a medicine trolley is used to store medicines, it is lockable and secured when not in use.

Indicator 418: Lockable medicine refrigerators with maximum and minimum thermometers are provided for medicines requiring cool storage. They are used solely for this purpose.

Indicator 419: Temperatures are regularly monitored and recorded and action is taken where a temperature varies from an acceptable range.

12 INFECTION CONROL, HYGIENE AND WASTE MANAGEMENT

12.1 INFECTION CONTROL

Standard 44: The organisation designs and implements a coordinated program to reduce the risks of nosocomial infections in patients, visitors/attendants, contractors and staff.

Indicator 420: The hospital establishes an infection control program designed to prevent or reduce the incidence of nosocomial infection, based on current scientific knowledge and accepted practice guidelines and developed and monitored with multidisciplinary involvement.

Indicator 421: The infection control program includes all areas of the hospital and describes the scope, objectives, annual activities, surveillance methods, resources and processes associated with infection risks, including respiratory tract, urinary tract and surgical wound infections, are identified and included in the infection control program.

Indicator 422: Responsibility for coordinating the infection control program is assigned to an infection control committee with representatives of all relevant disciplines and departments including medical, nursing, microbiology/pathology, kitchen and laundry staff.

Indicator 423: The infection control committee has clear written Terms of Reference that include the following responsibilities:

- Coordination of infection control activities
- Development, implementation and monitoring of the infection control program
- Approval of infection control policies and procedures
- Approval of surveillance activities
- Reviewing and analysing infection control data

- Following up identified infection control issues with relevant action, including education
- Evaluating the effectiveness of actions taken

Indicator 424: The infection control committee is linked with Waste Management Control

Indicator 425: The infection control program is adequately resourced and staffed with appropriately qualified health professionals (nurses and/or doctors) with responsibilities defined in a job description for:

- Implementing the infection control program in consultation with staff and patients
- Implementing policies
- Educating staff
- Providing infection control advice
- Developing and implementing methods of surveillance, including reviewing infection control practices
- Providing reports and making recommendations to the infection control committee

Indicator 426: Infection risks, rates and trends are tracked, analyzed and reported.

Indicator 427: Surveillance of multiple resistant organisms and organisms associated with antimicrobial use is conducted as part of the infection control program.

Indicator 428: There is evidence of regular infection control audit.

Indicator 429: Cultures are obtained regularly from designated sites in the hospital with significant infection risks and action taken to minimise any identified infection.

Indicator 430: Relevant support staff are appropriately inducted and trained in basic aspects of infection control relevant to their work including:

- Basic concept of microbes
- Proper hand washing
- Segregation of waste and hazards associated with waste

Indicator 431: Staff are appropriately inducted and trained in all aspects of infection control relevant to their work, including proper hand washing.

Indicator 432: Written and dated organisation wide infection control and waste management policies and procedures are used by staff. Procedures include, but are not limited to, the following topics:

- Use of standard precautions including hand washing techniques
- Sterilisation and decontamination of equipment
- Food hygiene
- Laundry and linen management
- Identification and management of organisation-acquired infections
- Management of outbreaks of infection

- High risk and communicable diseases
- Operation of the mortuary, where applicable
- Collection, storage and disposal of infectious waste, body fluids, tissues, blood and blood products
- Disposal of sharps and needles
- Cleaning of all hospital surfaces, supplies and equipment, E.g., floor, walls, ceilings, beds and basins
- Management and cleaning of spillage
- Vaccination of staff

Indicator 433: Gloves, gowns, masks, soap and disinfectants are available and correctly used in situations where there is a risk of infection.

Indicator 434: Procedures are used for the isolation of patients specific to the reason for isolation.

Indicator 435: There are procedures in place for identifying and treating patients admitted with MRSA.

12.2 STERILE SUPPLIES

Standard 45: Equipment and supplies are sterilised to minimise risk of infection in patients and staff.

Indicator 436: The Infection Control Committee oversees the provision of sterile supplies.

Indicator 437: There is a defined department or area for sterilisation which physically separates the functions of cleaning, processing and sterile storage and distribution.

Indicator 438: In all areas where instruments are cleaned there is airflow to prevent cross-contamination and to keep material within the area.

Indicator 439: There is at least one functioning steriliser with a drying cycle

Indicator 440: The responsibilities of relevant staff members managing the provision of sterile supplies are clearly defined and specified in writing.

Indicator 441: Staff responsible for the decontamination, inspection, function testing, assembly and packaging, terminal processing, storage and distribution of supplies are adequately trained.

Indicator 442: Current written policies and procedures covering the functions of sterilisation, including the following, are available with documented evidence of routine compliance:

- Receiving, cleaning and disinfection of used items
- Preparation and processing of sterile packs
- Storage of sterile supplies and expiry dates

- Decontamination of instruments prior to sending for repair, maintenance or servicing
- Handling of instruments following an infected case
- Handling of equipment identified as “bio-hazard"
- Product labelling, batch numbering and identification
- Restricted personnel access to the clean production area
- Cleaning procedures, manual methods
- Housekeeping procedures
- Infestation control
- Personal hygiene
- Microbiological and environmental monitoring
- Criteria for testing and replacing air filters
- Recall procedures

Indicator 443: Sterilisation procedures are based on existing provincial or national/international guidelines.

Indicator 444: The sterilisation status of sterilised goods is assessed by the use of temperature sensitive tapes, using indicators as recommended by the manufacturer.

Indicator 445: Reports of quality control tests on sterilisers are reported to the infection control committee at least quarterly.

Indicator 446: The person using sterilised equipment checks that the decontamination of the equipment has been done before using that equipment.

Indicator 447: Stock levels of sterilised goods are checked by an ongoing inventory management process.

Indicator 448: Records are available for:

- Acceptance of load procedures
- Plant history records
- Sterile goods issued to wards/departments
- Sterilisers and autoclaves (history and servicing)
- Servicing and calibration

Indicator 449: All trays/packs/containers are stored in conditions that preserve the integrity of their packaging to prevent damage and/or contamination.

Indicator 450: All packs are marked with:

- Name of the article
- Contents of the pack
- Initials of the person who packed it
- Date and initials of the person who sterilized it

Indicator 451: Each tray, container or pack of instruments has a completed checklist which is used at the time of packing, at the time of use in the OT, and at the time of return of the instruments for re-sterilization.

12.3 CLEANLINESS AND SANITATION

Standard 46: All hospital facilities, equipment and supplies are kept clean and safe for patients, visitors/attendants and staff.

Indicator 452: Staff follows written policies and procedures and schedules for:

- Disinfection and cleaning of all equipment, furniture, floors, walls, storage areas and other surfaces and areas
- Cleaning of specialized areas, e.g. OT, Labour Room, Emergency Ward, Dressing Room, Laboratory and ICU

Indicator 453: Hospital premises are free from litter and other refuse.

Indicator 454: Sufficient covered, clean dustbins are provided for patients, visitors/attendants and staff and the dustbins are emptied on a regular basis.

Indicator 455: Equipment, floors and walls are free from bodily fluids, dust and grit and the masonry is intact.

Indicator 456: Cleaners are trained and provided with sufficient appropriate equipment and cleaning material and work according to cleanliness and sanitation policies and procedures.

Indicator 457: Laundry staff is trained and work according to linen and laundry policies and procedures including but not restricted to the following:

- Collection of sluiced and dirty linen from the individual departments
- Transportation with clear separation of clean and dirty laundry
- Separate storage of clean and dirty linen
- Sorting of linen into soiled, infected and foul linen and washing processes and washing processes for this linen
- Removal of blood stains/sluicing
- Disinfection/autoclaving
- Washing / hydro extraction
- Drying
- Repairs of linen if required
- Pressing
- Distribution to individual departments
- Storage in individual departments
- Record keeping for receipt and distribution of clean linen

Indicator 458: Kitchen staff and/or those handling foods are trained and work according to policies and procedures including but not limited to the following:

- Cleaning of all areas and surfaces on which food is stored and prepared, E.g., all preparation surfaces are cleaned and dried between uses for different activities
- Food storage, e.g. all food is stored separately from non-foods, cooked food is stored separately from uncooked/raw food and the covering and labelling of food
- Use and cleaning of equipment for food preparation, handling and transport, e.g. separate cutting boards are used for raw and cooked foods
- Testing and monitoring of safe temperatures for cooked food
- Testing and monitoring of refrigerator temperatures for safe food storage

Indicator 459: Access to the kitchen is restricted.

Indicator 460: All staff handling food has health checks prior to appointment and at regular intervals during their employment and records are kept.

Indicator 461: A written Dress Code for those working in the kitchen is enforced including wearing of head cover for hair, clean uniforms and appropriate footwear.

Indicator 462: The kitchen and food stores have proper ventilation.

Indicator 463: All windows in food preparation and storage areas have suitable fly screens and insectocutors (ultra-violet electric flying insect removers) are present in designated problem areas.

Indicator 464: Kitchen walls are made of material

Indicator 465: Kitchen waste is put in covered secure containers and removed immediately from places where food is prepared pending disposal.

Indicator 466: Kitchens are arranged to be away from waste storage, ward areas, laboratories and other areas of risk of contamination and infection.

12.4 WASTE MANAGEMENT

Standard 47: Clinical and other infectious or injurious waste is handled, stored and disposed of to minimise harm and risk of infection/injury to patients, visitors, contractors, staff and the community.

Indicator 467: The hospital has a written waste disposal plan, specifying procedures, responsibilities, timetable for waste collection and necessary equipment such as bins and bags.

Indicator 468: The waste disposal plan includes written guidelines for the regulation, identification, containment and storage, transport, treatment and subsequent disposal of different categories of infectious waste in accordance with the relevant national/provincial laws, including if appropriate:

- Pathology waste

- Cytotoxic and chemical liquid waste
- Heavy metals, radio-active or any other form of high-risk waste

Indicator 469: Infection control and waste management personnel use the

Indicator 470: Suitably qualified and experienced person(s) with designated responsibility lead the development and regular updating of plans and policies and procedures for waste management and the process is overseen by the Infection Control Committee and infection control personnel.

Indicator 471: Responsibilities for waste management are defined in all job descriptions.

Indicator 472: Staff is trained in and uses procedures for different types of waste:

- Collection
- Segregation at source
- Storage
- Transportation
- Disposal

Indicator 473: All staff who works in areas where infectious waste is handled is trained on hazards of waste, management of waste and infection control.

Indicator 474: Incineration facilities, where provided, are certified as conforming to health and safety and environmental health requirements by the Local Authority.

Indicator 475: If contractors are used for the removal and incineration of clinical waste, a written contractual agreement and consignment procedure is used which includes identification of the origin, contents and quantity of the waste.

Indicator 476: All waste is protected from theft, vandalism or scavenging by persons or animals.

Indicator 477: A clear guide for waste segregation and storage is visibly posted in area(s) where this waste is generated and includes waste segregation in clearly labelled coded bins in accordance with the relevant national/provincial laws.

Indicator 478: Prior to collection and disposal, waste is kept in a suitable location which does not cause a hazard.

Indicator 479: Records on the quantity of waste generation in each category of waste are maintained, analyzed and the resulting information is used for statistical and quality improvement activities by the Hospital.

13 SAFE AND APPROPRIATE ENVIRONMENTS

13.1 HEALTH AND SAFETY

Standard 48: Promotion of health and safety and the avoidance of risk to human life as well as to the property of the Hospital are integrated within the organisation and among all levels of staff.

Indicator 480: The responsibility for health and safety of hospital management and other relevant staff is included in their job descriptions and performance reviews.

Indicator 481: A Health and Safety Committee meets on a regular basis, includes representatives of management and staff from different departments and enables two-way communication between management and employees on issues of interest and concern related to health and safety.

Indicator 482: Health and Safety Committee meetings follow a set agenda that includes follow-up from the last meeting, minutes of each meeting are kept and the agendas and minutes are readily available to all staff.

Indicator 483: The Health and Safety Committee participates in the development of the Risk Management Plan.

Indicator 484: All new employees are trained in Health and Safety procedures relevant to their duties within one month of taking up their post.

Indicator 485: All staff attends continuing training for health and safety and records are kept of the trainings

Indicator 486: Each department uses a systematic process to:

- Regularly identify and record actual and potential hazards in a hazard register (at least annually)
- Assess identified hazards to determine which are significant
- Eliminate, isolate or minimise the impact of the significant hazards

Indicator 487: Staff reviews significant hazards that have been isolated or minimised in accordance with a set timetable appropriate for the identified hazards.

Indicator 488: All emergency telephone numbers concerned with Health and Safety are displayed prominently.

Indicator 489: Health and Safety policies and procedures are followed by staff and include:

- Contamination incidents
- Sharps and needle-stick injuries
- Drug dependence
- HIV/AIDS
- Hepatitis B and C
- Lifting and manual handling of patients and equipment
- Basic life support

Indicator 490: Organisation wide health and safety policies and procedures contain comprehensive information, instruction and safety protocols for:

- Control of waterborne diseases
- Storing and handling of inflammable liquid
- Personal protective equipment and clothing
- Review of pressure vessels and systems
- Body fluid spillage
- First aid procedures at work
- Violence and aggression towards staff
- Outbreak and prevention of fire
- Other internal accidental events such as explosion
- Safe use of electrical equipment
- Safe disposal of clinical waste
- Safe handling of gas cylinders
- Safety precautions necessary when storing, handling and using liquefied gases, E.g., nitrogen and oxygen
- Control and prevention of spillage of hazardous substances, like mercury and glutaraldehyde
- Cytotoxic drugs
- introduction of new technology

Indicator 491: Current health and safety notices, including hazard notices, and key extracts from the Health and Safety manual are prominently displayed in relevant areas and brought to the attention of staff.

Indicator 492: There is a procedure for ensuring that all contractors are provided with relevant information regarding health and safety issues within the hospital.

Indicator 493: A written policy and procedure on pest control including measures to prevent, detect and remove pests is available and implemented.

Indicator 494: Security measures are taken in accordance with written policies and procedures to protect:

- Staff working alone or in isolation
- Patients, visitors and staff from assault and loss of property during the day and at night
- Drugs from being taken illegally
- Hospital's facilities and assets from damage and loss

Indicator 495: A procedure ensures that all hospital keys are available at all times to the relevant staff on duty.

Indicator 496: An internal communication system connecting all units of the hospital enables a continuous flow of communication and immediate reporting of any incident.

13.2 FIRE SAFETY AND EMERGENCY PREPAREDNESS

Standard 49: The organisation minimises the risks of fire and protects patients, visitors and staff in case of fire and is prepared for disasters and emergencies.

Indicator 497: A fire safety plan exists including prevention/risk reduction, early detection, suppression, abatement, and safe exit from fire.

Indicator 498: The hospital building, e.g. doors, exits and corridors, is constructed in a way to minimise the risk of fire and conform to fire safety rules, including:

- Doorways, corridors, ramps and stairways being wide enough for the evacuation of non-ambulatory patients
- Fire and smoke doors being able to be opened and closed manually or by an electric release system
- Doors to patient rooms and exit doors not being locked from the inside

Indicator 499: Access and exit ways are kept free of obstruction at all times to allow for safe evacuation in a fire or other emergency.

Indicator 500: An annual inspection of fire safety in the Hospital results in identification of fire risks and strategies to minimise the risks and prevent fire.

Indicator 501: A person responsible for Hospital Safety carries out and records regular tests of alarm systems, fire extinguishers and other facilities and equipment for fire prevention and control.

Indicator 502: Action is taken to address any recommendations made during inspections and testing.

Indicator 503: All hospitals have an alarm system

Indicator 504: Pictograms indicating fire exits and escape routes are properly illuminated, clearly visible, unobstructed and are displayed at appropriate locations.

Indicator 505: Potentially explosive, flammable or highly combustible materials are clearly identified, securely stored and storage areas are clearly signed.

Indicator 506: Areas where smoking is dangerous, restricted and allowed are clearly signed and monitored.

Indicator 507: Hydrants are provided in the hospital.

Indicator 508: Staff is trained at least annually in fire safety and other emergency procedures.

Indicator 509: Fire procedures and evacuations are tested and disaster and emergency drills are practiced regularly.

Indicator 510: The Hospital develops a disaster plan with all departments/services.

.and is reviewed and revised at least every two years.

Indicator 511: The plan outlines individual responsibilities, linkages with external institutions, resources required in the case of a disaster and individuals within the hospital who must be informed in the case of a disaster.

Indicator 512: Rehearsals of the disaster plan are carried out in association with the emergency services and local authorities.

13.3 SAFE AND APPROPRIATE EQUIPMENT

Standard 50: There are clear and documented responsibilities, policies and procedures for procurement, use, maintenance, repair and disposal of equipment to minimise the potential for harm.

Indicator 513: A team with clearly defined roles meets as required and includes those in charge of the hospital, nursing, maintenance and stores and other relevant departmental representatives.

Indicator 514: Basic responsibilities of the team include:

- Assessment of need for new equipment
- Consultation with the requesting department on their requirements and specifications for the equipment
- Procurement of equipment
- Assessment of utilisation of equipment
- Condemnation of equipment as appropriate
- Conducting regular equipment audits

Indicator 515: The procurement policy for equipment and supplies includes the criteria that equipment and supplies purchased are consistent in type and brand with others in the Hospital to facilitate maintenance and repair.

Indicator 516: Placement of supply orders of equipment is done in accordance with the hospital rules or GFR (Government Financial Rules) in case of public hospitals and a copy of supply orders for equipment is kept in the Hospital records.

Indicator 517: A written procedure is used for receiving ordered equipment and includes at least the following activities:

- At time of delivery the equipment is inspected as per specifications given in the supply order by the equipment committee/user department.
- On satisfactory receipt, installation and commissioning of the equipment a certificate to that effect is given by the equipment committee/user department.
- Payment of the supplier is only made on production of such a certificate
- Originals or a copy of the service contract and operational manual are kept in the

maintenance department or other designated department

Indicator 518: Equipment is certified as conforming to health and safety requirements and regulations.

Indicator 519: For costly equipment annual maintenance contracts are made including:

- Regular service and maintenance for at least five years after the warranty period
- Warranty with cost-free provision of spares
- Continuous supply of consumables
- Training of staff to handle the equipment
- Reliable and prompt after-sale service
- Penalty clause if any delay occurs due to the negligence of the supplier

Indicator 520: The suppliers contact details and emergency telephone number is available.

Indicator 521: Staff is allowed to operate equipment or machinery are appropriately trained

Indicator 522: Records of equipment are kept including procurement, equipment defects and failures, maintenance, repair and disposal.

Indicator 523: A maintenance workshop with qualified and experienced persons having basic knowledge of physics and electronics has defined responsibilities for maintenance and repair of smaller equipment.

Indicator 524: The equipment maintenance staff is trained by the suppliers in the following issues:

- Use and practice of equipment including proper handling of the equipment
- Preventive maintenance and trouble shooting
- Following the instruction manual in day-to-day use of the equipment
- Common and recurrent causes of break-down
- Common spare parts responsible for frequent break-downs
- Inspection and routine maintenance
- Calibration
- Testing and safety guidelines
- Technology up-gradation
- Documentation of procedures for maintenance (SOPs)

Indicator 525: A list of all electrical equipment that requires routine testing is used and a record of maintenance and testing of this equipment is kept for three years, e.g. generator, emergency lighting.

Indicator 526: Regular and routine checks of equipment (equipment audit) are carried out in accordance with the operational manual, maintenance contract and/or a history sheet of the equipment by the Store in-charge.

Indicator 527: Safeguards for electronic equipment are used such as:

- Voltage stabilizer
- Automatic switch over for emergency (generator)

Indicator 528: A logbook for all critical equipment is kept and a record of incidence of defects and failures in equipment is maintained

Indicator 529: There is a form known to all staff and used to request equipment repairs and defects

Indicator 530: An adequate and sufficiently large room and supplies are available for maintenance and minor repairs. Supplies include but are not limited to:

- A bank of spare parts
- Toolkit

Indicator 531: A list of maintenance/backlog items is kept and reviewed regularly.

Indicator 532: Written procedures exist for

- Requests for repair from outside agencies if equipment cannot be repaired in-house
- Condemnation and disposal of obsolete equipment

Indicator 533: A list of approved external repair workshops is kept and regularly updated

Indicator 534: All requests for repair, work carried out and response time to reported defects is monitored and documented.

Indicator 535: The procedure for condemnation and disposal of obsolete equipment includes criteria for defining 'condemned' and 'obsolete' equipment, such as:

- Non-functional and beyond economical repair
- Non-functional and obsolete
- Functional but obsolete
- Functional but hazardous
- Functional but no-longer required

Indicator 536: An annual budget is provided for the maintenance and scheduled replacement of equipment.

13.4 SAFE AND APPROPRIATE FACILITIES

Standard 51: The Hospital's physical environment contributes to the safety and well-being of patients, staff and visitors.

Indicator 537: The hospital complies with relevant laws and regulations related to design and layout of the facility and inspection requirements are fulfilled.

Indicator 538: Corridors, storage areas, passageways and stairways are well lit.

Indicator 539: Access ways and exits are unobstructed at all times.

Indicator 540: Signage allows safe passage through the hospital and exit from the facility in case of an emergency, disaster or fire.

Indicator 541: The environment in all patient areas is clean, well lit, ventilated with adjustable controls for lighting and heating, and decor is in good repair.

Indicator 542: Floor surfaces are non-slip and even.

Indicator 543: Facilities and equipment for the safety and comfort of patients and visitors are available and functioning and include:

- Refreshment facilities and canteen
- Quiet rooms for consultations
- A public telephone
- Baby changing/feeding facilities
- Wheel chair / stretcher
- Defined and understandable signage system
- Adequate Chairs
- Cooling device, fans
- Separate queues for male and females wherever required
- Safe drinking water facilities
- Sheltered outside areas with planting and greenery

Indicator 544: A functional call bell system is available for use in private and isolated wards (single occupancy rooms), within easy reach of the patient.

Indicator 545: Each nursing area has a clean storage and preparation space and is separate from soiled materials, domestic equipment and sluice areas.

Indicator 546: Separate male and female toilets and bathrooms are available and adequate for the number of patients in the ward or department (at least one toilet for every twelve patients). The toilets and bathrooms:

- Are kept clean
- Are lockable by the patient from the inside but un-lockable from the outside
- Have doors that open outwards
- Ensure privacy at all times
- Have a non-slip base
- Have grab rails positioned on either side of the toilet
- Have an alarm-call within easy reach of the bath and toilet

Indicator 547: Shower facilities are available, with warm water for winter months.

Indicator 548: Separate male and female functioning, clean toilets are available for use by visitors/attendants.

Indicator 549: Bed tables are available.

Indicator 550: Potable water and electrical power are available 24 hours a day, seven days a week.

Indicator 551: Alternate sources of water and power for heat and lighting in case of breakdown of the systems are identified, functioning and regularly tested. Priority areas such as ICU and Operating Theatres are identified.

Indicator 552: Electrical, water, ventilation, medical gas, and other key systems are regularly inspected, maintained and improved, if necessary.

SCHEDULE-VI

(See regulation 1, Ch.1, Part IX)

IHRA STANDARDS FOR PRIMARY HEALTH CARE FACILITY

1. REQUIREMENTS FOR SERVICE MANAGEMENT:

1.1 Primary Care Management Committee

A Primary Care Management Committee plans and manages its resources, supports the Service's processes and communicates decisions and information to relevant persons and organizations.

a. The Primary Care Management Committee includes representatives from local government, staff and users.

b. Clients/Users who are members of the committee are provided with information to enable them to contribute to the decisions of the health committee.

c. All members of the committee are oriented and trained in healthcare system, processes for running meetings and in basic management skills.

d. The committee meets regularly according to a set agenda that includes follow-up from the last meeting.

e. Minutes of meetings are kept for five years and are available at the facility.

f. An annual planning process results in an annual plan which is implemented and reviewed on a regular basis.

g. The annual plan includes goals, planned actions, staffing and financial and physical resources to implement the planned actions.

h. Monthly HMIS Reports are submitted to EDO Health and include progress against the annual plan, identify problems and make recommendations.

1.2 Client/Patient information

Client/Patient information is registered, coded, analysed and used as a mechanism for monitoring and planning

a. Client/Patient registers are used, up to date, complete and accurate.

b. Written information in the registers includes dates, client/patient characteristics (name, sex, age and address), diagnosis and treatment (dosage, times/day, no of days) and follow-up in line with operating procedures.

   i. Registers used to document client/patient information include but are not limited to:

   ii. Health card (mother and child) which is maintained and used as a mechanism for informing the client/patient about their care;

   iii. Immunization card which is maintained and used as a mechanism for informing the client/patient about their care;

   iv. Register of expectant mothers and deliveries which are maintained and analysed.

   v. OPD register.

c. A consistent disease coding system is used and analysed

d. Analysis of the information is used by staff and results are fed back to the community.

1.3 Notifiable disease

Notifiable diseases are reported promptly and appropriate action is taken to minimize the spread of the disease.

a. A list of Notifiable diseases is available.

b. Notifiable diseases are reported within a specified time period, but no longer than 24 hours.

c. Procedures for managing Notifiable diseases are based on infection control principles, are used and roles and responsibilities are clearly defined.

d. The 'Zero report' is completed and submitted weekly (for polio)

1.4 Provision of utility facilities and monitoring of equipment

The equipment and utilities are functional, meet the defined needs of planned services, and are properly maintained and used.

a. Equipment is registered, maintained, repaired and disposed of according to an equipment maintenance and replacement schedule.

b. The facility has functioning electricity and natural gas.

c. A backup generator in working condition and the budget for its maintenance and for its fuel are available.

d. A stretcher and at least two examination couches,

   i. are available

   ii. are clean with no visible dust, stains or blood, and

   iii. are covered with a clean, uniform Macintosh or a plastic sheet.

e. Each health worker providing curative services has the following functioning equipment:

   iv. Thermometer

   v. Stethoscope

   vi. BP machine

   vii. Screen for privacy

   v. Gloves, masks, apron

   vi. Torch.

f. The following additional functioning equipment is available in the facility and ready to use:

   i. Baby weighing scale, fetoscope, neonatal weighing scale, speculum

   ii. Refrigerator, stools, lantern or alternate lighting source such as solar lamps or torch, equipment for boiling/ sterilizer, timing device, stainless steel bowls, kidney bowls, dressing drum, gloves, masks, aprons

   iii. Adult weighing scale, nebuliser, suction machine, oxygen cylinder(?), x-ray viewer, suture set, needle safety box, resuscitation kit

   iv. ORS corner [including the following ORT equipment: water jug: 2 cups and 2 spoons]

   v. ENT diagnostic set

   vi. D&C set

g. Additional equipment, based on the defined needs of the planned services, is available and functioning.

1.5 WATER SUPPLY

There is a reliable, clean and safe supply of water from a protected water source.

a. Running water (pipe) is available within the facility

   OR there is a water tank within the facility

   OR there is a protected water source within 200 metres of the facility: borehole, water tank or protected spring (with tubing of water for outflow, concrete slab, drainage and the spring is at least 33 meters away from latrines/toilets) and temporary storage containers, e.g. jerry cans or drum.

b. A supply line and storage system that keeps water clean and free from contamination.

1.6 WAITING AREA

The waiting area is clean and protected.

a. The waiting area protects clients/patients from the sun, rain and extremes of temperature.

b. There are designated separate male and female waiting areas and toilets/latrines.

c. The waiting area has chairs or other seating arrangements.

d. The floor is swept or mopped and the area is clean of debris/ trash.

e. The walls and ceiling are intact with no broken masonry and are free from dirt and stains.

1.7 LATRINE FACILITY

The facility has clean latrines or toilets.

a. Latrines or toilets exist within the facility or facility compound.

b. Staff and clients/patients have access to separate latrines or toilets which are clearly signed and are lockable from the inside.

c. The client/patient latrine or toilet is not locked from the outside.

d. The toilet bowl is clean and empty and/or the latrine slab is clean.

e. Soap and water are available at the washing point near the toilet(s)/ latrine(s)

1.8 WORK AREA

The facility compound is clean and uses a rubbish pit for disposal of refuse and medical waste.

a. The compound is free from litter such as plastic bags, refuse and medical waste.

b. There is a rubbish pit within the compound (possibly a garbage bin in urban settings)

c. The pit (bin) is not overflowing and is properly used, i.e. rubbish is not disposed of anywhere else

d. Medical waste is disposed of in a functional covered pit, e.g. not accessible for children and animals, within the compound.

1.9 OPERABILITY OF THE PROCEDURES AND GUIDELINES

The staffs work to written Operating Procedures for managing Primary Care services, written guidelines for management of clients/patients and written guidelines for common illnesses.

a. Standard Operating Procedures are used for managing the facility, finances, equipment, cleaning procedures, and stocks, e.g. equipment maintenance

b. National and Provincial Treatment Guidelines for the priority illnesses are available at the facility, form the basis of regular training for relevant staff and are followed in providing care to the patients/clients.

c. Where National and Provincial Treatment Guidelines are not available, they are developed and used by the Primary Care service.

d. Written guidelines for the management of clients/patients exist and are used, e.g. confidentiality, privacy, registration, recording and coding.

1.10 AVAILABILITY OF STAFF

Primary Care staff is available for service delivery during all official times.

a. An updated roster is kept of who is on duty at what time.

b. A qualified healthcare provider is available whenever the facility is open.

1.11 STAFF

Staff are appointed, trained and evaluated in accordance with documented procedures, job descriptions and service needs.

a. Staff appointments are made in line with the required qualifications and experience for the job and the job description.

b. All staff are oriented to the Primary Care services and their specific positions through a documented induction programme.

c. The induction programme includes:

    i. The Service's mission, values, goals and relevant planned actions for the year

ii. Services provided
iii. Roles and responsibilities
iv. Relevant policies and procedures, including confidentiality
v. Use of equipment
vi. Safety
vii. Emergency preparedness
viii. Quality improvement.

d. All staff has a copy of their job description that is kept current. The job description includes the responsibilities, accountabilities, tasks, performance measures and reporting relationships.

e. All staff has a copy of their conditions of employment.

f. Well-maintained and secure staff housing with all utilities is provided as per staff terms and conditions.

g. Staff performance is evaluated annually with the staff member against their job description and agreed targets and is used to identify strengths, areas for improvement and training needs.

h. Accurate and complete personnel records are kept at the facility.

i. Staff receives on-going in-service training relevant to their job and the healthcare service and in areas such as health and safety, quality improvement and client/patient rights.

j. Documents guide the work of staff and cover staff appointments, performance evaluations, disciplinary procedures and terms and conditions of employment.

1.12 HEALTH AND SAFETY

The health and safety of clients/patients, staff and visitors are protected.

a. The Service is designed to allow service delivery to be safe, accessible and respect clients'/patients' needs for privacy.

b. The Service is inspected annually by the Works and Services Department and declared safe.

c. A current Safety Certificate has been issued and is displayed in the facility.

d. Chemicals, drugs and equipment are stored safely.

e. Risks and hazards are identified and eliminated, isolated or minimized as

appropriate.

f. Guidelines exist for major risks and hazards and are known to the staff.

g. Incidents, accidents and near misses are reported and analysed to identify causes and the analysis is used to improve systems and processes, e.g. needle stick injuries.

h. Staff is provided with and use protective equipment, e.g. gloves, aprons, masks.

i. Staff is trained in fire safety and other emergencies and drills are practised regularly.

j. Staff health is protected by the provision of immunization for infections such as Hepatitis A and B and influenza.

1.13 CLIENT/PATIENT FEEDBACK

Client/Patient feedback is collected and used to improve services.

a. Clients/Patients have access to a culturally appropriate feedback mechanism, e.g. suggestion box, questionnaires, regular interviews with clients by an independent person.

b. Data collected on client/patient satisfaction with services and treatment is analyzed and used to improve services.

1.14 Complaint Handling

Clients/Patients have the right to complain about services and treatment and their complaints are investigated in a fair and timely manner.

a. Clients/Patients are informed of their right to express their concerns or complain either verbally or in writing.

b. A documented process which is fair and timely is used for collecting, reporting and investigating complaints.

c. Clients/Patients are informed of the progress of the investigation at regular intervals and are informed of the outcome.

1.15 CONTINUAL IMPROVEMENT

The Service identifies opportunities to continuously improve its processes and services, makes improvements and evaluates their effectiveness.

a. Performance indicators for priority diseases and key processes are measured,

reported and used for continuous improvement.

b. Performance data from activities such as audits, complaints, incident reports, satisfaction surveys and risk assessments are collected, analysed and used to identify improvement opportunities. This is coordinated by the quality group.

c. Improvements are planned, appropriate action is taken, the effectiveness of the action is evaluated and the results are fed back to staff and clients/patients.

d. All relevant legal requirements are identified and compliance is monitored.

2. REQUIREMENTS FOR SERVICE PROVISION

2.1 ACCESSIBILITY TO HEALTH SERVICES

The facility and the services provided are easily accessible to the catchment area population

a. The facility is located within 5 km of the patient.

b. Costs involved in using the services are addressed in the annual plan and steps are taken to minimize costs, such as fees, drugs, lost income, and transportation costs.

c. Major obstacles affecting access for clients/patients to the facility and its services are addressed in the annual plan and steps are taken to minimize them, e.g.

   i. The attitude of employees working at the facility;

   ii. The perception of the need and utility of health care by the community;

   iii. Cultural constraints on clients about using the facility and its services.

1.2 ACCESSIBILITY TO THE INFORMATIN

A list of available services and applicable fees is posted where the clients/patients can see them.

a. A poster with listed services, opening times and emergency contacts during closing times is displayed in a prominent place where the clients/patients can see it. The text is in an understandable format, e.g. local or national language.

b. A list with all fees and possible exemptions is displayed in a prominent area where the clients/patients can see it. The text is in an understandable format, e.g. local or national language.

2.3 BEHAVIOUR WITH CLIENT/PATIENT AND THEIR ATTENDANT

Clients/Patients and their attendants are received in a friendly and respectful manner irrespective of their sex, age, race, religion or physical appearance

a. Clients/Patients are treated in a kind, patient and respectful manner at all stages from registration through to end of service.

b. The healthcare provider uses open ended questions (why, who, what, when, how) to obtain information from clients/patients.

c. The healthcare provider listens carefully to what the clients/patients say and does not jump to conclusions.

d. The healthcare provider explains to the client/patient the diagnosis, care management, and follow-up.

e. The healthcare provider takes feedback from the client/patient to ensure the client/ patient understands the message communicated.

2.4 PRIORITY ON SERVICE PROVISION

Providers give priority to extremely sick clients/patients and those of extreme age (early new-born's and elderly).

a. A system using the time of arrival recorded on the registration chit is used to prioritize clients/patients.

b. The order prioritizes extremely sick clients/patients first, those of extreme ages (elderly and babies) second and then others.

c. Extremely sick clients/patients are seen by the healthcare provider within five minutes, and those of extreme ages within 15 minutes.

2.5 EMERGENCY CASES

Providers use a defined process for referring emergency cases.

a. SOPs exist for identification of types of clients/patients who need to be referred.

b. A referral form provides sufficient information to allow continuity of care.

c. When possible transportation to the referral facility is provided.

d. In other cases, the Service provides some type of assistance for moving a sick client/patient to a referral facility such as communication to the next level, or arranging community transport.

e. A copy of the referral form is kept at the facility.

2.6 DEALING WITH NON-PRIORITY PATIENT

Non-priority clients/patients wait no more than one hour after arrival at the facility before being seen by the provider.

a. A system is used to prioritize the order in which non-priority clients/patients are seen on a first-come first-serve basis.

b. Waiting times are no more than one hour and are monitored.

c. Waiting times are analyzed and results used to improve services.

2.7 PRIVACY

The privacy of patients/clients is ensured during consultation and examination.

a. Consultations and examinations are held behind curtains/screens at all times.

b. Healthcare providers ensure privacy at the time of consultation.

2.8 ALL CLIENTS/ PATIENTS RECEIVE APPROPRIATE ASSESSMENT, DIAGNOSIS, PLAN OF CARE, TREATMENT AND CARE MANAGEMENT, AND FOLLOW-UP

a. The registration chit is completed promptly for all clients/patients.

b. The time the client/patient arrives is documented on the registration chit and monitored

c. Basic assessment is undertaken and includes temperature, blood pressure, and symptom identification.

d. Basic assessment for children under five includes weight, immunization status, temperature, level of consciousness and symptom identification.

e. A client/patient history is taken and documented.

f. Treatment and care management is provided in accordance with the assessment, test results, diagnosis and care management guidelines.

g. Referrals to other services are made when required.

h. Appointments for future care are made.

i. Results of previous care are used in follow-up visits.

2.9 NATIONAL AND PROVINCIAL TREATMENT GUIDELINES ARE

AVAILABLE AND USED FOR THOSE SERVICES LISTED AS OFFERED

a. Healthcare providers provide technically correct services according to guidelines for but not limited to the following areas:

   i. First Aid and Emergency care, Injury management, minor surgical procedures

   ii. IMCI, ANC, Delivery, PNC, Family planning

   iii. Malaria, TB & DOTS, HIV/ AIDS VCT, STD, Diarrhoea, Polio, Hepatitis, HIV/AIDS, Measles, ARI, Hypertension, Diabetes, Anaemia, Common skin problems, EPI

   iv. Dental care.

b. Staff is trained to follow these guidelines.

c. Justification is available for variations from the guidelines.

2.10 ALL CHILDREN WHO VISIT THE FACILITY HAVE THEIR WEIGHT PLOTTED CORRECTLY ON THEIR HEALTH CARD AND HAVE THEIR IMMUNIZATION

a. All under five children coming to the facility are weighed.

b. Weight is accurately plotted on the child's health card and follow-up action taken based on the plot.

c. Immunization status is checked and missing immunizations given

d. Weight and vaccination information are given to the parent/carer.

2.11 HEALTHCARE PROVIDERS REGULARLY EDUCATE THEIR CLIENTS ON HEALTH ISSUES IN A WAY THAT IS EASY TO UNDERSTAND

a. Healthcare providers conduct group health education sessions at least four times a month.

b. Healthcare providers use the following materials during client/patient counselling/education sessions: posters, family planning material, brochures, leaflets, flipcharts and cue cards.

c. Health education messages (posters and charts with pictures and minimal text) are visibly posted in prominent areas within the facility.

d. Health education written material is available for clients/patients to read and take home.

2.12 CLIENTS/PATIENTS ARE GIVEN ACCURATE INFORMATIN ABOUT

THEIR MEDICATION REGIME TO ENABLE THEM TO MANAGE IT

a. The healthcare provider/dispenser instructs clients/patients about the medication, the amount of medication to take, what time to the day it should be taken and for how long it should be taken.

b. The healthcare provider/dispenser checks that the client/patient understands the instructions.

2.13 STAFF FOLLOWS CORRECT ASEPTIC TECHNIQUES AND WASHES THEIR HANDS BETWEEN CLIENTS/PATIENTS

a. Health workers perform the following aseptic procedures in line with SOPs or guidelines: wound dressing, suturing, catheterization, injections, intravenous infusion and dental extraction.

b. Soap (where possible liquid soap) and water or antiseptic gel are available at the washing point(s) in or near the consulting/examination room(s) and a clean hand towel or alternate is available.

c. Hand washing instructions are posted above the washing point(s).

d. Healthcare providers wash their hands between clients/patients and between procedures.

2.14 RATIONAL PRESCRIBING IS PRACTISED TO MINIMIZE THE RISK OF DRUG RESISTANCE, ENSURE APPROPRIATE TREATMENT AND ENABLED COST-EFFECTIVE CARE.

a. An essential drug list is available and followed.

b. Good prescribing practice guidelines for antibiotics are available and followed.

c. The probable diagnosis is written on the prescription.

d. If the diagnosis changes as a result of follow-up assessment or test results the prescription is reviewed.

2.15 ESSENTIAL DRUGS AND SUPPLIES AVAILABLE AT ALL TIMES DURING OPEN HOURS

a. Stock cards are up to date and correspond to physical stock.

b. There is a stock of the essential drugs.

c. There is a process for checking date of expiry.

d. No expired drugs are in stock.

2.16 COLD CHAIN VACCINE

The cold-chain for vaccines is maintained

a. A Cold Chain procedure for vaccines is used and includes clear directions on the following practices.

   i. Vaccine stock management including vaccine storage, potency, stock quantities, stock records, and arrival report

   ii. Equipment for vaccine transport and storage

   iii. Maintenance of equipment

   iv. Control and monitoring of temperature

   v. Cold chain during immunization sessions

   vi. Syringes, needles and sterilization and

   vii. Breakdown of equipment and emergency actions to minimize risks.

2.17 SINGLE USE ITEM

Items for single use are not reused.

a. Disposal systems and processes for single-use items are available and used.

2.18 SHARPS AND NEEDLES ARE USED AND DISPOSED OF SAFELY

b. Labelled needle safety boxes are available in the examination, injection and dressing rooms.

c. Staff safely disposes of sharp objects and needles in the containers provided.

SCHEDULE-VII

(See regulation 1, Ch.1, Part IX)

IHRA Standards for Clinical Laboratories

1 RESPONSIBILITIES OF MANAGEMENT

Standard 1: The laboratory is easily identifiable.

Indicator 1: The laboratory is identifiable with name on a sign board.

Indicator 2: The laboratory sign board conforms to the prescribed local legal standards.

Indicator 3: The laboratory is registered with Islamabad Healthcare Regulatory Authority.

Indicator 4: The laboratory is licensed with Islamabad Healthcare Regulatory Authority.

Indicator 5: Associated collection centers are reflected in the Registration Certificate/ License issued by the Islamabad Healthcare Regulatory Authority.

Indicator 6: Signed valid MOU, showing linkage with any other Laboratory or organization for referral of specialized tests, exists.

Standard 2: A technically qualified and experienced individual heads the laboratory.

Indicator 7: The individual heading the laboratory is a qualified pathologist having valid professional registration and requisite experience.

Standard 3: Responsibilities of Management are defined.

Indicator 8: Those responsible for lab management lay down the laboratory's mission statement.

Indicator 9: Those responsible for management lay down a detailed laboratory policy and standard operating procedures (SOPs).

Indicator 10: Those responsible for management develop an emergency policy and standard operating procedures.

Indicator 11: Those responsible for management approve sufficient budget and allocate the resources required to accomplish the mission.

Indicator 12: Those responsible for management establish the laboratory's organogram.

Indicator 13: Those responsible for management, appoint the section heads in the laboratory.

Indicator 14: Those responsible for management, support research activities.

1.2 FACILITY MANAGEMENT AND SAFETY

Standard 4: The management is aware of and complies with the laws, bylaws, rules and regulation, and facility inspection requirements under the relevant building and associated codes applicable to laboratory.

Indicator 15: The management is conversant with the relevant laws and regulations and knows their applicability to the laboratory.

Indicator 16: The management regularly updates any amendments in the prevailing relevant laws and rules.

Indicator 17: The management ensures implementation of these requirements.

Standard 5: Facility work flow design conforms to scope of services.

Indicator 18: Space allocation and effective separation exists between administration and technical laboratory areas.

Indicator 19: Measures are taken to restrict movement of the technical staff working in different sections of the laboratory.

Standard 6: The laboratory has plans for fire and non-fire emergencies within the sections.

Indicator 20: Plans and provisions for early detection of fire and non-fire emergencies exit.

Indicator 21: Provisions for abatement of fire and non-fire emergencies exist.

Indicator 22: Provisions for containment of fire emergencies exist.

Indicator 23: Displayed safe exit points in case of fire and non-fire emergencies exist.

Indicator 24: Mock drills are held at least twice in a year.

Indicator 25: Staff members are trained for their role in case of such emergencies.

1.3 HUMAN RESOURCE MANAGEMENT

Standard 7: Staff deployment is in accordance with the scope of laboratory work.

Indicator 26: Job description for every post is identified and documented.

Indicator 27: Eligibility criteria, regarding qualification and experience for every job is available.

Indicator 28: Recruitments are according to laid down eligibility criteria.

Standard 8: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs.

Indicator 29: An appropriate orientation plan exists for newly inducted employees.
Indicator 30: Each staff member is made aware of laboratory wide policies and procedure as well as section/unit/services/program specific policies and procedures.
Indicator 31: Each staff member is made aware of their rights and responsibilities.

Indicator 32: All employees are oriented on dealing with patients and responsibilities.

Standard 9: An annual appraisal system for evaluating the performance of employees exists as an integral part of the human resource management process.

Indicator 33: Well documented performance appraisal tools exist in the laboratory.
Indicator 34: All the employees/consultant/ students/ voluntary workers are made aware the performance appraisal tools at the time of induction.

Indicator 35: The appraisal is used as a tool for further development

Indicator 36: Performance appraisal is carried out at pre- defined intervals and is documented.

Standard 10: Documented personal record for each staff member exists.

Indicator 37: Personal files are maintained in respect of all full time/part time employees, which include records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel.

Standard11: In- service staff capacity building record is documented.

Indicator 38: In-service training plan for staff members is available.

Indicator 39: All records of in-service training and education are contained in the personal files.

Standard 12: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of laboratory professionals,

including doctors, technologists and others.

Indicator 40: A system for the verification of documents of and certificates of employees exists in the laboratory

Indicator 41: Verification of credentials/documents is done in the laboratory for any newly added qualification/training certificate.

1.4 MANAGEMENT OF EQUIPMENT AND REAGENTS

Standard 13: Ensure quality of equipment and reagents through standardized procurement procedures.

Indicator 42: The procurement procedure of the laboratory is laid down.

Indicator 43: Specification for all the equipment and reagents/kits/consumables to be purchased is documented.

Indicator 44: Procurement orders are clear, dated and signed. Indicator 45: Procured items are regularly entered into stock registers.

Standard 14: Safe handling and storage of laboratory reagents.

Indicator 46: Documented policies and procedures guide the safe storage and use of reagents to ensure the continuing quality, integrity and confidentiality of sample materials, documents, equipment, reagents, consumables, records, results, and any other items that could affect quality of examination results.

Indicator 47: An accurate and up-to-date inventory of reagents, biological agents and toxins is maintained.

Indicator 48: The policies of reagent management include a procedure of alert for near expiry reagents.

Indicator 49: Labeling of reagents is as per SOPs.

Standard 15: Comprehensive procedure for equipment management and maintenance exist in the laboratory.

Indicator 50: Logbooks of all equipment are available.

Indicator 51: Regular periodic maintenance and calibration record of all the equipment is available in the logbooks.

Indicator 52: Document and relevant log sheet is displayed on each equipment.

Indicator 53: Emergency contact number/s is/are displayed on all equipment.

Indicator 54: Equipment inventory is maintained having following information:

a) Identity of the equipment

b) Manufacturer's name, type identification, and serial number or other unique identification

c) Contact information for the supplier or the manufacturer and on-call service

d) Date of receiving and date of entering into service

e) Location

f) Condition when received (E.g., new, used or reconditioned)

g) Manufacturer's instructions

h) Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory

i) Up to date, current instructions on use, safety and maintenance of equipment, including relevant manuals and directions for use provided by the manufacturer
Indicator 55: Equipment are registered with Drugs Regulatory Authority of Pakistan (DRAP).

1.5 RECORDING AND REPORTING SYSTEM

Standard 16: The Laboratory has a complete accurate laboratory record for every patient.

Indicator 56: Electronic record of every patient is maintained.
Indicator 57: Every laboratory record has a unique identifier.

Indicator 58: The record provides an up-to-date and chronological account of each patient's record of tests.

Indicator 59: Only authorized person to make entries in the laboratory record and results shall be reviewed by authorized person before they are released.

Indicator 60: Every laboratory record entry is dated, timed and the person making entries can be identified.

Standard 17: A comprehensive reporting system exists in the laboratory.

Indicator 61: A computerized reporting system is available.
Indicator 62: Critical results and notifiable diseases are reported.

Standard 18: The laboratory record supports continuity of patient care.

Indicator 63: Minimum reporting time for every test is documented.

Indicator 64: Reports are accessible to individual patients through a specific code.

1.6 QUALITY ASSURANCE

Standard 19: The laboratory has a comprehensive and documented quality assurance (QA) program.

Indicator 65: Laboratory has quality assurance (QA) SOPs.

Indicator 66: There is a designated focal person responsible for quality assurance (QA) activities in the laboratory.

Indicator 67: Quality assurance (QA) SOPs are communicated and coordinated among the staff.

Standard 20: External quality assurance (EQA) compliance procedure and tools are available in the laboratory.

Indicator 68: External quality assurance (EQA) of the laboratory is ensured through external assessment by national/internally recognized bodies.

Indicator 69: Records of external quality assurance (EQA) reports are maintained.

Standard 21: Internal quality assurance (IQA) is ensured through standardized laboratory practices.

Indicator 70: Policies and procedures guide the safe collection of specimens.

Indicator 71: Policies and procedures guide the identification and proper labeling of specimens.

Indicator 72: Policies and procedures guide the safe handling of specimens. Indicator 73: Policies and procedures guide the safe transportation of specimens. Indicator 74: Policies and procedures guide the safe processing of specimens. Indicator 75: Policies and procedures guide the safe disposal of specimens. Indicator 76: Availability of controls for internal quality assurance (IQA) is ensured. Indicator 77: Process cycle records are maintained.

Standard 22: Continuous laboratory improvement is documented.

Indicator 78: Gaps are identified through QA reports and used as tools for improvement.

Indicator 79: Corrective actions are implemented upon identification of gaps.
Indicator 80: Measures are taken to minimize recurrence of errors.

1.7 BIOSAFETY AND BIOSECURITY

Standard 23: The laboratory has a comprehensive and coordinated biosafety program.

Indicator 81: Availability of laboratory biosafety SOPs.

Indicator 82: Biosafety SOPs are communicated to the laboratory staff.

Indicator 83: The laboratory has a designated qualified technical for ensuring biosafety activities.

Indicator 84: Regular biosafety monitoring reports are generated in the laboratory.

Standard 24: Continuous staff biosafety measures are ensured and documented.

Indicator 85: The laboratory has appropriate consumable, equipment and facilities to ensure bio-safety.

Indicator 86: All staff involved in the handling and disposal of laboratory waste shall receive regular vaccination.

Indicator 87: Annual medical check-up of all staff is documented.

Standard 25: Patient and visitor biosafety is ensured and documented.

Indicator 88: Proper ventilated waiting areas for patients and visitors are available.

Indicator 89: Patients and visitors are not allowed inside the laboratory working area.

Standard 26: There is a documented procedure of bio-risk management.

Indicator 90: All incident reports are documented.

Indicator 91: Required disinfectants/spill kits are available in the laboratory.

Standard 27: Measures to ensure biosecurity in the laboratory are practiced.

Indicator 92: Only authorized persons are permitted to enter the sample storage area.

Indicator 93: Any transportation of samples is properly recorded.

Standard 28: The laboratory has a well-designed, comprehensive and coordinated waste management plan.

Indicator 94: Written laboratory waste management SOPs are available.

Indicator 95: Waste management SOPs are communicated to the laboratory employees.

Indicator 96: The laboratory has appropriate consumable, collection and handling systems and equipment for waste management.

Indicator 97: Contracts with waste disposal service organizations are available. Indicator 98: Waste transported from collection centers for final disposal is recorded.

1.8 ACCESS, ASSESSMENT AND CONTINUITY OF CARE

Standard 29: Laboratory services are easily accessible.

Indicator 99: The laboratory's location for collection of samples is easily accessible.
Indicator 100: Basic facilities are accessible in the laboratory.

Indicator 101: There are clean toilets/washrooms with bolts, preferably separate for males and females.

Indicator 102: Facilitated toilets for disabled patients with wheel chair access are available in the laboratory.

Indicator 103: Disabled patients are facilitated for phlebotomy.

Indicator 104: Directional arrows pointing towards various important areas for patients are displayed in the laboratory.

Standard 30: Laboratory services are provided as portrayed/claimed.

Indicator 105: Laboratory services being provided are displayed.

Standard 31: A comprehensive audit system for laboratory performance assessment exists in the laboratory.

Indicator 106: There is a system to monitor and measure the performance of the laboratory biannually against the stated mission.

Indicator 107: Procured kits and their consumption are compared with test performed during laboratory performance audit.

1.9 CARE OF PATIENTS

Standard 32: Emergency handling of patients is guided by protocols.

Indicator 108: Protocols for providing first aid/emergency care to the patients are documented.

Indicator 109: Relevant contact numbers for emergency evacuation/referral are available in the laboratory.

Standard 33: Sentinel events are intensively analysed.

Indicator 110: The laboratory has defined sentinel events.

Indicator 111: Sentinel events are intensively analyzed when they occur.

Standard 34: The laboratory policies and procedures support domiciliary services to the patients (where applicable/claimed).

Indicator 112: The laboratory is equipped with means of communication and transport services for home-based patient sample collection.

Indicator 113: The laboratory has appropriate means of collection and transportation of home-based samples.

1.10 PATIENT RIGHTS AND EDUCATION

Standard 35: A system exists for obtaining consent when it is required.

Indicator 114: The laboratory has listed those situations where specific informed consent is required.

Indicator 115: The policy describes who can give consent when a patient is incapable of independent decision-making.

Standard 36: Patient and families have a right to information on expected costs.

Indicator 116: The tariff list is available to patients.

Indicator 117: Patient/families are informed about the additional reports which are generated or included in the report with the same sample and cost.

Standard 37: Patient rights for appeal, complaints and confidentiality are protected.

Indicator 118: Patient's complaints are accepted by the laboratory and properly registered.

Indicator 119: Proper actions and remedial measures are taken in response to patients' complaints.

Indicator 120: Confidentiality of patient record is maintaine.

SCHEDULE-VIII

(See regulation 1, Ch.1, Part IX)

STANDARDS AND INDICATORS

1 RESPONSIBILITIES OF MANAGEMENT

Standard 1: The clinic is identified as an entity and easily accessible.

Indicator 1: The clinic is identifiable with the name and Registration/ license number on the sign boards.

Indicator 2: The patient/client has easy access to the clinic. Indicator 3: The dental clinic is registered/licensed with the IHRA.

Indicator 4: Door plate clearly displays name and qualifications of the dental surgeon.
Indicator 5: The staff on duty uses identity badges.

Indicator 6: Consultation hours are displayed.

Standard 2: The manager and the healthcare service providers at the clinic is/are suitably qualified.

Indicator 7: The clinic manager is duly designated and has requisite qualifications.
Indicator 8: PMC & IHRA Registration certificate of the dental surgeon is displayed

Standard 3: Clinic premises support the scope of work/services.

Indicator 9: The size/premises of the dental clinic is as per the minimum requirement.
Indicator10: The dental clinic has adequate facilities for the comfort of the patients.
Indicator 11: The dental clinic has adequate arrangements to maintain the privacy of patients during consultation/examination/procedures.

Standard 4: The responsibilities of the management are defined.

Indicator 12: The dental clinic management intimates any change in scope or portrayal of services, the location of the HCE or the service providers etc to the IHRA.

Indicator 13: The dental clinic management addresses social and community responsibilities.

2 FACILITY MANAGEMENT AND SAFETY

Standard 5: The dental staff is aware and complies with the relevant laws, rules, regulations, bylaws inspection requirements under the applicable codes.

Indicator 14: The clinic plans for equipment in accordance with its scope of services.
Indicator 15: The clinic management is conversant with the relevant laws and regulations.

Indicator 16: The management ensures implementation of relevant laws.
Indicator 17: There is mechanism to regularly update licenses, registrations and certifications.

Indicator 18: The staff has the knowledge about early detection and containment of fire and non-fire emergencies.
Indicator 19: Arrangement to combat fire and non-fire emergencies are in place.

Standard 6: The clinic has a program for management of dental and support service.

Indicator 20: The clinic plans for equipment in accordance with its scope of services.
Indicator 21: Dental equipment is selected by a collaborative process.

Indicator 22: Qualified and trained personal operate and maintain the equipment.
Indicator 23: Equipment is periodically inspected, serviced and calibrated to ensure its proper functioning.

3 HUMAN RESOURCE MANAGEMENT

Standard 7: There is documented personnel record of dental surgeons and staff.

Indicator 24: Personal record/credentials in respect of all staff are maintained.

Standard 8: The employees joining the dental clinic/practice are oriented to the environment, respective sections and their individual jobs.

Indicator 25: Each regular/part time employee, student and voluntary worker is appropriately oriented to the overall environment of the dental clinic/relevant section/units/service and program policies and procedures.
Indicator 26: Each regular/part time employee is made aware of the job description.
Indicator 27: Performance evaluations are based on the JDs.

Indicator 28: Each regular/part time employee is made aware of his/her rights and responsibilities and patient rights and responsibilities.

4 INFORMATION MANAGEMENT SYSTEMS

Standard 9: Patient clinical record is maintained at the dental clinic.

Indicator 29: Every patient's record has a unique identifier and particulars for identification.

Indicator 30: Only authorized persons make entries in the record.
Indicator 31: Every record entry is dated, time and signed.

Indicator 32: The record provides an up-to-date and chronological account of patient care.

5 QUALITY ASSURANCE/IMPROVEMENT

Standard 10: The dental clinic has a quality assurance/quality improvement system in place.

Indicator 33: Service provision is as per portrayal.

Indicator 34: A quality improvement system is in practice.

Standard 11: The clinic identifies key indicators to monitor the inputs, process and outcomes which are used as tools for continual improvement.

Indicator 35: Monitor includes appropriate patient assessment.

Indicator 36: Monitoring includes safety and quality control programs of the diagnostic services.

Indicator 37: Monitoring includes all invasive procedures.

Indicator 38: Monitoring includes adverse drug events.

Indicator 39: Monitoring includes use of anesthetics.

Indicator 40: Monitoring includes availability and consent of the clinic records.

Standard 12: Sentinel events are assessed and managed.

Indicator 41: The clinic has enlisted the sentinel events to be assessed and managed.

6 ASSESSMENT AND CONTINUITY OF CARE

Standard 13: Portrayed services conform to the legal provision.

Indicator 42: The services being provided at the clinic are displayed as per code of

Ethics.

Indicator 43: specialized services being provided conform to the standards.
Indicator 44: The use and maintenance of specialized equipment conforms to the standards.

Indicator 45: Dental laboratory services, provided, conform to the respective standards.

Indicator 46: Dental radiological diagnostic services, if being provided, conform to the respective standards.

Indicator 47: Dental health education is provided as per guidelines.
Indicator 48: Preventive services are provided as per guidelines.

7 CARE OF PATIENTS

Standard 14: The clinic has a well-established patient management system.

Indicator 49: The clinic has an established registration and guidance process.
Indicator 50: Standard/Ethical practice is evident from the patient record.
Indicator 51: The clinic has referral SOPs.

Indicator 52: The clinic has list of contact numbers of the referral facilities, medico legal authorities, concerned police station, ambulance/rescue services and social services organizations.

Standard 15: The clinic has essential arrangements for providing care to emergency cases.

Indicator 53: The clinic has essential arrangements to cater for emergency care

8 MANAGEMENT OF MEDICATION/DISPENSING

Standard 16: Prescribing practices conform to the standards.

Indicator 54: Standards for prescription writing are followed.

Indicator 55: Prescriptions are clear, legible, dated, timed, named / stamped and signed.
Indicator 56: Prescriptions are provided to the patients.

Standard 17: Storage and dispensing/usage confirms to the guidelines.

Indicator 57: Medicines/disposable/dental materials are stored as per guidelines.
Indicator 58: Expiry dates/ shelf life are checked prior to administering, as applicable.
Indicator 59: Labeling requirements are implemented.
Indicator 60: Dispensing/utilization is by an authorized person.

9 PATIENT RIGHTS/RESPONSIBILITIES AND EDUCATION

Standard 18: There is a system for awareness/education of patients and others regarding the charter of Rights and Responsibilities for compliance.

Indicator 61: The charter of Rights and Responsibilities are displayed and patient/families are guided on it.

Standard 19: PRE-2: There is a system for obtaining consent for treatment.

Indicator 62: The dental surgeon obtains consent from patient before examination.
Indicator 63: The clinic has listed those situations where specific informed consents required from a patient or family.

Standard 20: Patient and family have a right to information about expected costs.

Indicator 64: The patient/family is informed about the cost of treatment.

Standard 21: Patients and families have a right to refuse treatment and lodge a complaint.

Indicator 65: Patients and families have a right to refuse the treatment.
Indicator 66: Patients and families have a right to complain and there is a mechanism to address the grievances.

10 INFECTION CONTROL

Standard 22: The clinic has a well-designed, comprehensive and coordinated infection control system aimed at reduced/eliminating risks to patients, visitors and care providers.

Indicator 67: The infection control plan is documented which aims at preventing and reducing the risk of nosocomial infections.

Indicator 68: The clinic has designated staff and defined responsibilities for infection control and waste management activities.

Indicator 69: The clinic has appropriate consumable, collection and handling systems, equipment and facilities for control of infection.

Indicator 70: All staff involved in the creation, handling and disposable of dental/clinical waste shall receive regular training and ongoing education in the infection control and safe handling of dental waste.

Standard 23: There are documented procedures for sterilization activities in the clinic.

Indicator 71: There is adequate space available for sterilization activities.

Indicator 72: Regular validation tests for sterilization are carried out and documented.

Indicator 73: There is an established procedure for recall in case of breakdown in the sterilization system.

SCHEDULE-IX
(See regulation 1, Ch.1, Part IX)

1 STANDARDS & INDICATORS

1.1 RESPONSIBILITIES OF MANAGEMENT (ROM)

Standard-1: The HCE is identifiable as a legal entity and easily accessible to the patients and the surveyors

Indicator-01: The HCE is identifiable with a signboard conforming to the legal requirements and depicting Name and IHRA Registration / License Number on the Sign Board/s.

Indicator-02: The HCE is registered/licensed with IHRA.

Indicator-03: The HCE is easily reachable**.**

Standard-2: The Staff on duty is identifiable

Indicator-04: The Staff on duty uses the authorized Identity Badge.

Indicator-05: Door plate/s at clinics/offices clearly displays name, qualification/s, and designation/s of the staff on duty.

Standard-3: The HCE premises support the scope of work / services

Indicator-06: The HCE premises have demarcated areas according to the scope of work/services.

Indicator-07: HCE has adequate facilities/civic amenities for the comfort of the patients and attendants and these are adequately maintained.

Indicator-08: The HCE has adequate arrangements for the privacy of patients during consultation, examination, procedures etc.

Indicator-09: The HCE has arrangements to provide safe recreational activities.

Indicator-10: The HCE provides psychosocial rehabilitation services.

Standard-4: Responsibilities of management are defined.

Indicator-11: The management of the facility has laid down mission statement of the HCE.

Indicator-12: Those responsible for management establish the HCE organogram.

Indicator-13: The management ensures appointment of competent professionals according to organogram.

Indicator-14: Those responsible for management appoint a technically qualified and experienced professional to head the HCE.

Indicator-15: Those responsible for management lay down the overall Policy, Standing Orders and SOPs.

Indicator-16: The management is responsible for arranging/designating a substitute when particularly the head or any section in charge is absent due to any reason.

Indicator-17: Those responsible for management lay down standing orders and SOPs for emergency situations.

Indicator-18: Those responsible for management lay down security standing orders and SOPs.

Indicator-19: Those responsible for management monitor and measure the performance of the HCE against the assigned roles.

Indicator-20: The HCE management addresses the HCE's social and community responsibilities.

Indicator-21: Those responsible for management support research activities.

Standard-5: The management ensures functioning of the HCE according to relevant statutes.

Indicator-22: The management ensures availability of the applicable laws/by-laws/codes/rules/ regulations.

Indicator-23: The management is conversant with the relevant laws/bylaws/codes/rules/regulations and knows their applicability to the HCE.

Indicator-24: The management regularly updates any amendments in the prevailing relevant laws/Rules/ regulations/SOPs and SMPs.

Indicator-25: The management ensures implementation of the applicable laws/rules/regulations/SOPs and SMPs.

1.2 FACILITY MANAGEMENT AND SAFETY (FMS)

Standard-6: Facility design supports the scope of work.

Indicator-26: There is effective separation between different areas including administrative, clinical consultation, Indoor and counseling etc.

Indicator-27: HCE design supports the arrangements for the security of premises against unauthorized entry/exit.

Standard-7: The HCE maintains a safe and secure environment for patients/attendants and the staff.

Indicator-28: The HCE has arrangements to ensure physical safety of patients/attendants in the HCE.

Indicator-29: There are arrangements to ensure safety / security of food / eatables for resident patients/attendants/staff in the HCE.

Indicator-30: There are arrangements to ensure safety of medicines/drugs for resident patients in the HCE.

Indicator-31: There are arrangements for provision of clean clothing/linen to the resident patients.

Standard-8: The HCE has plans for fire and non-fire emergencies.

Indicator-32: There is plan and provisions for early detection of fire and non-fire emergencies.

Indicator-33: There are provisions for abatement of fire and non-fire emergencies.

Indicator-34: Provisions are made for containment of fire and non-fire emergencies.

Indicator-35: Safe exit points in case of fire and non-fire emergencies are displayed.

Indicator-36: Mock drills are conducted at least once in a year.

Indicator-37: Staff members are trained for their role in case of such emergencies.

Standard-9: The HCE has a system for management of equipment for clinical and support services.

Indicator-38: The HCE has equipment in accordance with the scope of its services.

Indicator-39: Equipment is operated and maintained by qualified/trained personnel.

1.3 HUMAN RESOURCE MANAGEMENT (HRM)

Standard-10: Staff deployment is in accordance with scope of services.

Indicator-40: Eligibility criteria regarding qualification and experience for each job are available.

Indicator-41: Recruitment is made according to the laid down criteria.

Indicator-42: Job description for every post is defined and documented.

Indicator-43: Requisite staff is available at HCE for provision/supervision of prescribed psychiatric and/or addiction treatment services.

Standard-11: Staff members joining the HCE are oriented to HCE environment, different sections and their Individual jobs.

Indicator-44: There is an appropriate orientation plan for newly Inducted staff.

Indicator-45: Each staff member is aware of his/her rights and responsibilities.

Indicator-46: All employees are educated with regard to patient's rights and responsibilities.

Indicator-47: Staff receives refresher training/certification to continue to perform the jobs effectively.

Standard-12: An appraisal system for evaluating the performance of employees exists as an integral part of the Human Resource Management.

Indicator-48: There is a well-documented performance appraisal system and tools in the HCE.

Indicator-49: All of the employees / Consultants / Students / voluntary workers are made aware of the performance appraisal tools at the time of Induction.

Indicator-50: The appraisal is used as a tool for further development.

Indicator-51: Performance appraisal is carried out at pre-defined intervals and is documented.

Standard-13: Documented personal record for each staff member exists.

Indicator-52: Personal files are maintained in respect of all full time/part time employees.

Standard-14: There is a system for collecting, verifying and evaluating the credentials. Education, registration, training & experience of professionals including doctors, and others

Indicator-53: System for verification of documents and certificates of employees exists in the HCE.

Indicator-54: Only medical professionals permitted by law/regulation provide patient care without supervision.

1.4 INFORMATION MANAGEMENT SYSTEM (IMS)

Standard-15: **The HCE has a complete and accurate medical record for every patient**.

Indicator-55: Every medical record has a unique identifier.

Indicator-56: The staff authorized to make entries in the medical record is reflected in the HCE's policy/SOPs and is identifiable.

Indicator-57: Every medical record entry is dated, timed and signed.

Indicator-58: Complete medical record of the patients is maintained at HCE.

Indicator-59: The progress notes are recorded by the professionals responsible for the care of the patient.

Indicator-60: Every dormant record has a discharge summary.

Indicator-61: The SOPs for safety and security of patient record exist and are practiced.

Indicator-62: Authorized care providers have access to current and past medical records.

Standard-16: The HCE regularly carries out review of medical records.

Indicator-63: The medical records are reviewed regularly / periodically.

Indicator-64: The review focuses the timeliness, legibility and completeness of both active/current and discharged patient (closed/dormant) records.

Indicator-65: Any deficiency, found in the review and corrective measure taken, is documented.

1.5 CONTINUOUS QUALITY IMPROVEMENT (CQI)

Standard-17: The HCE has a structured Quality Improvement system in place.

Indicator-66: A comprehensive plan covering ALL the major elements related to quality improvement is developed, implemented and maintained by a notified CQI Committee.

Indicator-67: There is a designated Individual for coordinating and implementing the quality improvement program.

Indicator-68: The CQI program is communicated and coordinated amongst all the employees of the HCE, through proper training mechanism.

Indicator-69: The quality improvement program is a continuous process and updated

at least once in a year.

Standard-18: The monitoring system for CQI exists at the HCE.

Indicator-70: Monitoring includes appropriate patient assessment.

Indicator-71: Monitoring includes adverse drug events.

Indicator-72: Monitoring includes availability and content of medical records.

Indicator-73: Monitoring includes recommendations from appropriate services concerning follow-up or aftercare.

Standard-19: Sentinel events are assessed and managed.

Indicator-74: The HCE has defined sentinel events.

Indicator-75: Sentinel events are intensively analyzed when they occur.

1.6 ACCESS, ASSESSMENT AND CONTINUITY OF CARE (AAC)

Standard-20: Services are provided as portrayed / claimed.

Indicator-76: Only the services registered with IHRA are provided and the same are displayed at the HCE.

Indicator-77: Health education is provided as per guidelines.

Indicator-78: The preventive services are provided as per guidelines.

Standard-21: HCE has a well-established patient management system.

Indicator-79: The HCE employs a comprehensive patient management process.

Indicator-80: An initial assessment is made in order to diagnose and prioritize interventions in a coordinated treatment plan.

Indicator-81: The assessment of patients employs standard tools for classification of mental disorder.

Indicator-82: Patients being evaluated for addiction also undergo an assessment of mental health status and possible psychiatric disorders.

Indicator-83: Assessment of female patients includes their gynecological status.

Standard-22: Adequate diagnostic facilities are in place/accessible.

Indicator-84: Laboratory/testing arrangements to facilitate the assessment of patients are available.

Indicator-85: Imaging services are available / accessible as per the clinical requirements of the patients.

Indicator-86: Only those diagnostic services are provided / accessed which comply the prescribed minimum standards.

1.7 CARE OF PATIENTS (COP)

Standard-23: Emergency services are guided by policies, procedures and applicable laws and regulations.

Indicator-87: Documented SOPs for emergency care exist.

Indicator-88: Policies address handling of medico-legal cases.

Indicator-89: SOPs guide the prioritization of patients for initiation of appropriate care.

Indicator-90: Staff members are familiar with the SOPs for care of emergency patients and trained on the same and the patients receive care in consonance with the SOPs.

Standard-24: Policies and procedures guide the admission/detention and discharge of the patients.

Indicator-91: The reasons for admission/detention must be clearly documented as stated by the patient and/or others significantly involved.

Indicator-92: Admission/detention, discharge or referral to another HCE is documented.

Standard-25: Patient management is planned on the basis of assessment & diagnosis.

Indicator-93: A substantiated diagnosis is established and documented.

Indicator-94: A complete neurological assessment is also undertaken when indicated.

Indicator-95: A comprehensive treatment is planned for each female patient on the basis of her assessment including gynecological status.

Indicator-96: The treatment plan is reviewed, on the basis of patient's strengths and disabilities.

Indicator-97: The treatment provided is comprehensibly entered in the medical records.

Indicator-98: Contact with visitors is monitored/supervised and possibly restricted, particularly in the early stages of treatment.

Indicator-99: Psychotherapy services are provided as prescribed.

Indicator-100: SOPs for care of patients requiring any non-psychiatric intervention/s exist.

Indicator-101: Drug dependents are isolated in a nearby separate section of HCE as legally required.

Indicator-102: The treatment plans are periodically revised on the basis of regular patient monitoring/evaluation and the data on drug use trends in populations.

Indicator-103: Addiction treatment services are networked with other medical and social services for providing comprehensive care to the patients.

Indicator-104: Psycho-social interventions for rehabilitation of drug addicts and prevention of health and social consequences of addiction are operational.

Standard-26: Policies and procedures guide prevention of maltreatment of patient by the healthcare provider.

Indicator-105: SOPs to prevent maltreatment of patients by the care providers are practiced.

Standard-27: Policies and procedures guide the administration of anesthesia when required

Indicator-106: Documented SOPs for the administration of anesthesia exist.

Indicator-107: Informed consent for administration of anesthesia is obtained by the anesthetist.

Indicator-108: Periodic monitoring during anesthesia is regularly conducted.

1.8 MANAGEMENT OF MEDICATIONS (MOM)

Standard-28: Policies and procedures exist for the prescription of medications.

Indicator-109: Documented SOPs for prescription writing are available.

Indicator-110: SOPs are followed for prescription writing.

Indicator-111: Standardized drug treatment protocol is observed.

Standard-29: Policies and procedures guide the safe storage, dispensing and administration of medications.

Indicator-112: Medicines / disposables are stored as per guidelines.

Indicator-113: Expiry dates / shelf life are checked prior to administering, as applicable.

Indicator-114: Labeling requirements are implemented.

Indicator-115: Dispensing/utilization are by an authorized person.

1.9 PATIENT RIGHTS AND EDUCATIN (PRE)

Standard-30: Patients have the right to comprehensive and integrated mental health care that meets their Individual needs and achieves the best possible outcome in terms of their recovery/rehabilitation.

Indicator-116: Charter of rights and responsibilities is displayed and patients / families are guided.

Indicator-117: Patients/families are guided and facilitated in protecting patient's assets.

Standard-31: A documented process for obtaining patient and/or family consent exists for informed decision making about their care.

Indicator-118: The policy describes who can give consent when patient is incapable of Independent decision-making.

Indicator-119: Informed consent must be obtained from the patient / legal representative before the initiation of the examination / treatment/ management.

Standard-32: Patient and families have a right to information on expected costs.

Indicator-120: The patient/family is informed about the cost of treatment.

Indicator-121: There is uniform category specific pricing policy in a given setting.

Indicator-122: Patients and family are informed about the financial implications when a change in the treatment plan is necessitated due to patient's condition.

Standard-33: Patient Rights for Appeals and Complaints are respected.

Indicator-123: The HCE informs the patient of his/her right to express relevant concern or complain either verbally or in writing.

Indicator-124: There exists a documented complaint management process which is fair and timely.

Indicator-125: The HCE uses the results of complaints investigations as part of the quality improvement process.

Standard-34: Patient Rights regarding confidentiality of their ailment are respected.

Indicator-126: The HCE has documented SOPs to ensure confidentiality of patient identity and ailment

Indicator-127: The HCE ensures that patient identity is not disclosed to public through press or electronic media

1.10 INFECTION CONTROL (IC)

Standard-35: The HCE has a comprehensive and coordinated infection control program aimed at reducing/eliminating risks to patients, visitors and care providers

Indicator-128: The HCE infection control plan is documented which aims at preventing and reducing risk of nosocomial infections

Indicator-129: The HCE has an Infection Control Committee

Indicator-130: The HCE has designated a qualified infection control nurse(s)/officer for this activity.

Indicator-131: The HCE has appropriate consumables, collection and handling systems, equipment and facilities for control of infection.

Indicator-132: All staff involved in the patient care, creation, handling and disposal of medical waste shall receive regular training and ongoing education in infection control and safe handling of medical waste.

SCHEDULE-X

(See regulation 1, Ch.1, Part IX)

1 RESPONSIBILITY OF MANAGEMENT

Indicator-1:

The Tibb Clinic is identifiable with the name of Clinic, name of Healthcare Service Providers, professional qualification and National Council for Tibb registration number displayed on a signboard

Indicator-2:

The clinic is registered/licensed with the Islamabad Health Regulatory Authority (IHRA).

Indicator-3:

Door plate clearly displays name, professional qualifications and NCT registration number of Tabeeb/Tabeeba.

Indicator-4:

Consultation hours are displayed.

Indicator-5:

The clinic manager has requisite qualifications.

Indicator-6:

The NCT registration certificate of the Tabeeb/Tabeeba is displayed.

Indicator-7:

The size/premises of the Tibb clinics are as per the minimum requirement.

Indicator-8:

The clinic has adequate facilities for the comfort of the patients.

Indicator-9:

The clinic has adequate arrangements to maintain the privacy of patients during consultation/examination.

2 Facility Management and Safety (FMS)

Indicator-10:

The staff has knowledge about early detection and containment of fire and non-fire emergencies and arrangements available at Matab to combat these emergencies.

3 Human Resource Management (HRM)

Indicator-11:

Personal record/credentials in respect of all staff are maintained.

4 Information Management Systems (IMS)

Indicator-12:

The Clinic management has designated a person to maintain Clinic record and all entries in the patients record.

5 Assessment and Continuity of Care (ACC)

Indicator-13:

Only the Tibb services being provided at the clinic are displayed

6 Care of Patients (COP)

Indicator-14:

The Matab has essential arrangements to cater for emergency care according to Tibb-e-Unani.

7 Management of Medication (Remedies) (MOM)

Indicator-15:

Standards for prescription writing are followed with unique identification of every patient.

Indicator-16:

Record of prescriptions is available at the clinic.

Indicator-17:

Only the person(s) authorized by law can write the prescription.

Indicator-18:

Medicines are stored as per guidelines for safe storage.

Indicator-19:

Labelling requirements are implemented.

Indicator-20:

Authorize person to dispense the medicine in the clinic under supervision of registered Tabeeb/Tabeeba.

8 Patient Rights, Responsibilities and Education (PRE)

Indicator-21:

The situations requiring specific informed consent from a patient or family are listed at the clinic.

Indicator-22:

Patients have the right to ask for treatment's expenses.

Indicator-23:

Patients and families have a right to complain and a mechanism for complaint should exist to address the grievances.

Indicator-24:

The HCE Charter is displayed and patients/families are guided.

9 Infection Control (IC)

Indicator-25:

The clinic has arrangements for infection control aimed at preventing and reducing the risk of infections.

Secretary to the Board