

First Edition: January 2011

Standards for Accreditation of CLINICS Practicing Modern System of Medicine (Allopathy)



**National Accreditation Board for Hospital and
Health care Providers**

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**Standards for Accreditation of
CLINICS - Practicing Modern
System of Medicine (ALLOPATHY)**



**Natinal Accreditation Board for Hospital and
Health care Providers**

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INTRODUCTION

For convenience, the *standards* are grouped into *eight chapters* as follows:

CHAPTER 1 Access, Assessment & Continuity of Care (AAC)

CHAPTER 2 Care of Patients (COP)

CHAPTER 3 Patient Rights and Education (PRE)

CHAPTER 4 Infection Control (IC)

CHAPTER 5 Continuous Quality Improvement (CQI)

CHAPTER 6 Responsibilities of Management (ROM)

CHAPTER 7 Facilities Management and Safety (FMS)

*** CHAPTER 8** Community Participation and Integration (CPI)

Section 1

It comprises of chapters which has a description which explains its purpose. Each chapter contains a number of standards and objective elements which indicate the structures and processes necessary to deliver the standard.

Section 2

Guidebook comprises a brief detail of the objective elements providing interpretation and remarks. It explains the objective element and methods to achieve the same wherever possible.

The clinic participating in accreditation will be expected to provide three types of evidence:

- Approved documents that identify relevant service policy, protocols and/or strategies and set out how the service plans to deliver each standard statement and objective element therein.
- Evidence that demonstrate that the clinic/organization is implementing these policies, protocols and/or strategies.
- Evidence that demonstrates that the service is monitoring its performance regularly in the implementation of its policies, protocols and strategies.

*** CHAPTER 8** is not mandatory.

SCOPE OF SERVICES

DEFINITION OF CLINIC:

A standalone healthcare facility that provides allopathic services by Doctors registered with Medical Council of India or State Medical Council.

The Clinic may be located in the community or in the premises of an organization, such as school, factory, etc., and includes the following types of healthcare facilities:

Sl. No.	Healthcare facility	Definition
1.	Clinic	A standalone healthcare facility for services (other than OPD of a hospital).
2.	Polyclinic	A Clinic which provides services in 2 or more specialties, working in cooperation and sharing the same facilities
3.	Dispensary	A Clinic, which in addition to patient care, provides facilities for dispensing medicines.

In addition a “clinic” may have *add on* services as follows:

Diagnostic services such as:

- Laboratory
- Imaging
- Other

Therapeutic services such as:

- Procedures

Support services such as:

- Pharmacy
- Physiotherapy
- Nutrition
- Counselling etc.

In the Standards, the Dispensary/Polyclinic/ Clinic hereinafter will be referred to as “Clinic”

Exclusions:

1. Day-care Centres :

Day Care will include facilities that have admitting beds for treating patients, other than for overnight stay.

The services may, in addition, include services, diagnostics and treatments such as ambulatory surgical procedures, dialysis, chemotherapy etc.

These Standards are NOT APPLICABLE for non allopathic systems of medicine such as Ayurvedic, AYUSH, homeopathic, wellness centres Alternative medicine streams etc

Section 1

STANDARDS & OBJECTIVE ELEMENTS FOR ACCREDITATION OF CLINICS

CHAPTER 1

Access, Assessment and Continuity of Care (AAC)

AAC.1.	The Clinic defines and displays the services that it can provide.
a)	The services provided are clearly defined and are in consonance with the needs of the community it intends to serve, and its mission, resources and scope of services.
b)	Clinic identifies barriers to access and implements processes to reduce those barriers that have potential to limit access to the Clinic and its services
c)	The services provided are displayed.
AAC.2.	The Clinic has a well defined patient registration process and appropriate mechanism for referral of patients who do not match the Clinic's resources.
a)	Standardized policies and procedures are used for registering patients.
b)	Patients are registered only if their needs match and resources their needs match the clinic's mission
c)	If the patient's needs do not match the clinic's mission and resources, the clinic will assist the patient in identifying and/or obtaining appropriate sources of care.
AAC.3.	Patient's initial and continuing healthcare needs are identified through an established assessment process.
a)	The Clinic defines the scope and content of initial assessment conducted by different specialities / providers / disciplines based on applicable laws and regulations.
b)	The Clinic defines criteria when additional, specialized, or more in-depth special needs assessments are required for some patients.
c)	Initial assessment may use screening criteria or other mechanisms to identify patients who may need additional care.
d)	The Clinic has a policy and procedure which defines the process for how the outside assessments are incorporated into the assessment process.
e)	There is an established process for meeting patient care needs requiring continuing care.
f)	The assessment findings result in a documented plan of care.
g)	The plan of care also includes preventive aspects of the care as applicable.

AAC.4.	The Clinic has a process to identify those patients who may need additional care that is beyond the scope and mission of the Clinic and advises those patients to seek additional care , treatment or follow-up
a)	Policies and procedures are used to identify the additional care needs of the patients and to appropriately refer them to outside healthcare providers
b)	Written summaries are provided to the patients and referring provider
c)	The Clinic attempts to facilitate and coordinate sharing of information and plans of care between referral agencies to ensure proper coordination of care between multiple providers, if applicable.
AAC.5.	The Clinic has a process to identify the transportation needs of the patients and facilitate the same as applicable.
a)	Policies and procedures address identification of transportation needs of the patient and their facilitation
b)	Ambulance or patient transport services, if provided, are organised through defined policies and procedures for efficient and effective services
c)	Ambulance or patient transport services, if provided comply with the legal and regulatory requirements.
AAC.6.	Laboratory services if provided are as per the mission and scope of the Clinic.
a)	Lab services, if provided on site are commensurate with the scope of services and comply with applicable local and national standards, law and regulations.
b)	Lab services if provided on site will have a quality control and laboratory safety programme.
c)	Adequately qualified and trained personnel perform and/or supervise the investigations.
d)	Policies and procedures guide collection, identification, handling, safe transportation, processing and disposal of specimens.
e)	Laboratory results are available within a defined time frame.
f)	Critical results are intimated immediately to the concerned personnel.
g)	Laboratory tests not available in the Clinic are outsourced or referred to outside sources to meet patient needs.
AAC.7.	Imaging services if provided are as per the mission and scope of the Clinic.
a)	Imaging services if provided are as per applicable local and national standards, law and regulations
b)	Imaging services if provided on site will have a quality control and Radiation safety programme

c)	Adequately qualified and trained personnel perform and/or supervise the imaging.
d)	Policies and procedures guide the handling and disposal of radio-active and hazardous materials.
e)	Imaging results are available within a defined time frame.
f)	Critical results are intimated immediately to the concerned personnel.
g)	Imaging services if not available in the Clinic are outsourced or referred to outside resources to meet patient needs.

CHAPTER 2

Care of Patients (COP)

COP.1.	Care and treatment is provided in a uniform manner to ensure high level of patient care.
a)	Policies and procedures guide the uniform level of care for all patients, which reflect applicable laws and regulations.
b)	Care of patients should be in consonance with the defined scope
c)	Evidence based medicine and Clinical practice guidelines are adopted to guide patient care wherever possible.
COP.2.	Policies and procedures guide the care & treatment of patients with special identified needs
a)	Policies and procedures guide the provision of services to the high-risk patients.
b)	Policies and procedures guide the provision of services that are associated with risk in the clinic setting.
c)	Policies and procedure guide basic and first responder emergency care.
d)	Policies address handling of medico-legal cases.
e)	Policies and procedures guide the care & treatment of vulnerable patients and are in accordance with the prevailing laws and the national and international guidelines.
f)	Policies and procedures guide the care of patients undergoing minor procedures (e.g. stitching of wound, removal of stitches etc).
g)	Policies and procedures guide the provision of rehabilitative services and commensurate with the clinical requirements
h)	Policies and procedures guide the management of pain
I)	Policies and procedures guide the care of patients undergoing moderate sedation.
COP.3.	Medication use is organized to meet patient needs and complies with applicable laws and regulations
a)	Policies and procedures guide how the Clinic will meet medication needs of the patient.
b)	The medication use meets applicable laws & regulations.
c)	Antibiotic use is guided by evidence based guidelines.
d)	The medications available are appropriate to the Clinic's mission, scope of services and patient needs.
e)	Policies and procedures guide the procurement process, storage labelling and management of Samples
COP.4.	Medication prescription, dispensing and administration follow standardized processes to ensure patient safety.
a)	Medications are prescribed, dispensed and administered by authorised persons.

b)	Medications are prescribed in a clear legible manner, dated and timed
c)	In case medications are dispensed at the Clinic, standardized policies and procedures are used for safe dispensing
d)	Medication administration is guided by standardized policies and procedures
COP.5.	Medications use is monitored for patient compliance, clinical appropriateness and adverse effects and the medication errors are appropriately addressed.
a)	Medication use is monitored for patient compliance, clinical effectiveness and adverse medication effects; and the same is noted in patient's record.
b)	Adverse medication effects are defined, analyzed, documented and reported to the collaborating centre as applicable.
c)	Patients and family members are educated about safe and effective use of medication and food-drug interactions.
d)	Policies and procedures defines reporting mechanism, analysis and implementation of corrective and preventive actions for medication error and adverse drug events.
COP.6.	Policies and procedures guide all research activities.
a)	Policies and procedures guide all research activities in compliance with the applicable law and national and international guidelines.
b)	Policies and procedures address Patient's informed consent, their right to withdraw, and their refusal to participate in the research activities.

CHAPTER 3

Patient Rights and Education (PRE)

PRE.1.	The Clinic protects patient and family rights and informs them about their responsibilities during care.
a)	Patient and family rights and responsibilities are documented.
b)	Patients and families are informed of their rights and responsibilities in a format and language that they can understand.
c)	The Clinic's leaders protect patient's rights.
d)	Staff is aware of their responsibility in protecting patient's rights.
e)	Violation of patient rights is reviewed and corrective/preventive measures are taken.
PRE.2.	Patient rights support individual beliefs, values and involve the patient and family in decision making processes.
a)	Patient and family rights address any special preferences, religious and cultural needs.
b)	Patient rights include respect for personal dignity and privacy during examination, procedures and treatment.
c)	Patient rights include protection from physical abuse or neglect.
d)	Patient rights include treating patient information as confidential.
e)	Patient has the right to make an informed choice including the option of refusal.
f)	Patient rights include informed consent for any invasive / high risk procedures / treatment.
g)	Patient rights include information and consent before any research protocol is initiated.
h)	Patient rights include information on how to voice a complaint.
I)	Patient has a right to have an access to his / her Clinical records.
PRE.3.	A documented process for obtaining patient and / or families consent exists for informed decision making about their care.
a)	The Clinic has listed those procedures and treatment where informed consent is required.
b)	Informed consent includes information on risks, benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand.
c)	The policy describes who can give consent when patient is incapable of independent decision making.
PRE.4.	Patient and families have a right to information and education about their healthcare needs.

a)	When appropriate, patient and families are educated about the safe and effective use of medication and the potential side effects of the medication.
b)	Patient and families are educated about diet and nutrition.
c)	Patient and families are educated about immunizations.
d)	Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.
e)	Patient and families are educated about preventing infections.
PRE.5.	Patient and families have a right to information on expected costs.
a)	The tariff list is available to patients.
b)	Patients are educated about the estimated costs of treatment.
c)	Billing, receipts and records are maintained as per statutory requirements.
d)	Patients are informed about the estimated costs when there is a change in the patient condition or treatment setting.

CHAPTER 4

Infection Control (IC)

IC.1.	The Clinic has a well-designed, comprehensive and coordinated Infection Control programme aimed at reducing / eliminating risks to patients, visitors and providers of care.
a)	The Clinic has documented policies and procedures for infection control as applicable to its scope.
b)	It focuses on adherence to standard precautions at all times.
c)	Cleaning, Disinfection of surfaces, equipment cleaning and sterilization practices are included.
d)	Laundry and linen management processes are also included.
e)	Staff in Clinic receive regular training in infection control practices
f)	Occupational risks are known to staff and they are trained to prevent these; and to take corrective and preventive actions in case of exposure.
IC.2.	The Clinic complies with Bio Medical Waste regulations as applicable
a)	Bio Medical waste is collected, handled, segregated and disposed of as per the regulations
b)	Staff is trained to handle BMW, and follow precautions

CHAPTER 5

Continuous Quality Improvement (CQI)

CQI.1.	There is a structured quality improvement and continuous monitoring programme.
a)	The quality improvement programme is commensurate with the size and complexity of the clinic and is documented.
b)	The quality improvement programme is comprehensive and covers all the major elements related to quality improvement and risk management.
c)	The activities to achieve conformance with the defined quality management programme are communicated and coordinated amongst all the employees of the Clinic through proper training mechanism.
d)	The quality improvement programme is reviewed at predefined intervals and opportunities for improvement are identified.
CQI.2.	The clinic identifies key indicators to monitor the Clinical and managerial structures, processes and outcomes which are used as tools for continual improvement
a)	The clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.
b)	The clinic develops appropriate key performance indicators suitable to monitor managerial structures, processes and outcomes
c)	There is documentation of monitoring activity.
d)	Corrective and preventive actions are taken and monitored for effectiveness with respect to activities being managed or monitored.

CHAPTER 6

Responsibilities of Management (ROM)

ROM.1.	The responsibilities of the management are defined.
a)	Those responsible for governance lay down the clinic's mission statement, budget and resources
b)	Those responsible for governance establish the Clinic's organogram, as applicable.
c)	Administrative policies and procedures for each section are maintained.
d)	The organisation complies with the laid down and applicable legislations and regulations.
e)	Those responsible for governance address the organisation's social responsibility.
ROM.2.	The Clinic is managed by the leaders in an ethical manner.
a)	The Clinic functions in an ethical manner.
b)	The Clinic discloses its ownership.
c)	The Clinic honestly portrays its affiliations and accreditation.
d)	The Clinic accurately bills for its services based upon a standard billing tariff.
ROM. 3.	The Clinic initiates and maintains a patient record for every patient.
a)	Only authorized persons make entries in the patient record.
b)	Every patient record has a unique identifier and the record contains sufficient information to meet patient care needs and regulatory requirements.
c)	The retention period and storage requirements are defined and implemented.
d)	Standardized forms and formats are used.
ROM. 4.	Those responsible for management have addressed all applicable aspects of human resource management.
a)	The Clinic maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.
b)	The required job specifications and job description are well defined for each category of staff.
c)	The Clinic verifies the antecedents of the potential employee with regards to credentials, criminal/negligence background, training, education and skills.
d)	Each staff member, employee and voluntary worker is appropriately oriented to the mission of the Clinic, policies and procedures as well as relevant department / unit / service/ programme's policies and procedures.
e)	The Clinic staff participates in continuing professional education programs.
f)	Performance evaluation systems are in place, as applicable.
g)	Staff Health Problems are addressed.

CHAPTER 7

Facility Management and Safety (FMS)

FMS.1.	The Clinic's environment and facilities operate to ensure safety of patients, their families, staff and visitors.
a)	Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.
b)	There is internal and external sign posting in the Clinic in a language understood by patient, families and community.
c)	The provision of space shall be in accordance with the available literature on good practices (Indian or International Standards)
FMS.2.	The Clinic has a programme for equipment management, safe water, electricity, medical gases and vacuum system as applicable.
a)	The Clinic plans for equipment in accordance with its services and strategic plan.
b)	Potable water and electricity are available.
c)	Alternate sources are provided for in case of failure.
d)	The organisation regularly tests the alternate sources.
e)	Safety precautions are followed with respect to medical gases and where applicable piped medical gas, compressed air & vacuum installation/equipment.
FMS.3.	The Clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.
a)	The Clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.
b)	Staff is trained for their role in case of such emergencies.
c)	The Clinic has addressed identification, spill management, training of staff storage and disposal of Hazardous materials.
d)	The Clinic defines and implements its policies to reduce or eliminate smoking.

CHAPTER 8

Community Participation and Integration (CPI)

CPI.1.	The commitment of the Clinic to Health promotion and disease prevention is evident in its mission statement, value statement, collaborative arrangements with local, regional and national agencies and relevant policies and community participation.
a)	The clinic defines Policies and procedures for health promotion / wellness and disease prevention / control programs that it participates in, as applicable.
b)	The Clinic keeps abreast and implements national/regional or local standards and guidelines which are in consonance with its mission and objectives.
c)	Clinic provides education, counselling and information to community partners and priority population on variety of topics for health promotion, Health protection, and disease prevention and control.
d)	Clinic cooperates and collaborates with the community partners in provision of surveillance, epidemiological investigations, data collection, when required..
e)	There is a process in place for reporting notifiable diseases as per prevailing law and regulations.

Section 2

GUIDEBOOK - STANDARDS & OBJECTIVE ELEMENTS FOR ACCREDITATION OF CLINIC

CHAPTER 1

Access, Assessment and Continuity of Care (AAC)

AAC.1. The Clinic defines and displays the services that it can provide.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The services provided are clearly defined and are in consonance with the needs of the community it intends to serve and its mission, resource and scope of services.	A policy to be framed clearly stating the services the clinic may/may not provide.	The needs of the community should be considered especially when planning a new Clinic or adding new services. Claims of services and expertise being available should actually be available
b)	Clinic identifies barriers to access and implements processes to reduce those barriers that have potential to limit access to the Clinic and its services.	The served community may have diverse population with patients having same health needs but quite different in terms of language and cultural context. The leaders of the Clinic recognise the common barriers like physical, language, cultural and others within their patient population, and implements processes to overcome or limit these barriers to access and to the delivery of services.	
c)	The services provided are displayed	The services so defined should be displayed prominently in an area visible to all patients entering the Clinic. The display could be in the form of boards, citizen's charter, scrolling messages etc. Care should be taken to ensure that these are displayed in the language(s) the patient understands.	Display in the form of brochures only is not acceptable. Display should be at least bi-lingual.

AAC.2. The Clinic has a well defined patient registration process and appropriate mechanism for referral of patients who do not match the Clinic's resources.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Standardized policies and procedures are used for registering patients.	Clinic has prepared document (s) detailing the policies and procedures for registration of patients	
b)	Patients are registered only if their needs match the clinic's mission and resources.	The staffs handling registration needs to be aware of the services that the Clinic can provide.	The patient registration and assessment process is designed to give priority to those who are obviously sick or those with urgent needs
c)	If patients needs do not match the clinic's mission and resources the clinic will assist the patient in identifying and/or obtaining appropriate sources of care.	Matching patients' needs and condition with the Clinic mission, resources depends on information usually gathered at the time of first contact through triage, visual evaluation, a physical examination, or the results of previously conducted physical, psychological, Clinical laboratory, or diagnostic imaging evaluations done outside the Clinic or from a referral source. There is an appropriate mechanism for referral of patients who do not match the Clinic's mission and resources. Outpatient clinic shall at the outset define such patients. The Clinic gives a summary of patient's condition mentioning the significant findings and treatment given.	These patients include those who have come to the Clinic but need to be referred to another organization.

AAC.3. Patient's initial and continuing healthcare needs are identified through an established assessment process.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The Clinic defines the scope and content of initial assessment conducted by different specialities/ providers/ disciplines based on applicable laws and regulations	<p>The initial assessment modified depending on the type of patient / service provided however it shall be the same in that particular area e.g. in a paediatric OPD the weight and height may ne a must whereas it may not be so for orthopaedics OPD Appropriate criteria based on EBM are used as applicable</p> <p>Assessments are performed by each discipline within its scope of practice, licensure, applicable laws, and regulations or certification</p> <p>The scope and content of initial assessment conducted by different providers/ disciplines may ne defined in a policy and procedure or may be identified on assessment form.</p>	
b)	The Clinic defines criteria when additional, specialized, or more in depth special needs assessments are required for some patients.	Some patients like elderly, pregnant women, very young children, patients with infectious disease may have special needs and require additional assessment. The assessment process for these special needs patients is appropriately modified to reflect their needs and risks.	

c)	Initial assessment may use screening criteria or other mechanisms to identify patients who may need additional care.	<p>Many patients have healthcare needs that may seemingly be unrelated to the reason they came to the Clinic. Such needs may include for e.g. screening for nutritional needs, behavioural health needs, immunization, and pain as applicable.</p> <p>The screening criteria or other mechanisms are based on guidelines / protocols developed by the relevant professional national or international bodies</p>	<p>Assessment of nutritional needs may be done by the treating doctor and / or dietician.</p> <p>Since care will include a large aspect of primary care, which includes disease prevention and promotion, immunization history and advice should be included wherever applicable.</p>
d)	The Clinic has a policy and procedure which defines the process for how the outside assessments are incorporated into the assessment process.	<p>The patient assessment process may include the relevant findings from outside assessments (referral source, laboratory etc). The policy and procedure will address:</p> <ul style="list-style-type: none"> • Process of obtaining and using outside assessment findings. • outside assessments requiring review and verification. • Situations when outside assessments are not available 	For e.g. the laboratory / imaging reports are accepted only if duly signed by qualified / authorised personnel.
e)	There is an established process for meeting patient care needs requiring continuing care.	The patients's visit to the clinic may be one time or ongoing. Patients reassessed based on continuing needs, to determine their response to treatment or to plan further treatment.	

f)	The assessment findings result in a documented plan of care.	The assessment findings are documented in a uniform manner and uniform location in a patient's record and the patient's record is readily available to those responsible for the patients care.	
g)	The plan of care also includes preventive aspects of the care as applicable.	The documented plan of care should cover preventive actions as necessary in the case and should include diet, drugs etc.	This could also be done through counselling, booklets/patient information leaflets etc. e.g. diabetes, hypertension.
AAC.4. The Clinic has a process to identify those patients who may need additional care that is beyond the scope and mission of the Clinic and advises those patients to seek additional care , treatment or follow-up			
Sl. no	Objective Element	Interpretation	Remarks
a)	Policies and procedures are used to identify the additional care needs of the patients and to appropriately refer them to outside healthcare providers.	These additional needs may be identified at the time of assessment or reassessment.	Referral is based on the patient's health status and need for additional/ continuing care or services. Referral may be for speciality, diagnostic, rehabilitative psychological services etc.
b)	Written summaries are provided to the patients and referring provider.	The Clinic frequently provides care and services to patients based on referral of the patient for speciality services (for e.g. cardiac evaluation / particular test). The Clinic has a process through which it communicates to patients (when appropriate patient family) about the ongoing health needs and types of care and services they should seek in future. The referred provider provides a written summary to convey the findings back to the referring provider	The information (written summary) includes as appropriate, a medication list, significant diagnosis and treatments, follow up instructions and any test results.

c)	The Clinic attempts to facilitate and coordinate sharing of information and plans of care between referral agencies to ensure proper coordination of care between multiple providers, if applicable.	The patient care can involve many care providers. The care planning and delivery needs to be integrated and coordinated amongst care providers.	
AAC.5. The Clinic has a process to identify the transportation needs of the patients and facilitate the same as applicable.			
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	Policies and procedures address identification of transportation needs and their facilitation		Tie up with ambulance providers/ referral centres Coordination/ facilitation
b)	Ambulance or patient transport services, if provided, are organised through defined policies and procedures for efficient and effective services	<ul style="list-style-type: none"> • Policies and procedures shall guide the maintenance, readiness, dispatch • There is adequate space for parking. • Ambulance(s) is appropriately equipped • The ambulance is manned by the trained staff • There is a Checklist of equipment/ medicines • There is a proper communication system • Licensing of drivers, pollution control, registration of vehicle etc . 	<p>It is expected that ambulance / PTV shall be equipped with at least basic life support equipment.</p> <p>The staff shall be trained in ACLS and / or BLS</p> <p>The Ambulance / Equipments / Emergency Medications shall be checked daily</p>
c)	Ambulance or patient transport services, if provided comply with the legal and regulatory requirements.		

AAC.6. Laboratory services if provided are as per the mission and scope of the Clinic.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Lab services, if provided on site are commensurate with the scope of services and comply with applicable local and national standards, law and regulations.	The Clinic may have availability of laboratory services commensurate with the health care services offered by it and the scope of the clinic services either by providing the same in house or by outsourcing/referral. See also (g) below for outsourced lab facilities.	In case the Clinic does not have a lab, or in addition to a lab, they may keep some “point of care” testing arrangements- For example the Clinic may have Glucometer testing in a Diabetic Clinic or other specific tests relating to the scope of service, to meet immediate diagnostic need.
b)	Lab services if provided on site will have a quality control and laboratory safety programme	<p>The laboratory quality assurance and safety programme:</p> <ul style="list-style-type: none"> • Is documented. • Addresses verification and validation of test methods. • Addresses surveillance of test results. • Includes periodic calibration and maintenance of all equipments. • Includes the documentation of corrective and preventive actions. • Addresses handling and disposal of infectious and hazardous materials and protective equipment • training of staff • integrates with other Clinical safety program 	Forms and formats & adequate record keeping are addressed.
c)	Adequately qualified and trained personnel perform and/or supervise the investigations.	The staff employed in the lab should be suitably qualified) and trained to carry out the tests.	For adequacy of qualification refer to NABL 112 (Annexure).
d)	Policies and procedures guide collection, identification, handling,	The Clinic has documented procedures for collection,	The policy should be in line with standard precautions. The

	safe transportation, processing and disposal of specimens.	identification, handling, safe transportation, processing and disposal of specimens, to ensure safety of the specimen till the tests and retests (if required) are completed.	disposal of waste shall be as per the statutory requirements (Bio-medical waste management and handling rules, 1998.)
e)	Laboratory results are available within a defined time frame.	The Clinic shall define the turnaround time for all tests. The Clinic should ensure availability of adequate staff, materials and equipment to make the laboratory results available within the defined time frame.	The turnaround time could be different for different tests and could be decided based on the nature of test and criticality of test.
f)	Critical results are intimated immediately to the concerned personnel.	The laboratory shall establish its biological reference intervals for different tests. The laboratory shall establish critical limits for tests which require immediate attention for patient management. The test results in the critical limits shall be communicated to the concerned after proper documentation.	If it is not practical to establish the biological reference interval for a particular analyte the laboratory should carefully evaluate the published data for its own reference intervals.
g)	Laboratory tests not available in the Clinic are outsourced or referred to outside sources to meet patient needs.	If services are outsourced adequate Quality Assurance criteria for selection and monitoring of the of the outsourced lab, will be applied	

AAC.7. Imaging services if provided are as per the mission and scope of the Clinic.

<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	Imaging services if provided are as per applicable local and national standards, law and regulations	<ul style="list-style-type: none"> The Clinic may have availability of Imaging services commensurate with the health care services offered by it either by providing the same in house or by outsourcing/referral. See also (g) below for outsourced lab facilities. The Clinic is aware of the legal and other requirements of imaging 	<p>In case the Clinic does not have an imaging service they may keep some “point of care” testing arrangements-</p> <p>For example USG in a cardiac Clinic, to meet immediate diagnostic need.</p> <p>All the statutory requirements are met with, like BARC</p>

		services and the same are documented for information and compliance by all concerned in the Clinic. The Clinic maintains and updates its compliance status of legal and other requirements in a regular manner.	clearance, dosimeters lead sheets, lead aprons, signages, display as per PNDD act, report to competent authority, etc
b)	Imaging services if provided on site will have a quality control and Radiation safety programme	<p>The Imaging quality assurance and Radiation safety programme:</p> <ul style="list-style-type: none"> • Is documented. • Addresses patient and staff safety • Addresses verification and validation of test methods. • Addresses surveillance of test results. • Includes periodic calibration and maintenance of all equipments. • Includes the documentation of corrective and preventive actions. • Addresses handling and disposal of infectious, radioactive and hazardous materials and protective equipment • Imaging personnel are provided with appropriate radiation safety devices • training of staff integrates with other Clinical safety program 	Refer AERB guidelines and NABH Accreditation standard for Medical Imaging service wherever applicable
c)	Adequately qualified and trained personnel perform and/or supervise the imaging.	The staff employed in the imaging should be suitably qualified and trained to carry out the procedure.	
d)	Policies and procedures guide the handling and disposal of radio-active and hazardous materials.	Radioactive and hazardous materials shall be disposed off as per bio-medical waste management and handling rules, 1998.	

e)	Imaging results are available within a defined time frame.	The Clinic shall define the turnaround time for all procedures. The Clinic should ensure availability of adequate staff, materials and equipment to make the Imaging results available within the defined time frame.	The turnaround time could be different for different tests and could be decided based on the nature of test and criticality of test.
f)	Critical results are intimated immediately to the concerned personnel.	The Imaging shall establish critical limits for the results which require immediate attention for patient management. The results in the critical limits shall be communicated to the concerned after proper documentation.	
g)	Imaging services if not available in the Clinic are outsourced or referred to outside resources to meet patient needs.	If services are outsourced adequate Quality Assurance criteria for selection and monitoring of the of the outsourced imaging centre, will be applied	

CHAPTER 2

Care of Patients (COP)

COP.1. Care and treatment is provided in a uniform manner to ensure high level of patient care.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Policies and procedures guide the uniform level of care for all patients, which reflect applicable laws and regulations.	Self explanatory. Same quality of services (diagnostics and treatment) for patients having same health needs / problems.	The access and appropriateness of the care do not vary by the ability to pay / source of payment / time of the day etc
b)	Care of patients should be in consonance with the defined scope	The clinic shall have appropriate Staff, facilities, protocols and procedures in consonance with the scope of service.	For example an obstetric clinic shall have examination room along with appropriate staff but will not perform procedures giving deep sedation when there is not adequate backup staff & facilities etc
c)	Evidence based medicine and Clinical practice guidelines are adopted to guide patient care wherever possible.	The Clinic could develop Clinical protocols based on these and the same could be followed in management of patients. These could then be used as parameters for audit of patient care.	e.g. Standardized protocols for care of malaria, diabetes, asthma etc (eg standard treatment guidelines) For definitions of evidence based medicine and Clinical practice guidelines, refer to glossary.
COP.2. Policies and procedures guide the care & treatment of patients with special identified needs.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Policies and procedures guide the care & treatment of high-risk patients identified by the Clinic.	•The Clinic identifies & clearly defines high-risk patients, such as neonates, elderly, patients with psychiatric disorders, HIV, patients of infectious or communicable disease etc.	Eg: a cardiac Clinic with TMT facilities may screen patients who are not fit for TMT at this centre and may refer to higher centre.

		<p>etc. The policies and procedures defines the scope of services to be rendered to these high risk patients and includes the mechanism of referral to identified sources for further management, in a coordinated and safe manner.</p> <ul style="list-style-type: none"> • The centre should have a list of specialised services available in the community or beyond as per the patient needs. • The persons caring for high risk patients are competent. 	
b)	Policies and procedures guide the provision of high-risk services.	The Clinic identifies & clearly defines high risk services which includes handling use and administration of IV medications, blood products etc.	
c)	Policies and procedure guide basic and first responder emergency care.	<p>The policies and procedures are based on the scope of services and patient needs and particularly address:</p> <ul style="list-style-type: none"> • The availability of Clinic of basic first aid facilities and resuscitative equipment, • Clinical guidelines / protocols to provide first aid, resuscitation and management of specific conditions like hypoglycaemia, allergic reaction and other conditions common in the served patients etc. • Training of staff to use the resuscitative equipment and provide resuscitative services. 	<p>The centre must have the names and contact details of ambulance providers</p> <p>The centre must be aware of emergency facilities in surrounding nearby areas.</p> <p>The staff needs to be trained in CPR</p>
d)	Policies also address handling of medico-legal cases.	If medico-legal cases are handled in the clinic the policy shall be in line with statutory requirements.	

e)	Policies and procedures guide the care & treatment of vulnerable patients and are in accordance with the prevailing laws and the national and international guidelines.	Self explanatory. The vulnerable patients include children, elderly, physically and/or mentally challenged. The Clinic provides for a safe and secure environment for this vulnerable group. Staffs are trained to care for this vulnerable group.	Refer to disability act, mental act. The Clinic shall provide proper environment taking into account the requirement of the vulnerable group.
f)	The policies and procedures guide the care of patients undergoing minor procedures	This shall include the list of surgical procedures as well as competency level, qualifications for performing these Procedures. An informed consent is obtained prior to the procedure. Persons permitted to perform procedure are competent and in consonance with the law	
g)	Polices and procedures guide the provision of rehabilitative services and are commensurate with the clinical requirements.	The scope of the department is in consonance with the scope of the Clinic.	For example, provision of antenatal and post natal exercise could form a part of obstetric rehabilitation programme.
h)	Policies and procedures guide the management of pain.	The Clinic shall define the group of patients for whom this is applicable. A good reference point for defining these patients could be those having pain as the predominant debilitating symptom. Patient and family are educated on various pain management techniques.	For example, cancer pain, neuralgias and arthralgia.
i)	Policies and procedures guide patients undergoing moderate sedation.	Competent person will administer the sedation and <ul style="list-style-type: none"> • monitoring facilities will be available. • recovery criteria will be used to send the patient home after period of 	

		<p>monitoring facility to rescue the patient in case of deeper level of sedation will be available</p> <ul style="list-style-type: none"> Records will be maintained. 	
COP.3.	Medication use is organized to meet patient needs and complies with applicable laws and regulations.		
Sl. no	Objective Element	Interpretation	Remarks
a)	Policies and procedures guide how the Clinic will meet medication needs of the patient.	<p>The Clinic may give prescription to obtain medication at community pharmacy or may dispense from the pharmacy operated by Clinic.</p> <p>The Clinic can also provide on-site pharmacy services through contracted agencies.</p>	
b)	The medication use meets applicable laws & regulations.	Applicable laws & regulations such as Pharmacy act, Drug & cosmetic act, narcotic and psychotropic substances act etc (as in annexure 1)	
c)	Antibiotic prescription is guided by evidence based guidelines.	Indiscriminate antibiotic usage is to be avoided /discouraged.	
d)	The medications available are appropriate to the Clinic's mission, scope of services and patient needs.	Self explanatory	
e)	Policies and procedures guide the procurement process, storage labelling and management of medications.		Inventory management of Medicine / consumables may follow first expiry first out principle. Samples should also be addressed.
COP.4.	Medication prescription, dispensing and administration follow standardized processes to ensure patient safety.		
Sl. no	Objective Element	Interpretation	Remarks
a)	Medications are prescribed, dispensed	These should be in compliance with regulations, licensure etc.	

	and administered by authorized persons.		
b)	Medications are prescribed in a clear legible manner, dated and timed.		
c)	In case medications are dispensed at the Clinic, standardized policies and procedures are used for safe dispensing.	These should address identification, storage, expiry dates, sound alike look alike segregation, licensing requirements etc.	
d)	Medication administration is guided by standardized policies and procedures.	<p>The Clinic shall ensure:</p> <ul style="list-style-type: none"> • Only authorized staff administer medications. • Staff is familiar with the composition, strengths, dilution requirements and broad indications, drug - drug interactions, side effects etc. Verification of indications, contraindications, and obtaining history of allergy/adverse reaction. • Proper identification of patient, and medication including route, dose, expiry dates, physical verification etc. • Knowledge of allergy test if required. • Proper infection control practices including gloves as applicable. 	
COP.5.	Medication use is monitored for patient compliance, clinical appropriateness and adverse effects and the medication errors are appropriately addressed.		
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	Medication use is monitored for patient compliance, clinical effectiveness and adverse medication effects; and the same is noted in patient's record.	Proper follow up advice to patient.	
b)	Adverse medication effects are defined, analyzed, documented and reported to the collaborating centre as applicable.	The adverse drug effects that are to be recorded in the patient's record and those that must be reported are defined.	

c)	Patients and family members are educated about safe and effective use of medication and food-drug interactions.	Methodology of patient education may include patient education pamphlets etc. They are advised to report any adverse drug reactions.	
d)	Policies and procedures will define reporting, analyzing and corrective and preventive actions for medication error and adverse drug events.	Prescription audit, to be carried out. Medication errors, near misses, patient reported outcomes, to be reviewed. Corrective and preventive actions to be recorded. Adverse drug events can be reported to agencies such as Govt / QCI / WHO as applicable.	Attempts are made as per recall mechanisms. Policies are modified to reduce adverse drug events when unacceptable trends occur.
COP.6. Policies and procedures guide all research activities.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Policies and procedures guide all research activities in compliance with the applicable law and national and international guidelines.	Self explanatory	For example: International conference on harmonization (ICH) of Good Clinical practices (GCP) and Declaration of Helsinki Somerset (1996) and Ethical Guidelines for Biomedical Research on Human Subjects (ICMR-2006). Also refer Schedule Y Drugs and Cosmetics Act.
b)	Policies and procedures address Patient's informed consent, their right to withdraw, their refusal to participate in the research activities.	Patients are informed of their right to withdraw from the research at any stage and also of the consequences (if any) of such withdrawal. Patients are assured that their refusal to participate or withdrawal from participation will not compromise their access to the Clinic's services.	

CHAPTER 3

Patient Rights and Education (PRE)

PRE.1. The Clinic protects patient and family rights and informs them about their responsibilities during care.			
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	Patient and family rights and responsibilities are documented.	The Clinic should respect patient's rights and inform them of their responsibilities. All the rights of the patients should be displayed in the form of a Citizens' Charter which should also give information of the charges and grievance redress mechanism.	For an example of "patient responsibility" refer to glossary.
b)	Patients and families are informed of their rights and responsibilities in a format and language that they can understand.	Self explanatory.	
c)	The Clinic's leaders protect patient's rights.	Protection also includes addressing patient's grievances w.r.t rights.	
d)	Staff is aware of their responsibility in protecting patient's rights.	Training and sensitisation programmes shall be conducted to create awareness among the staff.	
e)	Violation of patient rights is reviewed and corrective/preventive measures taken.	Where patients' rights have been infringed upon, management must keep records of such violations, as also a record of the consequences, e.g. corrective actions to prevent recurrences.	
PRE.2. Patient rights support individual beliefs, values and involve the patient and family in decision making processes.			
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	Patient and family rights address any special preferences, spiritual and cultural needs.		

b)	Patient rights include respect for personal dignity and privacy during examination, procedures and treatment.	<p>During all stages of patient care, be it in examination or carrying out a procedure, staff shall ensure that patient's privacy and dignity is maintained. The Clinic shall develop the necessary guidelines for the same. During procedures the Clinic shall ensure that the patient is exposed just before the actual procedure is undertaken.</p> <p>With regards to photographs/recording procedures; the Clinic shall ensure that consent is taken and that the patient's identity is not revealed.</p>	
c)	Patient rights include protection from physical abuse or neglect.	Special precautions shall be taken especially w.r.t vulnerable patients e.g. elderly, neonates etc.	Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations, manhandling etc.
d)	Patient rights include treating patient information as confidential.	The clinic shall keep the records in a secure manner and will release only under authorisation of the patient except under statutory obligation.	
e)	Patient has the right to make an informed choice including the	During management the patients should be	In case of refusal the treating doctor shall explain the

	option of refusal.	given the choice of treatment. The treating doctor shall discuss all the available options and allow.	consequences of refusal of treatment and document the same.
f)	Patient rights include informed consent for any invasive / high risk procedures / treatment.	Self explanatory.	Informed consent of the patient is mandatory for doing HIV test/TMT test etc
g)	Patient rights include information and consent before any research protocol is initiated.	The Clinic shall ensure that International conference on harmonization (ICH) of Good Clinical practice (GCP) and Declaration of Helsinki Somerset (1996) and ICMR requirements are followed.	
h)	Patient rights include information on how to voice a complaint.	Grievance redressal mechanism must be accessible and transparent.	
i)	Patient has a right to have an access to his / her Clinical records.	The Clinic shall ensure that every patient has access to his/her record. This shall be in consonance with The code of medical ethics and statutory requirements.	
PRE.3.	A documented process for obtaining patient and / or families consent exists for informed decision making about their care.		
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	The Clinic has listed those procedures and treatment where informed consent is required.	A list of procedures should be made for which informed consent should be taken.	The policy for HIV testing should follow the national policy on HIV testing (NACO).
b)	Informed consent includes information on risks, benefits, alternatives and as to who will perform the requisite procedure in a language that they can	The consent shall have the name of the doctor performing the procedure. Consent	

	understand.	form shall be in the language that the patient understands.	
c)	The policy describes who can give consent when patient is incapable of independent decision making.	The Clinic shall take into consideration the statutory norms. This would include next of kin/legal guardian. However in case of unconscious/unaccompanied patients the treating doctor can take a decision in life saving circumstances.	
PRE.4. Patient and families have a right to information and education about their healthcare needs.			
Sl. no	Objective Element	Interpretation	Remarks
a)	When appropriate, patient and families are educated about the safe and effective use of medication and the potential side effects of the medication.	Self explanatory.	
b)	Patient and families are educated about diet and nutrition.	Self explanatory.	
c)	Patient and families are educated about immunizations.	Self explanatory.	
d)	Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.	Self explanatory. This could also be done through patient education booklets/ videos/ leaflets etc.	
e)	Patient and families are educated about preventing infections	Self explanatory.	For example, hand washing and avoiding overcrowding near the patient.
PRE.5. Patient and families have a right to information on expected costs.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The tariff list is available to patients.	Ethical billing practices are ensured. The Clinic shall ensure	

		<p>that there is an updated tariff list and that this list is available to patients.</p> <p>The Clinic shall charge as per the tariff list. Additional charges should also be enumerated in the tariff and the same communicated to the patients.</p> <p>The tariff rates should be uniform and transparent.</p>	
b)	Patients are educated about the estimated costs of treatment.		
c)	Billing, receipts and records are maintained as per statutory requirements		
d)	Patients are informed about the estimated costs when there is a change in the patient condition or treatment setting.		

CHAPTER 4

Infection Control (IC)

IC.1. The Clinic has a well-designed, comprehensive and coordinated Infection Control programme aimed at reducing / eliminating risks to patients, visitors and providers of care.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The Clinic has documented policies and procedures for infection control as applicable to its scope.	Self explanatory	
b)	It focuses on adherence to standard precautions at all times.	Hand washing facilities in all patient care areas are accessible to health care providers. Adequate gloves, masks, soap, and disinfectants are available and used correctly	Refer to glossary For “standard precautions”.
c)	Cleaning, Disinfection of surfaces, equipment cleaning and sterilization practices are included.	As applicable to the type of Clinic and services, the policies and practices will address all relevant aspects.	
d)	Laundry and linen management processes are also included.	Clean, linen and laundry service as applicable. In case of minor procedures where sterile precautions are needed, these should be addressed.	
e)	Staff in Clinic receive regular training in infection control practices	Example Training on Hand hygiene, BMW, personal protective equipment, cleaning disinfection and sterilization etc	
f)	Occupational risks are known to staff and they are trained to prevent these; and to take	Pre exposure prophylaxis is	

	corrective and preventive actions in case of exposure.	<p>arranged.</p> <ul style="list-style-type: none"> • Hepatitis B immunizations • Staff is trained to handle spills • Needle sticks injury prevention, and first aid to be given in case of an accident. • Appropriate post exposure prophylaxis is quickly facilitated at nearest healthcare facility. 	
IC.2. The Clinic complies with Bio Medical Waste regulations as applicable			
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	Bio Medical waste is collected, handled, segregated and disposed of as per the regulations	Self explanatory. The rules for services apply.	
b)	Staff is trained to handle BMW, and follow precautions		

CHAPTER 5

Continuous Quality Improvement (CQI)

CQI.1 There is a structured quality improvement and continuous monitoring programme.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The quality improvement programme is commensurate with the size and complexity of the organization and is documented..	This should be documented as a manual. The manual shall incorporate the mission, vision, quality policy, quality objectives, service standards, important indicators as identified etc. The manual could be stand alone and should have cross linkages with other manuals.	.
b)	The quality improvement programme is comprehensive and covers all the major elements related to quality improvement and risk management.	This shall preferably cover all aspects including documentation of the programme, monitoring it, data collection, review of policy and corrective action.	Refer to glossary for definition of "Risk management" and "Quality improvement".
c)	The activities to achieve conformance with the defined quality management programme are communicated and coordinated amongst all the employees of the Clinic through proper training mechanism.	The clinic staff shall be familiarised with the tools & techniques of quality management in healthcare including accreditation. Self explanatory.	This could be done through regular training programme or printed materials.

d)	<p>The quality improvement programme is reviewed at predefined intervals and opportunities for improvement are identified.</p>	<p>A s q u a l i t y improvement is a dynamic process, it needs to be reviewed at regular pre-defined intervals (as defined by the Clinic in the quality improvement manual but at least once in a year) by conducting internal audits.</p> <p>The Clinic, if not having a full team, can organize an assessment using external peers. This audit shall be done by a multi-disciplinary team (preferably trained in NABH standards) including all the applicable standards and objective elements. At the end of the audit there shall be a formal meeting to summarise the findings and identify areas for improvement. During this meeting there shall be an analysis of key indicators as identified and determined by the organisation including the mandatory indicators as laid down in CQI 2 and 3. The minutes of the review meetings should be recorded and maintained.</p>	<p>The assessors shall be either trained internally or externally in NABH standards. They shall assess areas independent of their area of work.</p>
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CQI.2. The clinic identifies key indicators to monitor the Clinical and managerial structures, processes and outcomes which are used as tools for continual improvement			
Sl. no	Objective Element	Interpretation	Remarks
a)	The clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.	Monitoring may include: <ul style="list-style-type: none"> • appropriate patient assessment • safety and quality control programmes of the diagnostics services. • adverse drug events • content of medical records. • infection control activities. • Clinical research 	Refer to ICMR guidelines and GCP for reporting time of serious adverse events.
b)	The clinic develops appropriate key performance indicators suitable to monitor managerial structures, processes and outcomes	Monitoring may include <ul style="list-style-type: none"> • procurement of medication essential to meet patient needs. • reporting of activities as required by laws and regulations. • risk management. • patient satisfaction • employee satisfaction. • data collection to support further study for improvements. 	For law & regulations example, tax, EPF, notifiable diseases, PNDT act, AERB guidelines etc.
c)	There is documentation of monitoring activity.	The data could be collected at pre-defined intervals e.g. monthly/quarterly.	
d)	Corrective and preventive actions are taken and monitored for effectiveness with respect to activities being managed or monitored.	This data is analysed for improvement opportunities and the same are carried out. Also refer to CQI	

CHAPTER 6

Responsibilities of Management (ROM)

ROM.1. The responsibilities of the management are defined.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Those responsible for governance lay down the clinic's mission statement, budget and resources		
b)	Those responsible for governance establish the Clinic's organogram, as applicable.	The Clinic shall have a well defined Clinic structure/chart and this shall clearly document the hierarchy, line of control, along with the functions at various levels.	
c)	Administrative policies and procedures for each section are maintained.	This shall include administrative procedures like attendance, leave, conduct, replacement etc.	It could be common for the entire Clinic.
d)	The clinic complies with the laid down and applicable legislations and regulations.	Self explanatory. The responsibility of compliance lies with the first two level of the hierarchy.	This shall include central legislations (e.g. Drugs and Cosmetics act, PNDT Act, 1996), bio medical waste act, Air (Prevention and Control of Pollution) Act, 1981, Atomic Energy Regulatory Body Approvals, License under Bio-medical Management and Handling Rules, 1998, respective state legislations (Maharashtra Maintenance of Clinical Records act, Clinical

			establishment of West Bengal)and local regulations (e.g. building byelaws).
e)	Those responsible for governance address the organisation's social responsibility.	The leader/s of the Clinic shall willfully develop social responsibility policy and accordingly address it.	For example, free camps, outreach programmes, adoption of villages, PHCs, etc.
ROM.2. The Clinic is managed by the leaders in an ethical manner.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The Clinic functions in an ethical manner.	"Code of medical ethics" to be followed..	
b)	The Clinic discloses its ownership.	The ownership of the Clinic e.g. trust, private, public has to be disclosed.	The disclosure could be in the registration certificate/quality manual, etc.
c)	The Clinic honestly portrays its affiliations and accreditation.	Here portrays implies that the Clinic convey's its affiliations, accreditations for specific services or whole centre wherever applicable.	
d)	The Clinic accurately bills for its services based upon a standard billing tariff.	Self explanatory.	Also refer to PRE 5.
ROM3. The Clinic initiates and maintains a patient record for every patient.			
a)	Only authorized persons make entries in the patient record.		
b)	Every patient record has a unique identifier and the record contains sufficient information to meet patient care needs and regulatory requirements.		
c)	The retention period and storage requirements are defined and implemented.		
d)	Standardized forms and formats are used.		

ROM.4. Those responsible for management have addressed all applicable aspects of human resource management.			
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	The Clinic maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.	The staff should be commensurate with the workload.	
b)	The required job specifications and job description are well defined for each category of staff.	The content of each job should be well defined and the qualifications, skills and experience required for performing the job should be clearly laid down. The job descriptions should be commensurate with the qualification.	Refer to glossary for definition of "job description and job specification".
c)	The Clinic verifies the antecedents of the potential employee with regards to credentials, criminal/negligence background, training, education and skills.	M C I / N C I registration, police verification as applicable. This should include Clinical privileges also.	
d)	Each staff member, employee and voluntary worker is appropriately oriented to the mission of the Clinic, policies and procedures as well as relevant department / unit / service/ programme's policies and procedures.	This includes patient rights, employee rights and all departmental policies, safety, grievance redressal etc.	
e)	The Clinic staff participates in continuing professional education programs.		
f)	Performance evaluation systems are in place, as applicable.	Appraisal, training needs identification, support for training, C M E S etc is provided.	

g)	Staff Health Problems are addressed.	This includes occupational health issues, medical checkups as applicable and preventive immunization.	
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CHAPTER 7

Facility Management and Safety (FMS)

FMS.1. The Clinic's environment and facilities operate to ensure safety of patients, their families, staff and visitors.			
Sl. no	Objective Element	Interpretation	Remarks
a)	Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.	Self explanatory	
b)	There is internal and external sign posting in the Clinic in a language understood by patient, families and community.	Self explanatory.	These signages shall guide patients and visitors. It is preferable that signages are bi-lingual. Statutory requirements shall be met.
c)	The provision of space shall be in accordance with the available literature on good practices (Indian or International Standards)	Self explanatory.	
FMS.2. The Clinic has a programme for equipment management, safe water, electricity, medical gases and vacuum system as applicable.			
Sl. no	Objective Element	Interpretation	Remarks
a)	The Clinic plans for equipment in accordance with its services and strategic plan.	Self explanatory. This shall also take into consideration future requirements.	
b)	Potable water and electricity are available.	The Clinic shall make arrangements for supply of adequate potable water and electricity.	For water quality refers to IS 10500.
c)	Alternate sources are provided for in case of failure.	Alternate electric supply could be from DG Sets, solar energy, UPS and any other suitable source.	
d)	The organisation regularly tests the alternate sources.	Self explanatory.	
e)	Safety precautions are followed	Self explanatory.	

	with respect to medical gases and where applicable piped medical gas, compressed air & vacuum installation/equipment.		
FMS.3. The Clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.			
<i>Sl. no</i>	<i>Objective Element</i>	<i>Interpretation</i>	<i>Remarks</i>
a)	The Clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.	<p>The Clinic has conducted an exercise of hazard identification and risk analysis (HIRA) and accordingly taken all necessary steps to eliminate or reduce such hazards and associated risks.</p> <p>a) fire plan covering fire arising out of burning of inflammable items, explosion, electric short circuiting or acts of negligence or due to incompetence of the staff on duty.</p> <p>b) acquired adequate fire fighting equipment for this which records are kept up-to-date.</p> <p>c) Adequate training of staff.</p> <p>d) Exit plans well displayed.</p> <p>e) Emergency illumination system which comes into effect in case of a fire.</p> <p>Non-fire emergency situations include : Spillage of hazardous (acids, mercury, etc.),</p>	The National Building Code is a good reference guide.

		<p>infected materials (used gloves, syringes, tubing, sharps, etc.)</p> <p>medical wastes (blood, pus, amniotic fluid, vomits, etc.)</p> <p>fall or slips (from height or on floor) or collision of personnel in passageway</p> <p>fall of patient from bed</p> <p>sudden failure of supply of electricity, gas, vacuum, etc</p> <p>bursting of boilers and /or autoclaves</p> <p>The Clinic has established liaison with civil and police authorities and fire brigade as required by law for enlisting their help and support in case of an emergency.</p>	
b)	A staff is trained for their role in case of such emergencies.	In case of fire designated person are assigned particular work. Mock drills are also held	
c)	The Clinic has addressed identification, spill management, training of staff storage and disposal of Hazardous materials	The Clinic has identified and listed the hazardous materials and has a documented procedure for their sorting, storage, handling, transpirations, disposal mechanism, and method for managing spillages and adequate training of the personnel for these jobs.	The hazardous materials could be identified as per part II of Manufacture, Storage and Import of Hazardous Chemical (Amendment) Rules, 2000. In addition Biological materials like blood, body fluids and microbiological cultures, mercury, nuclear isotopes, medical gases, LPG gas, steam, ETO etc are some of the other

			common hazardous materials.
d)	The Clinic defines and implements its policies to reduce or eliminate smoking.	Smoking in public places including Clinics and hospitals has been banned in this country.	

CHAPTER 8

Community Participation And Integration (CPI)

CPI.1. The commitment of the Clinic to Health promotion and disease prevention is evident in its mission statement, value statement, collaborative arrangements with local, regional and national agencies and relevant policies and community participation			
Sl. no	Objective Element	Interpretation	Remarks
a)	The clinic defines Policies and procedures for health promotion / wellness and disease prevention / control programs that it participates in, as applicable.		
b)	The Clinic keeps abreast and implements national/regional or local standards and guidelines which are in consonance with its mission and objectives.	The clinic, as per its scope of services, shall participate in the National or local Health Programs / activities for Health promotion and prevention and control of diseases.	The participation may include education, counselling, health advice, screening and testing, immunizations (as per universal immunization program), medications and other preventive services including consultations, assessments, referrals etc
c)	Clinic provides education, counselling and information to community partners and priority population on variety of topics for health promotion, Health protection, and disease prevention and control.	IEC includes public health messages, breast-feeding, adolescent health, safe sex, anaemia, nutrition, vitamin A and D deficiencies, Healthy eating and life style, tobacco-free living, communicable diseases, HIV/AIDS	Staff and centers displays / distributes the plans and programs (specific to the area and as per the scope of the clinic) of the government by using IEC tools available e.g. posters, pamphlets, wall hangings, paintings, audio-visual aids etc. clinic may organize

		<p>etc. The clinic will give advice on sanitation, hygiene, safe and drinking water (potable). If available, it will distribute chlorine tablets to community. IEC can be in form of individual counselling, workshops, educational material, appropriate signage's inside and outside the facility etc.</p> <p>Clinic may train community on household remedies and first aid</p> <p>The IEC materials will be culturally appropriate and will also be in local languages particularly addressing low reading levels through use of symbols</p>	<p>campes, melas, health competitions</p> <p>Thrust may be given to reproductive and child health services as appropriate.</p> <p>The clinic will endeavor to mobilize community participation in health programs</p>
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d)	Clinic cooperates and collaborates with the community partners in provision of surveillance, epidemiological investigations, data collection, when required..	<p>The clinic will implement processes and protocols for this.</p> <p>The cooperation includes sharing / reporting of reliable and valid data and of trends, recognizing and reporting epidemiological alerts, cooperation in outbreak investigations and control. The clinic will identify diseases requiring outbreak investigations and prepare a short list of “warning signals” and the personnel are trained to remain alert about these signals and respond rapidly. In case the clinic is a surveillance site reporting to the surveillance system then it will maintain documentation of regular reporting of surveillance data.</p>	<p>This is used for identifying health problems, threats Preparedness for outbreak investigations and control</p> <p>Contingency plans, continuity plans and emergency response plan</p> <p>Training Laboratory Supplies IEC</p> <p>The scope of health data is broad and will include data as required by prevailing laws and regulations and guidelines of local / state / national agencies or professional bodies.</p>
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e)	There is a process in place for reporting notifiable diseases as per prevailing law and regulations.	The clinic ensures timely notification of Notifiable diseases and assists the appropriate authorities. Documentation includes tracking of reporting, lab tests and / or investigations with actual timelines noted.	The Clinic shall identify all notifiable diseases after taking into consideration the local laws, rules, regulations and notifications thereof. The Clinic shall ensure that this is sent at the specified frequency and in the format as required by statutory authorities.
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GLOSSARY

The commonly used terminologies in the NABH standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated where ever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

Accreditation	<p>1. A process of external review of the quality of the health care being provided by a health care organization. This is generally carried out by a non-governmental organization</p> <p>2. It also represents the outcome of the review and the decision that an eligible organization meets an applicable set of standards.</p>
Accreditation assessment	<p>The evaluation process for assessing the compliance of an organization with the applicable standards for determining its accreditation status.</p> <p>NABH assessment includes the following:-</p> <ul style="list-style-type: none"> Documentation review. Facility tour Interview of staff, patients and visitors On-site observations by assessors (e) Education about standards compliance
Ambulance	<p>A patient carrying vehicle having facilities to provide unless otherwise indicated atleast basic life support during the process of transportation of patient. There are various types of ambulances that provide special services viz. coronary care ambulance, trauma ambulance, air ambulance, etc.</p>
Basic life support	<p>Emergency procedures performed to sustain life that include cardiopulmonary resuscitation, control of bleeding, treatment of shock, stabilization of injuries and wounds and first aid.</p> <p>Basic life support consists of a number of life-saving techniques which are focused on the "ABC"s of prehospital emergency care:</p> <ul style="list-style-type: none"> Airway: the protection and maintenance of patient airway including the use of airway adjuncts such as an oral or nasal airway Breathing: the actual flow of air through respiration, natural or artificial, respiration often assisted by emergency oxygen Circulation: the movement of blood through the beating of the heart or the emergency measure of CPR <p>BLS may also include considerations of patient transport such as the protection of the cervical spine and avoiding additional injuries through splinting and immobilization.</p>
Bylaws	<p>A rule governing the internal management of an organization. It can supplement or complement the government law but cannot countermand it. e.g. municipal bylaws for construction of hospitals/ nursing homes, for disposal of hazardous and/or infectious waste</p>
Clinical audit	<p>Analysis of clinical aspects of patient care for improving the quality of health care services e.g. X-Ray audit, lab investigation audit, etc.</p>
Clinical practice guidelines	<p>Guidelines that assist practitioners to provide appropriate clinical care for specific clinical conditions, for example recommendation on management of cerebral malaria. The guideline include relevant history taking, physical signs to look for, lab investigations to be carried out and treatment to be prescribed.</p>

Competence	Demonstrated ability to apply knowledge and skills. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific action. For example, a competent gynaecologist knows about the pathophysiology of the female genitalia and can conduct both normal as well as abnormal deliveries.
Confidentiality	Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as privacy of information related to his/her health care records.
Consent	1. Willingness of a party to undergo examination/procedure/ treatment by a health care provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the health care provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to take an informed decision of his/her health care. 2. In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every <u>contract</u> and every agreement.
Credentialing	The process of obtaining, verifying and assessing the qualification of a health care provider.
Data	Raw facts, clinical observations, or measurements collected during an assessment activity.
Employees	All members of the health care organization who are employed full time and are paid suitable remuneration for their services as per the laid down policy.
Ethics	Medical ethics is the discipline of evaluating the merits, risks, and social concerns of activities in the field of medicine. (en.wikipedia.org/wiki/Medical_ethics)
Evidence based medicine	1. It is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patient 2. It also implies making medical decisions and applying the same to patients based on the best external evidence combined with the physician's clinical expertise and the patient's desires.
Family	The person(s) with a significant role in the patients life. It mainly includes spouse, children, parents. It may also include a person(s) not legally related to the patient but can make health care decisions for a patient if the patient loses decision making ability.
Formulary	An approved list of prescription drugs that a health care facilities may provide to their clientele. Some plans restrict prescriptions to those contained on the formulary and others also provide nonformulary prescriptions. Drugs contained on the formulary are generally those that are determined to be cost effective and medically effective. The list is compiled by professionals and physicians in the field and is updated preferably each year Changes may be made depending on availability or market
Grievance handling procedures	Sequence of activities carried out to address the grievances of patients, visitors, relatives and staff
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.

Hazardous waste	Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include biologic waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.
Health care organization	Generic term is used to describe the various types of organization that provide health care services. This includes ambulatory care centres, hospitals, laboratories, etc.
In service education/ training	Organised education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.
Indicator	A Statistical measure of the performance of functions, systems or processes overtime, For example, hospital acquired infection rate mortality rate, caesarian section rate, absence rate, etc.
Information	Processed data which lends meaning to the raw data.
Intent	A brief explanation of the rationale, meaning and significance of the standards laid down in a particular chapter.
Inventory control	The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure adequate supply without stockouts/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
Job description	1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job. 2. A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes job specifications that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.
Job specification	1. The qualifications/physical requirements, experience and skills required to perform a particular job/task. 2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.
Laws	Legal document setting forth the rules of governing a particular kind of activity e.g. organ transplantation act which governs the rules for undertaking organ transplantation.
Medical audit	A peer review carried out by analysis of medical records with a view to improve the quality of the patient care
Medical equipment	Any fixed or portable non drug item or apparatus used for diagnosis, treatment, monitoring and direct care of patient.
Mission	A written expression that sets forth the purpose of the organization. it usually precedes the formation of goals and objectives

Monitoring	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g. monitoring of growth and nutritional status, air quality in operation theatre. It requires careful planning and use of standardised procedures and methods of data collection.
Multi-disciplinary	A generic term which includes representatives from various disciplines, professions or service areas.
Nosocomial/ hospital acquired/ hospital associated infection (s)	An infection occurring in a patient in a hospital or other healthcare facility in whom it was not present or incubating at the time of admission; or the residual of an infection acquired during a previous admission. Includes infections acquired in the hospital but appearing after discharge, and also such infections among the staff of the facility (Synonym: hospital-acquired-infection).(www.hardydiagnostics.com/Glossary N.html)
Notifiable disease	Certain specified diseases which are required by law to be notified to the public health authorities. Under the international health regulation the following diseases are notifiable to WHO:- Cholera Plague Yellow fever In India the following diseases are also notifiable and may vary from state to state: Polio Influenza Malaria Rabies HIV/AIDS Louse-borne typhus Tuberculosis Leprosy Leptospirosis Viral hepatitis Dengue fever The various diseases notifiable under the factories act are lead poisoning, bysinnosis, anthrax, asbestosis and silicosis
Objective element	It is that component of standard which can be measured objectively on a rating scale. The acceptable compliance with the measureable elements will determine the overall compliance with the standard.
Occupational health hazard	The hazards to which an individual is exposed during the course of performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards.
Organogram	A graphic representation of reporting relationship in an organization.
Outsourcing	Hiring of services and facilities from other organization based upon ones own requirement in areas where such facilities are either not available or else are not cost-effective. e.g. out sourcing of house keeping, security, laboratory/certain special diagnostic facilities with other institutions after drawing a memorandum of understanding that clearly lays down the obligations of both the organizations, the one which is outsourcing and the one which is providing the outsourced facility. It also addresses the quality related aspects.
Patient care setting	The location where a patient is provided health care as per his needs e.g. ICU, speciality ward, private ward and general ward.

Patient record/ medical record/ clinical record	A document which contains the chronological sequence of events that a patient undergoes during his stay in the health care organization. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary. (Death certificate where required)
Performance appraisal	It is the process of evaluating the performance of employees during a defined period of time with the aim of ascertaining their suitability for the job, potential for growth as well as determining training needs.
Plan of care	A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.
Policies	They are the guidelines for decision making, e.g. admission, discharge policies, antibiotic policy, etc.
Privileging	It is the process for authorising all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.
Procedure	1. A specified way to carry out an activity or a process. (Para 3.4.5 of ISO 9000:2000) 2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
Process	A set of interrelated or interacting activities which transform inputs into outputs (Para 3.4.1 of ISO 9000:2000)
Program	A sequence of activities designed to implement policies and accomplish objectives
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	1. Degree to which a set of inherent characteristics fulfil requirements (para 3.1.1 of ISO 9000:2000) Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000 : 2000) Requirements are a need or expectation that is stated, generally implied or obligatory(para 3.1.2 of ISO 9000:2000) 2. Degree of adherence to pre-established criteria or standards.
Quality assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled. (Para 3.2.11 of ISO 9000:2000)
Re-assessment	It implies continuous and on-going assessment of the patient which are recorded in the medical records as progress notes.
Resources	It Implies all inputs in terms of men, material, money, machines, minutes (time), methods, meters (space), skills, knowledge and information that are needed for efficient and effective functioning of an organization.

Risk management	Clinical and administrative activities to identify, evaluate and reduce the risk of injury.
Safety	The degree to which the risk of an intervention/procedure, in the care environment are reduced for a patient, visitors and health care providers
Scope of services	Range of clinical and supportive activities that are provided by a health care organization.
Security	Protection from loss, destruction, tampering, and unauthorized access or use.
Sedation	<p>The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation: -</p> <p>Minimal sedation (anxiolysis) A drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are not affected.</p> <p>Moderate sedation / analgesia (Conscious sedation) – A drug induced deression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. No interventions are needed to maintain a patent airway.</p> <p>Deep sedation/Analgesia – A drug induced deression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. Patients may need help in maintaining a patent airway.</p>
Sentinel events*	<p>A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of health care services</p> <p>Major and enduring loss of function <i>refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.</i></p>
Social responsibility	A balanced approach for organization to address economic, social and environmental issues in a way that aims to benefit people, communities and society, e.g. adoption of villages for providing health care, holding of medical camps and proper disposal of hospital wastes.
Staff	All personnel working in the organization either as full paid employees or as consultants on honorarium basis
Standard precautions	<p>1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other bloodborne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping</p> <p>2. A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is "Don't touch or use anything that has the victim's body fluid on it without a barrier." It also assumes that all body fluid of a patient is infectious, and must be treated accordingly</p> <p>Standard Precautions apply to Blood, all body fluids, secretions, and excretions (except sweat) regardless of whether or not they contain visible blood, non-intact skin and mucous membranes</p>
Standards	A statment of expectation that defines the structures and process that must be substantially in place in an organization to enhance the qualify of care.
Sterilization	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.

Surveillance	The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.
Unstable patient	A patient whose vital parameters need external assistance for their maintenance.
Validation	<p>1. Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (Para 3.8.5 of ISO 9000: 2000) Objective Evidence – Data supporting the existence or variety of something (Para 3.8.1 of ISO 9000: 2000)</p> <p>2. The checking of data for correction or for compliance with applicable standards, rules or conventions. These are the tests to determine whether an implemented system fulfills its requirements. It also refers to what extent does a test accurately measures what it purports to measure.</p>
Vulnerable patient	Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status, e.g. infants, elderly, physically and mentally challenged, those on immunosuppressive and/or chemotherapeutic agents.

List of Licenses and Statutory Obligations

All of them might not be applicable to all the Clinics. The Clinic operator/owner has the responsibility to identify and update applicable state level Licenses/ statutory obligations and maintain them.

1. AERB Act and Rules of Safety Code Building Permit (From the Municipality).
2. No objection certificate from the Chief Fire officer.
3. License/regulations under Bio- medical Management and handling Rules, 1998.
4. No objection certificate under Pollution Control Act.
5. Radiation Protection Certificate in respect of all X-ray and CT Scanners from BARC.
6. Excise permit to store Spirit.
7. Income tax PAN.
8. Permit to operate lifts under the Lifts and escalators Act.
9. Narcotics and Psychotropic substances Act and License.
10. Sales Tax Registration certificate.
11. Vehicle registration certificates for Ambulances.
12. Retail drug license (Pharmacy).
13. Wireless operation certificate from Indian post and telegraphs. (if applicable)
14. Air (prevention and control of pollution) Act, 1981 and License
15. Arms Act, 1950. (if guards have weapons)
16. Atomic energy regulatory body approvals.
17. Biomedical waste management handling rules 1998.
18. Boilers Act 1923.
19. Cable television networks Act 1995.
20. Central sales tax Act, 1956.
21. Consumer protection Act, 1986.
22. Contract Act, 1982.
23. Copyright Act, 1982.
24. Customs Act, 1962.
25. Dentist regulations, 1976.
26. Drugs & cosmetics Act, 1940.
27. Electricity Act, 1998.
28. Electricity rules, 1956.
29. Employees provident fund Act, 1952.
30. ESI Act, 1948.
31. Employment exchange Act, 1969.
32. Environment protection Act, 1986.
33. Equal remuneration Act, 1976.
34. Explosives Act 1884.
35. Fatal accidents Act 1855.

36. Gift tax Act, 1958.
37. Hire Purchase Act, 1972.
38. Income Tax Act, 1961.
39. Indian Lunacy Act, 1912.
40. Indian medical council Act and code of medical ethics, 1956.
41. Indian Nursing council Act 1947.
42. Indian penal code, 1860.
43. Indian trade unions Act, 1926.
44. Industrial disputes Act, 1947
45. Insecticides Act, 1968
46. lepers Act
47. Maternity benefit Act, 1961
48. MTP Act, 1971.
49. Minimum wages Act, 1948.
50. National holidays under shops Act.
51. Negotiable instruments Act, 1881.
52. Payment of bonus Act, 1965.
53. Payment of gratuity Act, 1972.
54. Payment of wages Act, 1936.
55. Persons with disability Act, 1995.
56. Pharmacy Act, 1948.
57. PNDT Act, 1996.
58. Prevention of food adulteration Act, 1954.
59. Protection of human rights Act, 1993.
60. PPF Act, 1968.
61. Registration of births and deaths Act, 1969.
62. Sale of goods Act, 1930.
63. Tax deducted at source Act.
64. Sales tax Act.
65. SC and ST Act, 1989
66. License for the blood bank
67. Companies Act, 1956
68. Constitution of India
69. Insurance Act, 1938
70. Workers compensation Act, 1923
71. Urban land Act, 1976

Recommendatory practices (Reference Document)

1. National Building Code, 2005
2. National Electric code,
3. Other Applicable Indian Standards.



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