

# **ACCREDITATION STANDARDS FOR AYURVEDA CLINICS**

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**NATIONAL ACCREDITATION BOARD FOR  
HOSPITALS AND HEALTHCARE PROVIDERS**

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## Table of Contents

Sr. No.	Particulars	Page No.
1.	Introduction	4
2.	Scope of services	5
3.	Access, Assessment and Continuity of Care (AAC)	7
4.	Care of Patients (COP)	14
5.	Management of Medication ( MOM)	23
6.	Patient Rights and Education (PRE)	27
7.	Clinic Infection Control (CIC)	33
8.	Continuous Quality Improvement (CQI)	37
9.	Responsibilities of Management (ROM)	40
10.	Facility Management and Safety (FMS)	45
11.	Essential Documentation	50
12.	Glossary	51
13	List of Licenses and Statutory Obligations	58

## Introduction

Accreditation Standards for Ayurveda Clinics comprises objective elements and corresponding 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 clinic plans to deliver each standard and objective element therein.
- Evidence that demonstrate that the clinic is implementing these policies, protocols and/or strategies.
- Evidence that demonstrates that the clinic is monitoring and evaluating its performance regularly in the implementation of its policies, protocols and strategies.

## Scope of Services

### Definition of Ayurveda Clinic:

A standalone outpatient healthcare facility that provides AYURVEDA services by Doctor(s) registered with Central or State AYURVEDA Systems Practitioners' Board/Council.

In addition a "clinic" may have add on services such as diagnostic laboratory services, therapeutic procedures, pharmacy etc. *Such "add on services shall be controlled by the clinic to ensure that the best interests of the clinic and patients attending the clinic are served. Evidence of such control shall be maintained.*

### Exclusions:

Where a clinic seeks exclusion from the application of a particular standard objective element, justification shall be sought in writing. The accreditation process shall proceed only consequent to the on - site approval of the justifications by NABH team of assessors. The clinic shall retain its right of appeal as per NABH Appeals Procedure enunciated in its website: [www.nabh.co](http://www.nabh.co)

**ACCREDITATION STANDARDS  
FOR  
AYURVEDA CLINICS**

**Chapter 1**  
**Access Assessment and Continuity of Care (AAC)**

**Intent of the chapter:**

Patients are well informed of the services that a clinic provides. This will facilitate appropriately matching patients with the clinic's resources.

Patients that match the clinics resources are treated using a defined process. Patients treated, undergo an established assessment and periodic and regular reassessments. Patient care is continuous and multidisciplinary in nature.

The laboratory services, if present, are provided by competent staff in a safe environment for both patients and staff.

### Summary of Standards

<b>AAC.1.</b>	The Clinic defines and displays the services that it can provide.
<b>AAC.2.</b>	The Clinic has a defined patient registration process
<b>AAC.3.</b>	Patients cared for by the organisation undergo an established assessment before treatment.
<b>AAC.4.</b>	Patient care is continuous and multidisciplinary in nature.
<b>AAC.5.</b>	Laboratory services, where provided, are monitored by the clinics.



## Standards and Objective Elements

### Standard

<b>AAC.1.</b>	<b>The Clinic defines and displays the services that it can provide.</b>
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### Objective Elements

- a. The services provided are defined and displayed prominently.

**Interpretation:** The services so defined should be displayed prominently in an area visible to all patients entering the Clinic.

**Remark(s):** Claims of services should commensurate with the available expertise.

Care should be taken to ensure that the services are explained in a language the patient understands.

### Standard

<b>AAC.2.</b>	<b>The Clinic has a defined patient registration process.</b>
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### Objective Elements

- a. The Clinic has documented policies and procedures for registering the patients.

**Interpretation:** Clinic shall prepare document (s) detailing the policies and procedures for registration of patients.

- b. Patients are accepted only if the clinic can provide the required service.

**Interpretation:** The staff handling registration needs to be aware of the services that the clinic can provide. It is also advisable to have a system wherein the staff is aware as to whom to contact if they need any clarification on the services provided.

**Remark(s):** The patient registration and assessment process is designed to give priority to those who are obviously sick or those with urgent needs.

## Standard

<b>AAC.3.</b>	<b>Patients cared for by the organisation undergo an established assessment.</b>
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### Objective Elements

- a. The Clinic defines and documents the content of assessment.

**Interpretation:** The Clinic shall have a format using which a standardised assessment of patient is done.

**Remark(s):** Every assessment shall contain the findings of Roga and Rogi pareeksha.

## Standard

<b>AAC.4.</b>	<b>Patient care is continuous and multidisciplinary in nature.</b>
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### Objective Elements

- a. During all phases of care, there is a qualified individual designated as responsible for the patient's care.

**Interpretation:** The organisation shall ensure that the care of patients is always given by appropriately-qualified medical personnel (doctor, consultant and/or nurse).

**Remark(s):** Although care may be provided by a team, the clinic record shall identify a doctor as being responsible for patient care.

- b. Care of patients is coordinated in all care settings within the clinic.

**Interpretation:** Care of patients is co-ordinated among various care-providers in a clinic. The clinic shall ensure that there is effective communication of patient requirements amongst the care-providers.

- c. Information about the patient's care and response to treatment is shared among medical, nursing and other care-providers.

**Interpretation:** The organisation ensures periodic discussions about each patient (covering parameters such as patient care, response to treatment,

unusual developments if any, etc.) amongst medical, nursing and other care-providers.

**Remark(s):** This could be done on the basis of entries either on case sheet or on electronic patient records (EPR).

- d. The patient's record(s) is available to the authorised care-providers to facilitate the exchange of information.

**Interpretation:** Self-explanatory.

### Standard

<b>AAC.5.</b>	<b>Laboratory services, where provided, are monitored by the clinics.</b>
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### Objective Elements

- a. Lab services if provided on site will have a quality control and laboratory safety programme.

**Interpretation:** If present, laboratory services should commensurate with the health care services offered by the clinic.

The laboratory quality assurance and safety programme:

- 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
- Integrates with other Clinical safety program

**Remark(s):** If laboratory services are not available in the Clinic, patients may preferably be referred to laboratory based on their quality assurance system.

- b. Adequately qualified and periodically trained personnel perform and/or supervise the investigations.

**Interpretation:** The staff employed in the lab should be suitably qualified and trained to carry out the tests.

**Remark(s):** For adequacy of qualification refer to NABL 112 (Annexure).

- c. Documented policies and procedures guide collection, identification, handling, safe transportation, processing and disposal of specimens.

**Interpretation:** The Clinic has documented procedures for collection, identification, handling, safe transportation, processing and disposal of specimens, to ensure safety of the specimen till the tests and retests (if required) are completed.

**Remark(s):** The policy should be in line with standard precautions. The disposal of waste shall be as per the statutory requirements (Bio-medical waste management and handling rules, 1998.)

- d. Laboratory results are available within a defined time frame.

**Interpretation:** The Clinic shall define the turnaround time for all tests.

**Remark(s):** The turnaround time could be different for different tests and could be decided based on the nature of test and criticality of test.

- e. Critical results are intimated immediately to the concerned personnel.

**Interpretation:** 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.

**Remark(s):** If it is not practical to establish the biological reference interval for a particular analysis the laboratory should carefully evaluate the published data for its own reference intervals.

<b>AAC.6.</b>	<b>Clinic defines the content of treatment summary.</b>
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### Objective Elements

- a. Treatment summary is provided to the patients at the time of completion of treatment.

**Interpretation:** Summary of procedures, if any, undergone in the clinic. E.g. Nasya.

**Remark(s):** The treatment summary shall be signed by the treating doctor or a member of his/her team.

- b. Treatment summary contains the patient's name, unique identification number, treatment start date and treatment end date.

**Interpretation:** Self-explanatory.

- c. Treatment summary contains the reasons for treatment plan, significant findings and diagnosis and the patient's condition at the time of completion of treatment.

**Interpretation:** Self-explanatory.

- d. Treatment summary contains follow-up advice, medication and other instructions in an understandable manner.

**Interpretation:** Self-explanatory. This shall also incorporate preventive aspects, where appropriate.

**Remark(s):** The instructions shall be in a manner that the patient can easily understand and avoid use of medical terms, e.g. BID, TID, etc.

- e. Treatment summary incorporates instructions about when and how to obtain urgent care.

**Interpretation:** The organization should outline conditions regarding 'when' to obtain urgent care, in case of increase in any specific symptom related to treatment/procedure undergone.

**Remark(s):** This could be in the form of what medicines to take, when to consult a doctor or how to seek medical help and contact number of the clinic /doctor.

## Chapter 2 Care of Patients (COP)

### **Intent of the chapter:**

The clinic provides uniform care to all patients. Policies, procedures, applicable laws and regulations guide all patient care activities.

Policies, procedures, applicable laws and regulations also guide care of vulnerable patients (elderly, physically and/or mentally-challenged and children), paediatric patients, patients undergoing Panchakarma procedures, patients undergoing moderate sedation, administration of anaesthesia, patients undergoing para surgical procedures and research.

The standard aims to guide and encourage patient safety as the overall principle for providing quality care to patients.

### Summary of Standards

<b>COP 1:</b>	Care and treatment is provided in a uniform manner.
<b>COP 2:</b>	Patients with special needs & disabilities (vulnerable) shall be identified and treated accordingly.
<b>COP 3:</b>	Documented policies and procedures guide appropriate pain management.
<b>COP 4:</b>	Documented policies and procedures guide appropriate rehabilitative services.
<b>COP 5:</b>	Policies and procedures guide the care of patients undergoing para-surgical procedures.
<b>COP 6:</b>	Policies and procedures guide the Panchakarma Therapy.
<b>COP 7:</b>	Policies and procedures guide all research activities.

## Standards and Objective Elements

### Standard

COP.1.	Care and treatment is provided in a uniform manner.
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### Objective Elements

- a. Care of patients shall be in consonance with the defined scope.

**Interpretation:** The clinic shall have appropriate staff, facilities, protocols and procedures in consonance with the scope of service.

**Remark(s):** The access and appropriateness of the care do not mismatch the scope of services.

- b. Evidence based medicine and Clinical practice guidelines, as envisaged in Ayurveda, are adopted to guide patient care.

**Interpretation:** The Clinic could develop Clinical protocols and the same could be followed in management of patients. These could then be used as parameters for audit of patient care.



## Standard

<b>COP.2.</b>	<b>Policies and procedures guide the care of vulnerable patients</b>
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### Objective Elements

- a. **Vulnerable patients** shall be identified and treated accordingly.

**Interpretation:**

- The vulnerable patients include children, elderly, physically and/or mentally challenged.
- The Clinic provides for a safe and secure environment for this vulnerable group.
- Staff is trained to care for this vulnerable group.

**Remark(s):** Refer to disability act, mental act.

The Clinic shall provide proper environment taking into account the requirement of the vulnerable group.

## Standard

<b>COP.3.</b>	<b>Documented policies and procedures guide appropriate pain management.</b>
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### Objective Elements

- a. Documented policies and procedures guide the management of pain.

**Interpretation:** It shall include as to how patients are screened for pain, the mechanism to ensure that a detailed pain assessment is done (when necessary), pain mitigation techniques and monitoring.

- b. Patient and family are educated on various pain management techniques, where appropriate.

**Interpretation:** Self-explanatory.

**Remark(s):** This could be done only for patients who are likely to have long-term pain in view of the underlying condition not being treatable.

## Standard

<b>COP.4.</b>	<b>Policies and procedures guide appropriate rehabilitative services.(D)*</b>
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### Objective Elements

- a. Policies and procedures guide the provision of rehabilitative services.

**Interpretation:** Self-explanatory.

**Remark(s):** This includes physiotherapy, occupational therapy, speech therapy, etc.

- b. These scope of services are commensurate with the clinic requirements.

**Interpretation:** Self-explanatory.

## Standard

<b>COP.5.</b>	<b>Policies and procedures guide the care of patients undergoing Para-surgical procedures.</b>
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### Objective Elements

- a. The policies and procedures are documented.

**Interpretation:** This shall include the list of and para-surgical procedures as well as competency level for performing these procedures.

**Remark:** Para-surgical procedures such as Ksharasutra, Raktamokshana, Agnikarma, Kshara karma etc.

- b. An informed consent is obtained by a Physician/Surgeon prior to the procedure.

**Interpretation:** Self-explanatory.

The duly filled consent form shall be taken by the treating physician / surgeon or a member of his team. In case, the procedure is changed intra-op (and was not planned or an explicit consent taken for the same) a fresh consent needs to be taken.

- c. Para-surgical patients have a preoperative assessment and a provisional diagnosis documented prior to procedure.

**Interpretation:** All patients undergoing Para-surgical procedures are assessed pre-operatively and a provisional diagnosis is made which is documented. This shall be applicable for both routine and emergency cases.

**Remark(s):** This shall be done by the treating physician / surgeon.

- d. Policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong surgery.

**Interpretation: Self-explanatory.**

**Remark(s):** The organisation should be able to demonstrate methods to prevent these events, e.g. identification tags/ badges / cross-checks etc.

- e. Para-surgical procedures and local anaesthesia shall be performed only in facilities exclusively meant for that purpose.

**Interpretation:**

- Competent person will administer the local anaesthesia and monitoring facilities will be available.
- Recovery criteria will be used to send the patient home after period of monitoring. Facility to manage adverse events, if any, due to local anaesthesia should be available.

**Remark(s): Local Anaesthesia to be given by legally competent person.**

- f. The quality assurance program includes surveillance of the minor OT environment.

**Interpretation:** Surveillance activities include the monitoring of efficacy of Minor OT cleaning and disinfection processes etc.

## Standard

<b>COP.6.</b>	Policies and procedures guide the care of patients undergoing Panchakarma Therapy and other Treatment procedures.
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### Objective Elements

- a. The policies and procedures are documented.

**Interpretation:** This shall include the list of Panchakarma therapies and Treatment Procedures as well as competency level for performing these procedures.

**Remarks:** Examples of Treatment procedures: Abhyanga, Pinda sweda etc.; Shalakyia procedures like Kriya kalpas, Prasooti & Stree roga procedures like Uttara basti, pichu, prakshalana, etc.,

- b. An informed consent is obtained by the physician prior to procedure.

**Interpretation:** Self-explanatory.

In case of change in care plan, a fresh consent needs to be taken.

- c. Patients undergoing Panchakarma therapies have a pre-procedure assessment.

**Interpretation:** Self-explanatory.

**Remark(s):** This shall be done by the physician and includes yogya-ayogya for the particular therapy.

- d. Persons qualified by law are permitted to perform the procedures that they are entitled to perform.

**Interpretation:** The organization identifies the individuals who have the required qualification(s), training and experience to perform procedures in consonance with the law.

- e. A brief note of the procedure is documented prior to transfer of patient from therapy/Procedure room.

**Interpretation:** This note provides information about the procedure performed and the condition of the patient documented by the Physician/Paricharak.

**Remark(s):** It includes monitoring of *samyak* and *asamyak lakshanas* of the procedure. If it is documented by a person other than the physician, the same shall be countersigned by the Physician.

- g. The Physician documents the post-procedure plan of care.

**Interpretation:** Self-explanatory.

**Remark(s):** The plan shall include advice on *samsarjana krama* for *vamana/virechana*, *pathya-apathya* for other procedures, observing for any *vyapaths*, etc.

- h. Adequate area, appropriate facilities and equipment/instruments are available in the Panchakarma therapy and Treatment procedure room.

**Interpretation:** Panchakarma therapy and treatment procedure room may be combined or separate. If combined the minimum area shall be 180 sq. ft. and 150 sq. ft. if separate with attached toilet and bathroom with hot water facility. The rooms shall have sufficient light and ventilation.

**Remarks:** Refer annexure-II for list of equipment/instruments

- i. Standard precautions and asepsis is adhered to during the conduct of therapies.

**Interpretation:** Self-explanatory.

**Remark(s):** In case the organization has a policy of re-using instruments/devices it shall ensure that they are properly sterilized/cleaned, whichever is appropriate.

- j. A quality assurance program is followed for the Panchakarma therapy and other Treatment procedures.

**Interpretation:** This shall be an integral part of the organisation's overall quality assurance programme. It shall focus on *yogya-ayogya lakshanas*, *samyak-asamyak lakshanas*, *vyapaths*, etc.

- k. The quality assurance program includes surveillance of the Panchakarma theatre and treatment procedure room.

**Interpretation:** Surveillance activities include monitoring the efficiency of cleaning and disinfection processes etc.

- l. Guidelines for various Panchakarma therapy and other Treatment Procedures are prepared separately and adhered.

**Interpretation:** SOPs for the documented procedures are prepared based on classical texts like *Charaka Samhita*, *Susruta Samhita*, *Astangahridaya*, etc.

Remarks: *Vamana karma* protocol, *Abhyanga* protocol, *Netra tarpana* protocol, *pichu* protocol, etc

## Standard

<b>COP.7.</b>	<b>Policies and procedures guide all research activities.</b>
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## Objective Elements

- a. Policies and procedures guide all research activities in compliance with the applicable law and national and international guidelines.

**Interpretation:** Self-explanatory

**Remark(s):** 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).

- b. Policies and procedures address Patient's informed consent, their right to withdraw, their refusal to participate in the research activities.

**Interpretation:** 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** **Management of Medication (MOM)**

### **Intent of the chapter:**

The organisation has a safe and organised medication process. The process includes policies and procedures that guide the availability, safe storage, prescription, dispensing and administration of medications.

The standards encourage integration of the pharmacy into everyday functioning of clinics and patient care. The pharmacy should have oversight of all medications stocked out of the pharmacy. The pharmacy should ensure correct storage (as regards to temperature, look-alike, sound-alike etc.), expiry dates and maintenance of documentation.

The process also includes monitoring of patients after administration and procedures for reporting and analysing medication errors.

Patients and family members are educated about safe medication and food-drug interactions.

### Summary of Standards

<b>MOM 1:</b>	Medication use is organized to meet patient needs and complies with applicable laws and regulations.
<b>MOM 2:</b>	Medication prescription, dispensing and administration follow standardized processes to ensure patient safety.
<b>MOM 3:</b>	Adverse drug reactions & the medication errors, if any, are appropriately addressed.



## Standards and Objective Elements

### Standard

<b>MOM.1.</b>	<b>Medication use is organized to meet patient needs and complies with applicable laws and regulations.</b>
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### Objective Elements

- a. Policies and procedures guide how the Clinic will meet medication needs of the patient.

**Interpretation:** The Clinic shall give written prescription of medication to the patient.

- b. The medication used meets applicable laws & regulations.

**Interpretation:** Applicable laws & regulations (as in annexure ).

- c. The medications available are appropriate to the Clinic's mission, scope of services and patient needs.

**Interpretation:** Self explanatory

- d. Policies and procedures guide the procurement process, storage, labelling and management of medications.

**Remark(s):** Inventory management of Medicine / consumables may follow first expiry first out principle. Samples should also be addressed.

### Standard

<b>MOM.2.</b>	<b>Medication prescription, dispensing and administration follow standardized processes to ensure patient safety.</b>
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### Objective Elements

- a. Medications are prescribed, dispensed and administered by authorized persons.

**Interpretation:** These should be in compliance with regulations, licensure etc.

- b. Medications are prescribed in a clear legible manner, dated and timed.

**Interpretation:** Self explanatory

- c. In case medications are dispensed at the Clinic, standardized policies and procedures are used for safe dispensing.

**Interpretation:** These should address identification, storage, expiry dates, sound alike look alike segregation, licensing requirements etc.

### Standards

<b>MOM.3.</b>	<b>Adverse drug reactions &amp; the medication errors, if any, are appropriately addressed.</b>
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### Objective Elements

- a. Policies and procedures will define reporting, analysing and corrective and preventive actions for medication error and adverse drug reactions.

**Interpretation:** Prescription audit, to be carried out. Medication errors, near misses, patient reported outcomes, to be reviewed. Corrective and preventive actions to be recorded.

**Remark(s):** Attempts are made as per recall mechanisms. Policies are modified to reduce adverse drug events when unacceptable trends occur.

- b. Patients and family members are educated about safe and effective use of medication and food-drug interactions.

**Interpretation:**

- Methodology of patient education may include patient education pamphlets etc.
- They are advised to report any adverse drug reactions.

## Chapter 4

### Patient Rights and Education (PRE)

#### **Intent of the chapter:**

The clinic defines the patient and family rights and responsibilities. The staff is aware of these and is trained to protect patient rights. Patients are informed of their rights and educated about their responsibilities. They are informed about the disease, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to patient and/or family. The patients are educated about the mechanisms available for addressing grievances.

A documented process for obtaining patient and/or families consent exists for informed decision making about their care as per the prevailing law.

Patient and families have a right to information and education about their healthcare needs in a language and manner that is understood by them.

### Summary of Standards

<b>PRE 1</b>	The Clinic protects patient and family rights.
<b>PRE 2</b>	Patient rights support individual beliefs, values and involve the patient and family in decision making processes.
<b>PRE 3</b>	A documented process for obtaining patient and / or families consent exists for informed decision making about their care.
<b>PRE 4</b>	Patient and families have a right to information and education about their healthcare needs.
<b>PRE 5</b>	Patient and families have a right to information on expected costs.

## Standards and Objective Elements

### Standard

<b>PRE.1.</b>	<b>The Clinic protects patient and family rights.</b>
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### Objective Elements

- a. Patient and family rights and responsibilities are displayed.

**Interpretation:** The Clinic should respect patient's rights and inform them of their responsibilities.

- b. Staff is aware of their responsibility in protecting patient's rights.

**Interpretation:** Training and sensitisation programmes shall be conducted to create awareness among the staff.

### Standard

<b>PRE.2.</b>	<b>Patient rights support individual beliefs, values and involve the patient and family in decision making processes.</b>
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### Objective Elements

- a. Patient rights include respect for personal dignity and privacy during examination, procedures and treatment.

**Interpretation:**

- 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.
- With regards to photographs/recording procedures; the Clinic shall ensure that consent is taken and that the patient's identity is not revealed.

- b. Patient rights include protection from physical abuse or neglect.

**Interpretation:** Special precautions shall be taken especially w.r.t vulnerable patients e.g. elderly, neonates etc.

**Remark(s):** Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations, manhandling etc.

- c. Patient and family rights include treating patient information as confidential.

**Interpretation:** The clinic shall keep the records in a secure manner and will release only under authorisation of the patient except under statutory obligation.

- d. Patient has the right to make an informed choice including the option of refusal.

**Interpretation:** The treating doctor shall discuss all the available options and allow the patient to take the decision.

**Remark(s):** In case of refusal, the treating doctor shall explain the consequences of refusal of treatment and document the same.

- e. Patient rights include information and consent before any research protocol is initiated.

**Interpretation:** 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.

- f. Patient has a right to have an access to his / her Clinical records.

**Interpretation:** 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.

### Standard

<b>PRE.3.</b>	<b>A documented process for obtaining patient and / or families consent exists for informed decision making about their care.</b>
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### Objective Elements

- a. The Clinic has listed those procedures and treatment where informed consent is required.

**Interpretation:** A list of procedures should be made for which informed consent should be taken.

- 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.

**Interpretation:** The consent shall have the name of the doctor performing the procedure. Consent 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.

**Interpretation:** 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.

### Standard

<b>PRE.4.</b>	<b>Patient and families have a right to information and education about their healthcare needs.</b>
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### Objective Elements

- a. When appropriate, patient and families are educated about the safe and effective use of medication and the potential side effects of the medication.

**Interpretation:** Self-explanatory.

- b. Patient and families are educated about diet and nutrition.

**Interpretation:** Self-explanatory.

- c. Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.

**Interpretation:** Self-explanatory. This could also be done through patient education booklets/videos/leaflets etc.

## Standard

<b>PRE.5.</b>	<b>Patient and families have a right to information on expected costs.</b>
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### Objective Elements

a. The tariff list is available to patients.

***Interpretation:***

- Ethical billing practices are ensured.
- The Clinic shall ensure that there is an updated tariff list and that this list is available to patients.
- 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.
- The tariff rates should be uniform and transparent.

b. Patients are informed about the estimated costs of treatment.

***Interpretation:*** The patients are informed about the approximate cost of treatment in lieu with the line of treatment followed and the tariff list.

c. Billing, receipts and records are maintained as per statutory requirements.

***Interpretation:*** Self-explanatory.



## **Chapter 5**

### **Clinic Infection Control (IC)**

#### **Intent of the chapter:**

The standards guide the provision of an effective infection control programme in the clinic. The programme is documented and aims at reducing/eliminating infection risks to patients and providers of care.

The clinic measures and takes action to prevent or reduce the risk of nosocomial Infection in patients and employees.

The clinic provides proper facilities and adequate resources to support the Infection Control Programme.

The programme includes an action plan to control outbreaks of infection, disinfection/sterilisation activities, biomedical waste (BMW) management, training of staff and employee health.

### Summary of Standards

<b>CIC 1</b>	Infection control practices and adherence to standard precautions and hygienic practices shall be observed at all times in the clinic.
<b>CIC 2</b>	The Clinic complies with Bio Medical Waste Management Rules and associated regulations.

## Standards and Objective Elements

### Standard

<b>CIC.1.</b>	<b>Infection control practices and adherence to standard precautions and hygienic practices shall be observed at all times in the clinic.</b>
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### Objective Elements

- a. It focuses on adherence to standard precautions at all times.

**Interpretation:**

- Hand washing facilities are accessible to clinic staff.
- Adequate gloves, masks, soaps, and disinfectants are available and used correctly.

**Remark(s):** Refer to glossary for “standard precautions”.

- b. Cleaning, disinfection of surfaces, equipment cleaning, and laundry and sterilization practices are performed and monitored.

**Interpretation:** As applicable to the type of Clinic and services, the policies and practices will address all relevant aspects.

- c. Laundry and linen management processes are also included.

**Interpretation:**

- Clean, linen and laundry service as applicable.
- In case of minor procedures where sterile precautions are needed, these should be addressed.

- d. Staffs are aware of infection control practices.

**Interpretation:** Example Training on Hand hygiene, BMW, personal protective equipment, cleaning disinfection and sterilization etc.

- e. Staffs are aware of occupational hazard.

***Interpretation:***

- 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.

**Standard**

<b>CIC.2.</b>	<b>The Clinic complies with Bio Medical Waste Management Rules and associated regulations.</b>
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**Objective Elements**

- a. Bio Medical waste is collected, handled, segregated and disposed of as per the regulations.

***Interpretation:*** Self-explanatory.

- b. Staff is trained to handle BMW, and follow precautions.

**Chapter 6**  
**Continual Quality Improvement (CQI)**

**Intent of the chapter:**

The standards encourage an environment of continual quality improvement. The quality and safety programme should be documented and involve all aspects of the clinic including the staff members.

### Summary of Standards

<b>CQI 1</b>	The clinic identifies key indicators which are used as tools for continual improvement.
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## Standards and Objective Elements

### Standard

<b>CQI.1.</b>	<b>The clinic identifies key indicators which are used as tools for continual improvement.</b>
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### Objective Elements

- a. The clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.

***Interpretation:***

Monitoring may include:

- Appropriate patient assessment.
- Adverse drug reaction.
- Content of patient records(outpatient)
- Infection control activities.
- Clinical research.

- b. The clinic develops appropriate key performance indicators suitable to monitor managerial structures, processes and outcomes.

***Interpretation:***

Monitoring may include

- Procurement of medication essential to meet patient needs.
- Reporting of activities as required by laws and regulations.
- Risk management.
- Patient satisfaction
- Staff satisfaction.
- Data collection to support further study for improvements.

- c. Corrective and preventive actions are taken and monitored for effectiveness with respect to key indicators being monitored.

***Interpretation:*** This data is analysed for improvement opportunities and the same are carried out.

**Chapter 7**  
**Responsibilities of Management (ROM)**

**Intent of the chapter:**

The standards encourage the governance of the clinic in a professional and ethical manner. The responsibilities of the management are defined. The clinic complies with all applicable regulations.

Clinic ensures that patient-safety and risk-management issues are an integral part of patient care.



### Summary of Standards

<b>ROM 2</b>	The Clinic is managed by the leaders in an ethical manner.
<b>ROM 3</b>	The Clinic initiates and maintains a patient record for every patient.
<b>ROM 4</b>	Those responsible for management have addressed all applicable aspects of human resource management.

## Standards and Objective Elements

### Standards

ROM.1.	The Clinic is managed by the leaders in an ethical manner.
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### Objective Elements

- a. The Clinic functions in an ethical manner.

**Interpretation:** "Code of medical ethics" to be followed.

- b. The Clinic discloses its ownership.

**Interpretation:** The ownership of the Clinic e.g. trust, private, public has to be disclosed.

**Remark(s):** The disclosure could be in the registration certificate/quality manual etc.

- c. The Clinic honestly portrays its affiliations and accreditation.

**Interpretation:** Here portrays implies that the Clinic conveys its affiliations, accreditations for specific services or whole center wherever applicable.

- d. The clinic identifies documents and records evidence of compliance to applicable legislations and regulations.

**Interpretation: self-explanatory**

**Remark(s):** This shall include central legislations (e.g. Drugs and Cosmetics act, bio medical waste act, Air (Prevention and Control of Pollution) Act, 1981, 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. Appropriate authorities shall be informed about the notifiable diseases.

**Interpretation: self-explanatory**

**Remarks:** Eg.: Dengue fever, Cholera etc.

- f. The Clinic accurately bills for its services based upon a standard billing tariff.

**Interpretation:** Self-explanatory.

## Standards

<b>ROM.2.</b>	<b>The Clinic initiates and maintains a patient record for every patient.</b>
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### Objective Elements

- a. Every patient record has a unique identifier and the record contains sufficient information to meet patient care needs and regulatory requirements.

**Interpretation:** Self-explanatory.

- b. The retention period and storage requirements are defined and implemented.

**Interpretation:** Self-explanatory.

- c. Standardized forms and formats are used.

**Interpretation:** Self-explanatory.

- d. Remarks: ex: registration format, out patient assessment form

## Standards

<b>ROM.4.</b>	<b>The management have addressed all applicable aspects of human resource management.</b>
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### Objective Elements

- a. The Clinic maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.

**Interpretation:** The staff should be commensurate with the workload.

- b. The required job specifications and job description are well defined for each category of staff.

**Interpretation:** 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 description should be commensurate with the qualification.

**Remark(s):** 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.

**Interpretation:** Self-explanatory

- d. Each staff member, employee and voluntary worker is appropriately oriented to relevant department / unit / service/ programme's policies and procedures.

**Interpretation:** The relevant document is made available to the concerned department// unit / service/ personnel. This includes patient rights, employee rights and all departmental policies, safety, grievance redressal etc.

- e. Performance evaluation systems are in place, as applicable.

**Interpretation:** Appraisal, training needs identification, support for training, etc. is provided.

- f. Staff Health Problems are addressed.

**Interpretation:** This includes occupational health issues, medical check-ups as applicable.

## Chapter 8

### Facility Management and Safety (FMS)

#### **Intent of the chapter:**

The standards guide the provision of a safe and secure environment for patients and their families. The clinic shall take steps to ensure this.

The clinic provides safe water and electricity. The clinic provides medical gases and vacuum systems, if required.

The clinic has a programme for clinical and support service equipment management.

### Summary of Standards

<b>FMS 1</b>	The Clinic's environment and facilities operate to ensure safety of patients, their families and staff.
<b>FMS 2</b>	The Clinic has a programme for equipment management, safe water, electricity, medical gases and vacuum system as applicable.
<b>FMS 3</b>	The Clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.

## Standards and Objective Elements

### Standard

<b>FMS.1.</b>	<b>The Clinic's environment and facilities operate to ensure safety of patients, their families and staff.</b>
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### Objective Elements

- a. Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.

**Interpretation:** Self explanatory

**Remark(s):** Appropriate to the size of the clinic.

- b. There is internal and external sign posting in the Clinic in a language understood by patient, families and community.

**Interpretation:** Self-explanatory.

**Remark(s):** These signages shall guide patients and visitors. It is preferable that signages are bi-lingual. Statutory requirements shall be met.

### Standard

<b>FMS.2.</b>	<b>The Clinic has a programme for equipment management, safe water, electricity, medical gases and vacuum system as applicable.</b>
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### Objective Elements

- a. The Clinic plans for equipment in accordance with its services and strategic plan.

**Interpretation:** Self-explanatory. This shall also take into consideration of future requirements.

- b. Potable water and electricity are available.

**Interpretation:** The Clinic shall make arrangements for supply of adequate potable water and electricity.

**Remark(s):** For water quality refers to IS 10500.

- c. Alternate sources are provided for in case of power failure.

**Interpretation:** Alternate standby power supply to be available.

**Remark(s):** It could be from solar energy, UPS, Inverter, DG set or any other suitable source.

- d. Safety precautions are followed with respect to medical gases and where applicable piped medical gas, compressed air & vacuum installation/equipment.

**Interpretation:** Self-explanatory.

**Remark(s):** Where ever applicable.

### Standard

<b>FMS.3.</b>	<b>The Clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.</b>
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### Objective Elements

- a. The Clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.

**Interpretation:**

- 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.
  - 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.
  - b. Acquired adequate fire fighting equipment for this which records are kept up-to-date.
  - c. Adequate training of staff.
  - d. Exit plans well displayed.
- Non-fire emergency situations include :



- Spillage of hazardous (acids, mercury, etc.), infected materials (used gloves, syringes, tubing, sharps, etc.) medical wastes (blood, oil, pus, vomits, etc.)
- Fall or slips (from height or on floor) or collision of personnel in passageway
- Fall of patient from bed
- Sudden failure of supply of electricity, gas, vacuum, etc.
- Bursting of boilers and / or autoclaves
- 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.

**Remark(s):** The National Building Code is a good reference guide.

- b. **Staff is trained for their role in case of such emergencies.**

**Interpretation:** In case of fire designated person are assigned particular work. Mock drills are also held.

- c. **The Clinic defines and implements its policies to eliminate smoking.**

**Interpretation:** self explanatory

**Remarks:** No smoking signage to be displayed.

## Essential Documentation

Like all quality management systems documentation is an essential component of NABH clinic accreditation. NABH standards require documentation. It is suggested that the clinic prepare an apex manual (quality manual) incorporating the various standards and objective elements and providing appropriate linkages.

It is essential that document control\* be followed during documentation.

A suggested content is given below.

- Introduction of the clinic
- Management including ownership, ethical management, etc.
- Quality policy and objectives including service standards
- Scope of services provided by the clinic and the details of services
- Statutory and regulatory requirements
- Chapter-wise documentation
- Infection Control Manual.
- Quality Improvement Manual which also incorporates the quality assurance activities of lab and para surgical services.
- Policies and procedures for various clinical and non-clinical activities. Eg: Pain Management Policy, Para- Surgical Procedures, Registration policy, SOPs for various Panchakarma & other treatment procedures,
- Safety manual which also incorporates lab safety and radiation safety.
- Annexure (if any)

\* The above may be separate manuals or a part of the apex manual.

Some sample headings for a documented procedure are given below:

- Scope/Aim/Objective
- Definition
- Applicable areas
- Responsibility
- Contents/explanations/detailing or various processes
- Monitoring and analysis/indicators
- References

**Document control shall be adhered to for all documentation.**

## 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, wherever 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.

<b>Accreditation</b>	<p>1. A process of external review of the quality of the health care being provided by a clinic. 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>
<b>Accreditation assessment</b>	<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"> <li>○ Documentation review.</li> <li>○ Facility visit</li> <li>○ Interview of staff, patients and visitors</li> <li>○ On-site observations by assessors</li> </ul>
<b>Bylaws</b>	<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>
<b>Clinical audit</b>	<p>Analysis of clinical aspects of patient care for improving the quality of health care services.</p>
<b>Clinical practice guidelines</b>	<p>Guidelines that assist practitioners to provide appropriate clinical care for specific clinical conditions. The guidelines include relevant history taking, physical signs to look for, lab investigations to be carried out and treatment to be prescribed.</p>
<b>Competence</b>	<p>Demonstrated ability to apply knowledge and skills. (para 3.9.2 of ISO 9000: 2000)</p> <p>Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific action.</p>

<b>Confidentiality</b>	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.
<b>Consent</b>	<p>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.</p> <p>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 contract and every agreement.</p>
<b>Credentialing</b>	The process of obtaining, verifying and assessing the qualification of a health care provider.
<b>Data</b>	Raw facts, clinical observations, or measurements collected during an assessment activity.
<b>Employees</b>	All members of the clinic who are employed full time and are paid suitable remuneration for their services as per the laid down policy.
<b>Ethics</b>	Medical ethics is the discipline of evaluating the merits, risks, and social concerns of activities in the field of medicine.( <a href="http://en.wikipedia.org/wiki/Medical_ethics">en.wikipedia.org/wiki/Medical_ethics</a> )
<b>Evidence based medicine</b>	<p>1.It is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patient</p> <p>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.</p>
<b>Family</b>	The person(s) with a significant role in the patient's life. It mainly includes spouse, children, and 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.
<b>Formulary</b>	<p>An approved list of prescription drugs that the clinic may provide to their patients.</p> <p>The list is updated preferably each year. Changes may be made depending on availability or market.</p>

<b>Grievance handling procedures</b>	Sequence of activities carried out to address the grievances of patients, relatives and staff.
<b>Hazardous materials</b>	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
<b>Hazardous waste</b>	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 oils/therapy materials, used bandages, fluid soaked items etc.
<b>In service education/training</b>	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.
<b>Indicator</b>	A statistical measure of the performance of functions, systems or processes overtime. For example, hospital acquired infection rate, staff absence rate, etc.
<b>Information</b>	Processed data which lends meaning to the raw data.
<b>Intent</b>	A brief explanation of the rational, meaning and significance of the standards laid down in a particular chapter.
<b>Inventory control</b>	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 stock outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
<b>Job description</b>	<ol style="list-style-type: none"> <li>1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job.</li> <li>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.</li> </ol>
<b>Job specification</b>	<ol style="list-style-type: none"> <li>1. The qualifications/physical requirements, experience and skills required to perform a particular job/task.</li> <li>2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.</li> </ol>
<b>Laws</b>	Legal document setting forth the rules of governing a particular kind of activity.

<b>Local Anaesthesia</b>	The administration to an individual by a qualified and trained physician for the application of Ksharasutra.
<b>Medical audit</b>	A peer review carried out by analysis of medical records with a view to improve the quality of the patient care
<b>Medical equipment</b>	Any fixed or portable non drug item or apparatus used for diagnosis, treatment, monitoring and direct care of patient.
<b>Mission</b>	A written expression that sets forth the purpose of the organization. It usually precedes the formation of goals and objectives.
<b>Monitoring</b>	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment. It requires careful planning and use of standardised procedures and methods of data collection.
<b>Multi-disciplinary</b>	A generic term which includes representatives from various disciplines, professions or service areas.
<b>Notifiable disease</b>	<p>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:-</p> <ul style="list-style-type: none"> <li>○ Cholera</li> <li>○ Plague</li> <li>○ Yellow fever</li> </ul> <p>In India the following diseases are also notifiable and may vary from state to state:</p> <ul style="list-style-type: none"> <li>○ Polio</li> <li>○ Influenza</li> <li>○ Malaria</li> <li>○ Rabies</li> <li>○ HIV/AIDS</li> <li>○ Louse-borne typhus</li> <li>○ Tuberculosis</li> <li>○ Leprosy</li> <li>○ Leptospirosis</li> <li>○ Viral hepatitis</li> <li>○ Dengue fever</li> </ul> <p>The various diseases notifiable under the factories act are lead poisoning, bysinnosis, anthrax, asbestosis and silicosis.</p>
<b>Objective element</b>	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.
<b>Occupational health hazard</b>	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.

<b>Organogram</b>	A graphic representation of reporting relationship in an organization.
<b>Patient care setting</b>	The location where a patient is provided health care as per his needs.
<b>Patient record/ medical record/ clinical record</b>	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.
<b>Performance appraisal</b>	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.
<b>Plan of care</b>	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.
<b>Policies</b>	They are the guidelines for decision making, e.g. admission, discharge policies, policy for therapeutic procedures etc.
<b>Privileging</b>	It is the process for authorising all medical professionals to treat patients and provide other clinical services commensurate with their qualifications and skills.
<b>Procedure</b>	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.
<b>Process</b>	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000:2000)
<b>Program</b>	A sequence of activities designed to implement policies and accomplish objectives
<b>Protocol</b>	A plan or a set of steps to be followed in a study, an investigation or an intervention.

<b>Quality</b>	<p>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)</p> <p>2. Degree of adherence to pre-established criteria or standards.</p>
<b>Quality assurance</b>	<p>Part of quality management focussed on providing confidence that quality requirements will be fulfilled.                      (Para 3.2.11 of ISO 9000:2000)</p>
<b>Re-assessment</b>	<p>It implies continuous and on-going assessment of the patient which are recorded in the medical records as progress notes.</p>
<b>Resources</b>	<p>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.</p>
<b>Risk management</b>	<p>Clinical and administrative activities to identify evaluate and reduce the risk of injury.</p>
<b>Safety</b>	<p>The degree to which the risk of an intervention/procedure, in the care environment are reduced for a patient, visitors and health care providers</p>
<b>Scope of services</b>	<p>Range of clinical and supportive activities that are provided by a health care organization.</p>
<b>Security</b>	<p>Protection from loss, destruction, tampering, and unauthorized access or use.</p>
<b>Sentinel events</b>	<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 patient.                      Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun.</p>
<b>Staff</b>	<p>All personnel working in the clinic either as full paid employees or as consultants on honorarium basis</p>



<b>Standard precautions</b>	<p>1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood borne 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>
<b>Standards</b>	<p>A statement of expectation that defines the structures and process that must be substantially in place in an organization to enhance the quality of care.</p>
<b>Sterilization</b>	<p>It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.</p>
<b>Surveillance</b>	<p>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.</p>
<b>Unstable patient</b>	<p>A patient whose vital parameters need external assistance for their maintenance.</p>
<b>Validation</b>	<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 fulfils its requirements. It also refers to what extent does a test accurately measures what it purports to measure.</p>
<b>Vulnerable patient</b>	<p>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.</p>

## **Annexure**

### **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. 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. Excise permit to store Spirit.
6. Income tax PAN.
7. Permit to operate lifts under the Lifts and escalators Act.
8. Narcotics and Psychotropic substances Act and License.
9. Sales Tax Registration certificate.
10. Retail drug license (Pharmacy).
11. Wireless operation certificate from Indian post and telegraphs. (if applicable)
12. Air (prevention and control of pollution) Act, 1981 and License
13. Arms Act, 1950. (if guards have weapons)
14. Cable television networks Act 1995.
15. IMCC Act-1970. (Indian Medicine Central Council Act)
16. Central sales tax Act, 1956.
17. Consumer protection Act, 1986.
18. Contract Act, 1982.
19. Copyright Act, 1982.
20. Customs Act, 1962.
21. Drugs & cosmetics Act, 1940.
22. Drugs & Magical Remedies Act, 1954.
23. Electricity Act, 1998.
24. Electricity rules, 1956.
25. Employees provident fund Act, 1952.
26. ESI Act, 1948.
27. Employment exchange Act, 1969.
28. Environment protection Act, 1986.
29. Equal remuneration Act, 1976.
30. Explosives Act 1884.
31. Fatal accidents Act 1855.
32. Homeopathy Central Council Act (HCC), 1971
33. Hire Purchase Act, 1972.
34. Income Tax Act, 1961.
35. Indian Lunacy Act, 1912.

36. Indian medical council Act and code of medical ethics, 1956.
37. Indian Nursing council Act 1947.
38. Indian penal code, 1860.
39. Indian trade unions Act, 1926.
40. Industrial disputes Act, 1947.
41. Maternity benefit Act, 1961.
42. Minimum wages Act, 1948.
43. National building code.
44. National holidays under shops Act.
45. Negotiable instruments Act, 1881.
46. Payment of bonus Act, 1965.
47. Payment of gratuity Act, 1972.
48. Payment of wages Act, 1936.
49. Persons with disability Act, 1995.
50. Protection of human rights Act, 1993.
51. PPF Act, 1968.
52. Tax deducted at source Act.
53. Sales tax Act.
54. SC and ST Act, 1989
55. Companies Act, 1956
56. Constitution of India
57. Insurance Act, 1938
58. Workers compensation Act, 1923
59. Urban land Act, 1976
60. Clinical Establishment Act-2012.