ACCREDITATION STANDARDS FOR

HOMOEOPATHY CLINICS

1st Edition, March 2013

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS

FOREWORD

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Introduction

Accreditation Standards for Homoeopathy 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 HOMOEOPATHY Clinic:

A standalone outpatient healthcare facility that provides HOMOEOPATHY services by Doctor(s) registered with State HOMOEOPATHY 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:

1. 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's team of assessors. The clinic shall retain its right of appeal as per NABH Appeals Procedure enunciated in its website <www.nabh.co>

Accreditation Standards

For

HOMOEOPATHY 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

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

Standards and Objective Elements

Standard

AAC.1.	**The Clinic defines and displays the services that it can provide.**

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. The display could be in the form of boards, citizen's charter, scrolling messages etc.

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

AAC.2.	**The Clinic has a defined patient registration process.**

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

AAC.3.	**Patients cared for by the organisation undergo an established assessment before treatment.**

Objective Elements

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

Interpretation: The Clinic shall have a format for case taking using which a standardised assessment of patient is done based on the principles of Homoeopathy.

Remark(s): Every assessment shall contain the presenting complaints and its history, personal history, history of past illness, family history of diseases, mental state assessment as applicable and vital parameters (temperature, pulse, BP and respiratory rate) and salient examination findings etc, in accordance with Homoeopathic Philosophy.

Standard

AAC.4.	**Patient care is continuous and multidisciplinary in nature.**

Objective Elements

a. During all phases of care, there is a qualified individual identified 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 organisation.

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

AAC.5.	**Laboratory services, where provided, are monitored by the clinics.**

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 any accredited laboratory or laboratory with quality systems in place.

Forms and formats & adequate record keeping are addressed.

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

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. The Clinic should ensure availability of adequate staff, materials and equipment to make the laboratory results available within the defined time frame.

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.

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) as well as patients undergoing research.

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

Summary of Standards

COP 1:	Care and treatment is provided in a uniform manner.
COP 2:	Patients with special needs & disabilities (vulnerable) shall be identified and treated accordingly.
COP 3:	Documented policies and procedures guide appropriate pain management.
COP 4:	Documented policies and procedures guide appropriate rehabilitative services.
COP 5:	Policies and procedures guide all research activities.

Standards and Objective Elements

Standard

COP.1.	**Care and treatment is provided in a uniform manner.**

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 by respective systems of medicine, are adopted to guide patient care.

Interpretation: 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.

Remark(s): e.g. Standardized protocols for care of diabetes, asthma, arthritis etc.

Standard

COP.2.	**Patients with special needs & disabilities (vulnerable) shall be identified and treated accordingly.**

Objective Elements

a. Patients with special needs & disabilities (vulnerable) 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.

b. Medico-legal cases shall be handled to the extent of the clinic's capabilities.

Interpretation: If medico-legal cases are handled in the clinic the policy shall be in line with statutory requirements.

Standard

COP.3.	**Documented policies and procedures guide appropriate pain management.**

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. The organization respects and supports appropriate assessment and management of pain.

Interpretation: Self-explanatory.

c. 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

COP.4.	**Documented policies and procedures guide appropriate rehabilitative services.**

Objective Elements

a. Documented policies and procedures guide the provision of rehabilitative services.

Interpretation: Self-explanatory.

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

b. These services are commensurate with the clinic requirements.

Interpretation: The scope of the services is in consonance with the scope of the clinic.

Standard

COP.5.	**Policies and procedures guide all research activities.**

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 guide and audit medication processes. 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

MOM 1:	Medication use is organized to meet patient needs and complies with applicable laws and regulations.
MOM 2:	Medication prescription, dispensing and administration follow standardized processes to ensure patient safety.
MOM 3:	Noncompliance to drugs and adverse effects & the medication errors, if any, are appropriately addressed.

Standards and Objective Elements

Standard

MOM.1.	**Medication use is organized to meet patient needs and complies with applicable laws and regulations.**

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 use meets applicable laws & regulations.

Interpretation: Applicable laws & regulations (as in annexure 1).

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

MOM.2.	**Medication prescription, dispensing and administration follow standardized processes to ensure patient safety.**

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.

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.

d. Medication administration is guided by standardized policies and procedures.

Interpretation: The Clinic shall ensure:

- Only authorized staff administers 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

Standards

MOM.3.	**Noncompliance to drugs and adverse effects & the medication errors, if any, are appropriately addressed.**

Objective Elements

a. Medication w.r.t compliance, clinical effectiveness and adverse medication effects, if any, is noted in patient's record.

Interpretation: The adverse drug effects that are to be recorded in the patient's record and those that must be reported are defined.

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.

c. Policies and procedures will define reporting, analysing and corrective and preventive actions for medication error and adverse drug events.

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.

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.

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

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

Standards and Objective Elements

Standard

PRE.1.	**The Clinic protects patient and family rights.**

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.

All the rights of the patients should be displayed.

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.

c. Appropriate corrective/preventive measures are taken in case patient's rights are violated.

Interpretation: Where patients' rights have been infringed upon, clinic must keep records of such violations, as also a record of the consequences, e.g. corrective actions to prevent recurrences.

Standard

PRE.2.	**Patient rights support individual beliefs, values and involve the patient and family in decision making processes.**

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 and family rights include informed consent any invasive / high risk procedures / treatment.

Interpretation: Self-explanatory.

f. 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.

g. 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

PRE.3.	**A documented process for obtaining patient and / or families consent exists for informed decision making about their care.**

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

PRE.4.	**Patient and families have a right to information and education about their healthcare needs.**

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.

d. Patient and families are educated about preventing infections.

Interpretation: Self-explanatory.

Remark(s): For example, hand washing and avoiding overcrowding near the patient.

Standard

PRE.5.	**Patient and families have a right to information on expected costs.**

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.

Remark(s): The inference should be drawn based on the recorded line of management collaborating the cost.

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

Chapter 5

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

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

Standards and Objective Elements

Standard

IC.1.	**Infection control practices and adherence to standard precautions and hygienic practices shall be observed at all times in the clinic.**

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, 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:

- Pre exposure prophylaxis is arranged.

- 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

IC.2.	**The Clinic complies with Bio Medical Waste Management Rules and associated regulations.**

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. The clinic should collect data on structures, processes and outcomes, especially in areas of high-risk situations. The collected data should be collated, analysed and used for further improvements. The improvements should be sustained. Infection-control and patient-safety plans should also be integrated into the organisation's quality plan.

The organisation should define its sentinel events and intensively investigate when such events occur.

Summary of Standards

CQI 1:	There is a structured quality improvement and continuous monitoring programme.
CQI 2:	The clinic identifies key indicators which are used as tools for continual improvement.

Standards and Objective Elements

Standard

CQI.1.	**There is a structured quality improvement and continuous monitoring programme.**

Objective Elements

a. The quality improvement programme is commensurate with the size and complexity of the organization and is documented.

Interpretation: 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 reviewed at predefined intervals and opportunities for improvement are identified.

Interpretation:

- As quality 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.
- The Clinic shall do the needful to identify the areas for improvement. and the corrective measures shall be documented.

Standard

CQI.2.	**The clinic identifies key indicators which are used as tools for continual improvement.**

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.

- Safety and quality control programmes of the diagnostics services.
- Adverse drug events.
- Content of medical records.
- Infection control activities.
- Clinical research.

Remark(s): 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.

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.

Remark(s): For law & regulations example, tax, EPF, notifiable diseases, PNDT act, AERB guidelines etc.

c. Corrective and preventive actions are taken and monitored for effectiveness with respect to activities being managed or 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. The clinic is led by a suitably qualified and experienced individual.

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

Summary of Standards

ROM 1:	The clinic shall identify a responsible person, who has the defined responsibility and authority to ensure that the quality programme is maintained and run in an ethical manner.
ROM 2:	The Clinic is managed by the leaders in an ethical manner.
ROM 3:	The Clinic initiates and maintains a patient record for every patient.
ROM 4:	Those responsible for management have addressed all applicable aspects of human resource management.

Standards and Objective Elements

Standard

ROM.1.	**The clinic shall identify a responsible person, who has the defined responsibility and authority to ensure that the quality programme is maintained and run in an ethical manner.**

Objective Elements

a. The organogram shall be established.

Interpretation: The Clinic shall have a well-defined Clinic structure/chart.

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

Remark(s): Refer 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).

c. Appropriate authorities shall be informed about the notifiable diseases.

Standards

ROM.2.	**The Clinic is managed by the leaders in an ethical manner.**

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 accurately bills for its services based upon a standard billing tariff.

Interpretation: Self-explanatory.

Standards

ROM.3.	**The Clinic initiates and maintains a patient record for every patient.**

Objective Elements

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

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

c. Standardized forms and formats are used.

ROM.4.	**Those responsible for management have addressed all applicable aspects of human resource management.**

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: Due registration with respective Councils/Boards, police verification as applicable.

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.

Interpretation: 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.

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

g. Staff Health Problems are addressed.

Interpretation: This includes occupational health issues, medical checkups as applicable and preventive immunization.

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

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

Standards and Objective Elements

Standard

FMS.1.	**The Clinic's environment and facilities operate to ensure safety of patients, their families and staff.**

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

FMS.2.	**The Clinic has a programme for equipment management, safe water, electricity, medical gases and vacuum system as applicable.**

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 future requirements.

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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 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. The organisation regularly tests the alternate sources.

Interpretation: Self-explanatory.

e. 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

FMS.3.	**The Clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.**

Objective Elements

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

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.
    e. Emergency illumination system which comes into effect in case of a fire
- .Non-fire emergency situations include :
    - Spillage of hazardous (acids, mercury, etc.), infected materials (used gloves, syringes, tubing, sharps, etc.) medical wastes (blood, pus, amniotic fluid, 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 has addressed identification, spill management, training of staff for storage and disposal of Hazardous materials

Interpretation: 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.

Remark(s): 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 eliminate smoking.

Interpretation: Smoking in public places including Clinics and hospitals has been banned in this country.

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, vision, mission, ethical management, etc.
- Quality policy and objectives including service standards
- Scope of services provided by the clinic and the details of services
- Organogram
- 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.
- 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.

Accreditation	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 2. It also represents the outcome of the review and the decision that an eligible organization meets an applicable set of standards.
Accreditation assessment	The evaluation process for assessing the compliance of an organization with the applicable standards for determining its accreditation status. NABH assessment includes the following:- o Documentation review. o Facility visit o Interview of staff, patients and visitors o On-site observations by assessors
Bylaws	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
Clinical audit	Analysis of clinical aspects of patient care for improving the quality of health care services.
Clinical practice guidelines	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.

Competence	Demonstrated ability to apply knowledge and skills. (para 3.9.2 of ISO 9000: 2000) Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific action.
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 contract 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 clinic 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 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.
Formulary	An approved list of prescription drugs that the clinic may provide to their patients. The list 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, 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 oils/therapy materials, used bandages, fluid soaked items 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, staff absence rate, etc.
Information	Processed data which lends meaning to the raw data.
Intent	A brief explanation of the rational, 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 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.

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.
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. 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.

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:- o Cholera o Plague o Yellow fever In India the following diseases are also notifiable and may vary from state to state: o Polio o Influenza o Malaria o Rabies o HIV/AIDS o Louse-borne typhus o Tuberculosis o Leprosy o Leptospirosis o Viral hepatitis o 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.
Patient care setting	The location where a patient is provided health care as per his needs.
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.

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, policy for therapeutic procedures etc.
Privileging	It is the process for authorising all medical professionals to 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 transforms 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.
Sentinel events	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.
Staff	All personnel working in the clinic either as full paid employees or as consultants on honorarium basis

Standard precautions	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 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 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
Standards	A statement 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	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) 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.
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.

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 CodeBuilding 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 & TAN as applicabe.
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. Central sales tax Act, 1956.
16. Consumer protection Act, 1986.
17. Contract Act, 1982.
18. Copyright Act, 1982.
19. Customs Act, 1962.
20. Drugs & cosmetics Act, 1940.
21. Drugs & Magical Remedies Act, 1954.
22. Electricity Act, 1998.
23. Electricity rules, 1956.
24. Employees provident fund Act, 1952.
25. ESI Act, 1948.
26. Employment exchange Act, 1969.
27. Environment protection Act, 1986.
28. Equal remuneration Act, 1976.
29. Explosives Act1884.

30. Fatal accidents Act1855.
31. Homeopathy Central Council Act (HCC), 1971
32. Hire Purchase Act, 1972.
33. Income Tax Act, 1961.
34. Indian Lunacy Act, 1912.
35. Indian medical council Act and code of medical ethics, 1956.
36. Indian Nursing council Act 1947.
37. Indian penal code, 1860.
38. Indian trade unions Act, 1926.
39. Industrial disputes Act, 1947.
40. Maternity benefit Act, 1961.
41. Minimum wages Act, 1948.
42. National building code.
43. National holidays under shops Act.
44. Negotiable instruments Act, 1881.
45. Payment of bonus Act, 1965.
46. Payment of gratuity Act, 1972.
47. Payment of wages Act, 1936.
48. Persons with disability Act, 1995.
49. Protection of human rights Act, 1993.
50. PPF Act, 1968.
51. Tax deducted at source Act.
52. Sales tax Act.
53. SC and ST Act, 1989
54. Companies Act, 1956
55. Constitution of India
56. Insurance Act, 1938
57. Workers compensation Act, 1923
58. Urban land Act, 1976