Standard No.CEA/Dental Centre- 039

Clinical Establishment Act Standard for Dental Centre

Standard No.CEA/Dental Centre- 039

Introduction

In 2010 Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Ministry has notified the "National Council for Clinical Establishments" and 'The Clinical Establishments (Central Government) Rules, 2012" under this Act vide Gazette. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

Table of Contents

Sr. No.	Particulars	Page No.
1.	Definition	
2.	Scope	
3.	Infrastructure	
4.	Equipment / Instruments	
5.	Human Resource	
6.	Legal/Statutory Requirements	
7.	Record Maintenance and Reporting	
8.	Others	
9.	Annexure 1	
10.	Annexure 2	
11.		
12.		
13.		
14.		
15.		

1. Definition

Dental Centre isstand aloneclinical establishment having Dental Services without inpatient facility.

2. Scope (as applicable)

The scope of services that may be provided at a Dental Hospital may include any or all of the following, but not necessarily limited to:

2.1. Periodontology
2.2. Oral Medicine and Radiology
2.3. Oral Surgery
2.4. Conservative Dentistry and Endodontics
2.5. Prosthodontics
2.6. Community Dentistry
2.7. Orthodontics
2.8. Pedodontics
2.9. Implant Dentistry
2.10. First Stage Trauma Care

3. Infrastructure Requirements

3.1	Signage requirements
3.1.1.	The establishment shall have a prominent board/signage displaying the name of the clinic/centre in bilingual language at the gate or on the building.
Following informative signage's shall be displayed:	
3.1.2.	Name of the doctors with registration number.
3.1.3.	Fee structure of the various doctors/ specialist.
3.1.4.	Timings of the establishment (For ex – from 8am -2pm)
3.1.5.	Important contact numbers such as Referral Centers, Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area shall be displayed.
3.1.6.	Services provided within the establishment.
3.2	**Other infrastructure requirements**
3.2.1.	The establishment shall be developed and maintained to provide safe, clean and hygienic facility for patients, their attendants, staff and visitors.
3.2.2.	The establishment shall be clean, well illuminated, ventilated and with adequate water supply.
3.2.3.	The minimum space requirements shall be as per the scope of services/Number of beds/ (please refer **ANNEXURE 1).**
3.2.4.	The establishment shall provide privacy to the patient as and when applicable
3.2.5.	The clinical establishment shall have clean public toilet(s).
3.3	**Furniture & Fixtures requirements**

3.3.1.	Furniture and fixtures shall be available in accordance with the activities and workload of the establishment
3.3.2.	The furniture and fixtures shall be functional.
	*For Indicative list of items please refer **ANNEXURE 2.** This list is indicative and not exhaustive.*

4. Equipment/instruments/drug requirement

4.1.	**The establishment shall have adequate equipment/instrument commensurate to the scope of service and in adequate capacity to meet work load requirement..**
4.2.	The establishment shall keep all equipment in good working condition.Periodic inspection, cleaning, maintenance of equipment shall be done.
	*For Indicative list of minimum equipment/instrument please refer to **ANNEXURE 3.** This list is indicative and not exhaustive.*
4.3.	The establishment shall provide adequate space for storage of equipment.
4.4.	The establishment shall have adequate drugs. The drugs shall be stored as per manufacturer's guidelines.
	*For Indicative list of drugs & consumables please refer to **ANNEXURE 3.** This list is indicative and not exhaustive.*

5. Human Resource Requirements

5.1.	**The Dentist shall be registered with State Dental Council.**
5.2.	The services provided by the dental professionals shall be in consonance with their qualification, training and registration.
5.3.	In a Dental clinic/centre minimum one support staff must be available to meet the care treatment and service needs of the patient. However number may depend upon the workload and scope of the service being provided by the establishment.
5.4.	The Dental clinic/centreshall have basic minimal essential manpower as per **ANNEXURE 4**

6. Support Service

6.1.	**The establishment shall have a reception & billing counter. The billing shall be as per the tariff list.**
6.2.	The diagnostic services can be in house or outsourced. The diagnostic services shall be commensurate with the scope of services.

6.3.	If the establishment has in house diagnostic services, it shall comply with the applicable law and regulations.
6.4.	The establishment shall have facility for cleaning instruments.
6.5.	The establishment shall have facility for sterilization of instruments.
6.6.	Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per Bio medical waste handling rules, 1998.
6.7.	Mercury waste management guidelines shall be followed

7. Legal/Statutory Requirements

7.1.	**The establishment shall comply with the requirements of local laws and regulations. For indicative list please refer to Annexure 5.**
7.2.	The establishment shall have a formal MOU/MOA with all outsourced agencies, which detail various aspects of the services to be provided e.g. resources, financial implications, time frames etc.

8. Record Maintenance and reporting

8.1.	**The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishments shall be as prescribed in CG 2 Annexe as per Section 12 (1) (iii) of the Act**
8.2.	Medical Records shall be maintained in physical or digital format.
8.3.	The establishment shall maintain health information and statistics in respect of national programmes, notifiable diseases and epidemics and furnish the same to the district authorities in the prescribed formats and frequency.

9. Basic Processes

Registration	
9.1.	The establishment shall register all patients who visit the Dental clinic/centre.
Assessment	
9.2.	Every patient shall undergo assessment, during the course of assessment, the patient findings, medications and investigations should be documented with working diagnosis, legibly in the assessment/OPD prescription with the signature of the Dentist with date and time.
Infection Control	
9.3.	There must be adequate safe-guards and protocols in place , commensurate with the size and needs of the establishment, so as to

	provide sterilized instruments for use in each patient.
9.4.	There shall be adequate provision of resources to support infection control practices and same should be periodically reviewed.
9.5.	The establishment shall have standard precautions/protocols to control infection, washing, cleaning, dis-infection/sterilization activities and bio - medical waste management as per statutory provisions.
Medication Prescription, Administration And Monitoring	
9.6.	Prescription should include name of the patient, date, name of medication, dosage, route, frequency, duration, name, signature and registration number of the medical practitioner in legible writing.
9.7.	Drug allergy, patient identity, medication, dose, route, timing, expiry date shall be verified prior to administration of medication.
Safety and Security	
9.8.	The establishment shall undertake all necessary measures to ensure the safety of patients, attendants, staff and visitors.
First aid	
9.9.	The establishment shall have provision for First Aid in case of emergency.
9.10.	The establishment shall ensure that contact details of ambulance/ hospital etc is available when required.

Annexure 1

Indicative minimum space requirements for a dental hospital shall be as follows (These are indicative minimum figures, actual size will depend on scope of services of the hospital):

Common area	**Space for reception, waiting area, toilets etc.**	**35 sqft**
Operatory	Dental Chair unit including washing area and bio medical waste	60 sqftcarpet area for 1 dental chair
	Ancillary area/space for sterilization, dark room, storage, provision of compressed air and suction sterilization	30% of the carpet area for 1 dental chair
	For every additional chair 60% additional area required.	

Annexure 2

Following furniture and fixtures shall be available however the quantity shall be as per size of the hospital and workload so as to provide safe and secure patient care:

S.No.	ARTICLES
1.	Writing tables
2.	Chairs
3.	Almirah
4.	Waiting Benches/chairs
5.	Stretcher
6.	Instrument Trolley
7.	Screens/curtains
8.	Fans
9.	Tube Lights / CFL / Bulbs
10.	Wash Basin
11.	Colour coded bins for BMW as per state regulations

Annexure 3

Indicative list of minimum Equipment/Instruments /Drugs requirement in a Dental Hospital however the quantity shall be as per size of the hospital and workload so as to provide safe and secure patient care:

I. ESSENTIAL EQUIPMENT LIST FOR PRIMARY ORAL HEALTH DELIVERY:

Sl.no.	Equipment
1.	Dental chair with attachments like air motor/air rotor/micro motor
2.	Autoclave
3.	Compressor
4.	Stethoscope
5.	Sphygmanometer

II. ESSENTIAL INSTRUMENT LIST:

Sl. No.	Function	Instrument
1.	Essential Instrument	Mouth mirror Tweezer Probe Instrument tray
2.	Periodontology	Periodontal probe Scalers Curettes
3.	Oral Medicine and Radiology	X-ray equipment Lead apron
4.	Oral surgery	Elevators (various) Forceps Needle Holder Scissors –surgical BP blade and handle
5.	Conservative Dentistry	Filling instruments Cement spatula (metal/plastic) Waste receiver Dental hand pieces Excavators Explorers Glass slab/paper mixing pad Matrix retainer Protective glasses Cellophane strip
6.	Endodontic	Endo root canal explorer Endo root canal plugger Endo root canal spreader

		Endo root canal ruler Spirit lamp or similar instrument for heating purpose
7.	Prosthodontics	Impression trays Rubber bowl Ruler scale Spatula Carver Shade guide Finishing and polishing instruments (e.g Acrylic trimmer, etc) Wax Knife Wax Spatula Cement spatula (metal/plastic) Waste receiver Dental hand pieces Pliers Glass slab/paper mixing pad Spirit lamp or similar instrument for heating purpose
8.	Orthodontics	Pliers Applicable armamentarium
9.	Pedodontics	Relevant instruments as per procedures listed under various specialties.
10.	Implant Dentistry	Implants with surgical kit. Physio dispenser Other surgical instruments
11.	First Stage Trauma care	Splinting material as per requirement.

III. Essential Drugs list

Sl. No.	Drugs
1.	Local anesthetic with vasoconstrictor
2.	Local anesthetic without vasoconstrictor
3.	Alternate local anesthetics

IV. Essential Emergency Drugs

Sl. No.	Name of Drug
1.	Oxygen
2.	Epinehrine
3.	Atropine
4.	Ephedrine
5.	Hydrocortisone
6.	Nitroglycerine
7.	Antihistamine (diphenhydramine or chlorphenramine)

8.	Albuterol/Salbutamol
9.	Lorazepam
10.	Ethamsylate
11.	Hemostat sponge
12.	Glucose / dextrose-25% ampoule

V. LIST OF CONSUMABLES

This includes the minimum quantity of the commonly used consumables in the facility which should be made available.

Sl. No.	Category	Item
1.	Common Essential	BP blade Cotton Suture Hypodermic needles - disposable Saline solution Burs Gloves Masks Potable water Disinfectant (general cleaning) Disinfectant (Instruments) Lubricating oil for hand pieces Soap Surgical spirit
2.	Periodontology	as per procedural requirements
3.	Oral Medicine and Radiology (Please refer to Annexure6)	X-ray films X-ray film developer – manual/automatic processing X-ray film fixer - manual/automatic processing (If digital radiography available in the clinic, the above are optional)
4.	Oral surgery	as per procedural requirements
5.	Conservative Dentistry	Matrix Band Filling Materials Articulating Paper Wedges
6.	Endodontic	Chelating agent paste for root canal preparation Irrigation solutions

		Endodontic sealer Temperory filling materials GuttaPercha cones –various Files and reamers. Paper points- absorbent calcium hydroxide
7.	Prosthodontics	Wax Sheet Green Stick Impression Material Luting Cement
8.	Orthodontics	Wires Brackets Adhesive/bonding Materials
9.	Peadodontic	Flouride Pit and fissure sealant zinc oxide and eugenol calcium hydroxide Also relevant consumables as per procedures already listed above
10.	Implant Dentistry	Implants and abutments
11.	Emergency Services	All emergency drugs shall be checked periodically for expiry dates.

Annexure 4

Minimum Human Resource for Dental Hospitals shall be as follows h:

Sl. no.	Category	Strength	Registration with the concerned council (If applicable)
1.	Dentist	1	State Dental council
2.	Dental Hygienist	Depending on the work load	State Dental council
3.	Dental Assistant / Auxillary	Depending on the work load	-
4.	Dental technician	Depending on the work load	State Dental council
5.	Multipurpose worker	1	10^{th} Pass
6.	Others	There should be provision of an on call-Anesthetist, General Physician, General Surgeon as and when required.	

Annexure 5

LIST OF LEGAL REQUIREMENTS

Below is the list of legal requirements to be complied with by a Dental hospital as applicable by the local/state health authority (all may not be applicable):

Sl.	Name of Document	Valid From	Valid Till	Send for renewal by	Remark (Expired/ valid/NA)
1.	Registration under Nursing Home Act/Clinical Establishment Act				
2.	Bio-medical Waste Management Licenses				
	Authorization of HCO by PCB				
	MOU with Vendor				
3.	AERB License for Xray/OPG etc.				
4.	NOC from Fire Department				
5.	Lift license (if available)				
6.	DG Set Approval for Commissioning (if available)				
9.	Diesel Storage Licenses				
12.	Narcotic Drug Licenses				
13.	Medical Gases Licenses/ Explosives Act				
17.	MoU / agreement with outsourced human resource agencies as per labor laws				
18.	Spirit License				
19.	Electricity rules				
20.	Provident fund/ESI Act				
25.	PAN				
27.	Wireless operation certificate from Indian P&T				

Annexure 6

AERB requirement for OPG/Dental/Mobile Radiography

Please refer to Radiological Safety Division (RSD) DIAGNOSTIC RADIOLOGY SECTION Revised Guidelines for obtaining regulatory consents from AERB for medical diagnostic X-ray equipment

1) Applications for Registration (Radiography/R &F/Mammography/OPG/BMD/ Dental/ Mobile Radiography/ C-Arm) (details given in TABLE-A):

- Completely filled duly signed and stamped application form (AERB/RSD/MDX/REG).
- Layout shall be prepared as per the AERB guidelines for layout and shielding of x-ray equipment.

2) Application for License (Computed Tomography(CT)/ Interventional Radiology (IR) installations) (Details given in TABLE-B)

- Completely filled, duly signed and stamped application form (AERB/RSD/MDX-CT-CATH/LCO & RSO)
- Layout shall be prepared as per the AERB guidelines for layout and shielding of x-ray equipment

3) RSO Approval

- Completely filled, duly signed and stamped application form (AERB/RSD/MDX-RSO)
- Copy of certificates of qualifications (Refer Prescribed qualifications for personnel in DR practice)
- Availability of Personnel monitoring badge (TLD) for which he/she is nominated to become RSO.