



ODISHA STATE HEALTH & FAMILY WELFARE SOCIETY, ODISHA
OFFICE OF THE MISSION DIRECTORATE - NATIONAL HEALTH MISSION, ODISHA

NATIONAL COMPETITIVE BIDDING

BIDDING DOCUMENT

FOR

OPERATING HEMODIALYSIS FACILITY AT GOVT.
HEALTH FACILITIES (Phase II) IN A PPP MODE

Bid Reference No. : OSH&FWS/NDP-DS/6/2023

Date: 8.6.2023

Website: www.nhmodisha.gov.in
e-mail: proc.nhmodisha@gmail.com

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ODISHA STATE HEALTH & FAMILY WELFARE SOCIETY, ODISHA

Annex Building of SIH&FW, Nayapalli, Unit-8, Bhubaneswar - 751012

Website : www.nhmodisha.gov.in e-mail : proc.nhmodisha@gmail.com

Section - I NOTICE INVITING TENDERS (NIT)

Bid Reference No. : OSH&FWS/NDP-DS/6/2023

Date: 8.6.2023

1. Odisha State Health & Family Welfare Society (O S H & F W S) invites sealed bid from eligible service providers for **operating the Dialysis Services in a PPP mode** as given in Section-IV of this document.
2. This document contains eight sections as follows:
 - Section I : Notice inviting Tender
 - Section II: Instruction to Bidder
 - Section III: Procedure for evaluations of bids
 - Section IV: Job description
 - Section V: Eligibility Criteria
 - Section VI: Terms and Conditions
 - Section VII: Appendices (A to N)
 - Section VIII: Contract Format

3. Schedule of Events

Sl.	Description	Schedule
1	Date of availability of Bid Document	8.6.2023 to 29.6.2023
2	URL of website for downloading of Bid Document	www.nhmodisha.gov.in
3	Cost of the Bid Document	Rs.5,900/-
4	Pre-bid Meeting (Date & Time)	16.6.2023, 11.30 AM
5	Venue for Pre-bid Meeting / Opening of Bid	Mission Directorate-National Health Mission, Annex Building of SIH&FW, Nayapalli, Unit-8, Bhubaneswar - 751012
6	Closing Date and Time of Receipt of Bid	29.6.2023, 3 PM
7	Time, Date and Venue of Opening of Technical Bid	29.6.2023, 4 PM
8	Time, Date and Venue of Opening of Financial Bid	To be intimated to technically qualified bidders on a later date.

4. The bid document may be downloaded from the official website: www.nhmodisha.gov.in The bidder downloading the bid document from the website will be required to deposit **Rs.5,900/- (non-refundable)** in the form of Demand Draft drawn in favour of “Mission Director, NHM” payable at Bhubaneswar while submitting the bid. Bid without the fee of Rs.5,900/- will not be accepted.
5. All prospective bidders are requested to attend the Pre-bid meeting either in person or through their authorized representative. No representative is allowed to represent more than one prospective bidder. The venue, date and time are indicated in Schedule of Events as in Para 3 above.
6. Bidders shall ensure that their bids complete in all respects, are dropped in the Tender Box located at Mission Directorate - National Health Mission, Annex. Building of SIH&FW, Nayapalli, Unit-8, Bhubaneswar on or before the closing date and time indicated in the Para 3 above. Bids submitted after the prescribed time will be treated as late bid and will not be considered. The bids can also be submitted by Registered Post / Courier. The bids sent by Registered Post/Courier must reach the above said address on before the closing date & time indicated in Para 3 above, failing which the bid will be treated as late bid and will not be considered.
7. In the event of any of the above mentioned dates being declared a holiday/closed day for the bid inviting authority, the bids will be received/opened on the next working day at the same time.
8. The bid documents are not transferable.
9. All bids must be accompanied by **Earnest Money Deposit (EMD)** amount to **Rs 10.00 Lakhs (Rupees Ten Lakhs)** only in the form of **Demand Draft** favouring “Mission Director, NHM” payable at Bhubaneswar. Earnest Money Deposit in any other form will not be accepted. Earnest Money Deposit will not earn any interest. Bids without EMD shall be rejected.

Mission Director
National Health Mission, Odisha

Section - II

INSTRUCTIONS TO BIDDER

1. General Instructions

- a. The bidder should prepare and submit its offer as per instructions given in this section.
- b. The bids shall be complete with all documents. Those submitted by fax or by email with attachments shall not be considered.
- c. The bids which are for only a portion of the components of the job /service shall not be accepted. (The bid should be for all components of the job /service)
- d. The prices quoted shall be **firm** and shall include all applicable taxes and duties. This shall be quoted in the format as per attached **Appendix 'F'** only.
- e) The bids (technical and financial) shall be submitted (with a covering letter as per **Appendix 'E'**) before the last date of submission. Late bids shall not be considered.

2. Inspection of Site and Equipment

The interested bidder may inspect the locations (Appendix-A) where the services are to be rendered during 10.00 AM to 5.00 PM on all working days till last date of availability of the bid document as given in the schedule of events (Section-I). The Bid inviting authority shall not be liable for any expenditure incurred in such inspection or in the preparation of the bid(s).

3. Earnest Money Deposit (EMD)

- a. The bid shall be accompanied by Earnest Money Deposit (EMD) of **Rs.10 Lakhs** as specified in the Notice Inviting Tender (NIT) in the shape of **Demand Draft** from any Scheduled Bank in favour of Mission Director, NHM payable at Bhubaneswar
- b. It may be noted that no bidding entity is exempted from deposit of EMD. Bids submitted without EMD shall be rejected.
- c. The EMD of unsuccessful bidder will be returned to them without any interest, after conclusion of the resultant contract. The EMD of the successful bidder will be returned without any interest, after receipt of performance security as per the terms of contract.
- d. EMD of a bidder may be forfeited without prejudice to other rights of the procurer, if the bidder withdraws from the Bid in any respect within the period of validity of its Bid or if it comes to notice that the information /documents furnished in its Bid is incorrect, false, misleading or forged. In addition to the aforesaid grounds, the successful bidders' EMD will also be forfeited without prejudice to other rights of procurer, if it fails to furnish the required performance security within the specified period.

4. Preparation of Bid

The bids shall be made in **TWO SEPARATE SEALED ENVELOPES** as follows:

- I. The **first envelope** shall be marked in bold letter as **“TECHNCIAL BID”** which shall be sent with forwarding letter **Appendix ‘H’** and shall include the following:
 - 1) Check List
 - 2) Tender document cost in the shape of **Demand Draft** drawn in favour of “Mission Director, NHM” payable at Bhubaneswar.
 - 3) EMD in the shape of Demand Draft drawn in favour of “Mission Director, NHM” payable at Bhubaneswar.
 - 4) Confirmation regarding furnishing Performance Security in case of award of agreement.
 - 5) Original Bid document duly stamped and signed by the authorized personnel in each page along with the Forwarding Letter confirming the performing the assignment as per **Appendix ‘G’**
 - 6) Particulars of the bidder as per **Appendix “D”**
 - 7) Copy of the Income Tax Returns acknowledgement for last three financial years.
 - 8) Manufacturer’s Authorization letter as per **Appendix “B” from the Original Equipment Manufacturer (OEM) for RO Plant**
 - 9) Copy of the certificate of registration of PAN, EPF, ESI with the appropriate authority.
 - 10) A duly notarized declaration from the bidder in the format given in the **Appendix “J”** to the effect that the firm has neither been declared as defaulter or black-listed by any competent authority of a Government Department under Government of India or Government of any State.
 - 11) The bidder shall provide copies of work order / contract of hemodiaysis service (Own / PPP mode) provided in private/public sector in last three years and user’s certificate regarding satisfactory completion of such job as per proforma given in **“Appendix C”**
- II. The **second envelope** shall contain the financial proposal and shall be marked in bold letters as **“FINANCIAL BID”**. Prices shall be inclusive of all taxes & duties and quoted in the proforma enclosed at **Appendix “F”** as per scope of work / service to be rendered.
- III. Both the envelops (Technical Bid & Financial Bid) shall be put in **another outer third envelope** and shall be sealed and superscripted with **“Proposal for Dialysis Facility in PPP Mode - Phase II”, Bid Reference No. & Due date.**

5. Bid & Contract Validity Period

The bids shall remain valid for 180 days from the date of submission of bid for the purpose of finalization of bid and the contract to be finalized with the successful bidder shall be valid for a period of "5 years" for acceptance and the prices quoted shall remain for the duration of the contract with 3% escalation per annum on the quoted financial bid with respect to the preceding year. The contract may be extended for another term based on performance and mutual consent.

6. Bid Submission

The **two envelopes** containing **both technical and the financial bid** shall be put in an **Outer envelope**, which shall be sealed and superscripted with "BID Name & Reference No.....due for opening on....."

The offer shall contain no interlineations or overwriting except as necessary to correct errors, in which cases such correction must be initialled by the person or persons signing the bid. In case of discrepancy in the quoted prices, the price written in words will be taken as valid.

7. Opening of Bids:

The technical bid will be opened at the time & date specified in the schedule of events in Section-I. The bidders or their authorized representative may attend the bid opening if they so desire.

Section - III

EVALUATION OF BIDS

1. Scrutiny of Bids

The bids will be scrutinized by the selection committee appointed by the authority to determine whether they are complete and meet the essential and important requirements, conditions and whether the bidder is eligible and qualified as per criteria laid down in the bid document. The bids, which do not meet the aforesaid requirements, are liable to be treated as non-responsive and may be ignored. The decision of the procurer as to whether the bidder is eligible and qualified or not and whether the bid is responsive or not shall be final and binding on the bidders. Financial bids of only those bidders, who qualify on technical bid, will be considered and opened.

2. Infirmary / Non-Conformity

The procurer may waive minor infirmity and/or non-conformity in a bid, provided it does not constitute any material deviation. The decision of the procurer as to whether the deviation is material or not, shall be final and binding on the bidders.

3. Bid Clarification

Wherever necessary, the procurer may at its discretion, seek clarification from the bidders seeking response by a specified date. If no response is received by this date, the procurer shall evaluate the offer as per available information in the bid.

4. Bid Evaluation

The technical bids shall be evaluated based on the eligibility criteria, documents furnished in the bid in support of that including the requirement / terms & conditions of the bid and clarification received from the bidders. The technical bids which do not meet the aforesaid eligibility / requirements of the bid are liable to be treated as non-responsive. Financial bids of only those bidders, who qualify in their technical bid, will be opened and evaluated.

5. Selection Process

A single bidder will be selected for providing hemodialysis services at all Govt. Health Facilities (the details of which are mentioned at **Appendix A**). The bidders shall have to quote the **cost per hemodialysis session** (in the format of Price Bid - **Appendix F**) upto maximum **two decimal digits after the decimal point**. The technically qualified bidder with the **lowest cost per hemodialysis session shall be selected**. In case the cost per hemodialysis session figure quoted (in two decimal digits after the decimal point) by two or more bidders still become same, then the bidder having past experience in management & operation (in own / PPP mode) of **more** hemodialysis machines during the last three financial years shall be selected.

Section - IV

SCOPE OF THE WORK

The Service Provider shall be responsible for operationalization of Dialysis facility at district/ sub-district hospital to the patients referred by District Hospital. Ownership status of all movable assets created from the investments made by the Service Provider shall remain with the Service Provider. The scope of services would be as mentioned below:

- I. The service provider is allotted a space (@ 120 sq. ft. per machine + space for RO plant + Space for waiting area / store etc.) by the authority and the service provide shall make complete arrangements to make the hemodialysis facility operational with all required infrastructure (**except hemodialysis machine**), HR [trained Nephrologists, Medical Officer (trained in Dialysis), Nurses & technicians trained in Dialysis and other supportive staffs], supportive infrastructure, dialyzer and all other consumables etc., operational and maintenance cost for the project including consumables & facility for paediatric patients. The nursing station should be in an area that allows adequate surveillance of patients on hemodialysis machines. The facilities such as dialysis room, nursing station, observation rooms, recovery rooms, isolation rooms, dialyzer re-processing unit & dialyzer storage room, RO plant etc. shall have to be furnished by the Service Provider in the space (built room) provided by the authority. The dialysis room shall be furnished by the Service Provider with Patient Semi-fowler Bed (with Bed Sheet), Adequate Air Conditioners (Split ACs), Fan & Lighting. Only the built room of adequate size with electricity & water provision shall be provided by the authority.
- II. **Only the Hemodialysis machines shall be provided by the Authority:** Three Dialysis machines plus one dedicated machine for infective cases (Hepatitis B / Hepatitis C /HIV etc.) per location (for the SDHs / CHCs) and Four Dialysis Machines plus one dedicated machine for infected Cases per location (for the one DHH) **would be provided by the Authority** (as per location details at **Appendix A**) with three years warranty. However, the AMC/CMC cost of the hemodialysis machines after the warranty period shall have to borne by the service provider during the rest of the contract period if any. Similarly, the service provider needs to provide the **associated equipment and facilities** like RO Water Treatment Plant, Vital Signs Monitor and Defibrillators etc. and provide maintenance support for operation of the Dialysis Machines and allied equipment.
- III. The decision to refer a patient for dialysis in the district health facilities should originate from a qualified nephrologists /treating physicians trained in Nephrology (where qualified Nephrologist is not available) of a Govt. Hospital / Medical College. In all cases, the diagnostic tests (Urea, Creatinine, Sodium, Potassium, Complete biochemistry & hematology profile) before and after the dialysis should be done through the free diagnostic program OR Government health facilities laboratories. Incorrect laboratory tests may lead to wrong referral for dialysis and hence due precautions would be taken to refer a patient for dialysis and laboratory reports before and after the dialysis cycle should be recorded.
- IV. The facilities such as observation rooms, recovery rooms among other should be provided by the service provider.
- V. The Service Provider shall generate **ABHA IDs** for all patients and update the dialysis session details on PMNDP portal. Service provider shall provide ABHA ID card with QR

code to every new patient registered at the facility. IT hardware (desktop/laptop) with printer, barcode scanner, biometric device (UIDAI approved) and stable internet connection will be procured by the service provider for access to the PMNDP portal and maintaining electronic medical records for monitoring of service delivery.

- VI. The service provider shall provide the biometric registration system at each dialysis centre for patient registration and dialysis session scheduling in PMNDP portal.
- VII. The service provider shall provide **web based software driven dashboard** for monitoring of service delivery with due diligence to patient privacy for administrative Staff. Treating Nephrologist and the authority should have complete access to the dashboard.

SMS based appointment system for all patients enrolled for services.
- VIII. The obligations of the service provider under this service contract shall include all service activities and commitments. The number of dialysis machines for operationalization of the dialysis centers at different locations and type of facilities is given in **Appendix 'A'**.
- IX. The Service Provider **shall not levy any charge** to the patients referred by Govt. Hospitals. The services shall be provided **FREE OF COST** to all patients referred by the district/sub-district hospitals.
- X. The minimum requisite equipment and staffing norms for provisioning of Hemodialysis services by the service provider is placed as **Appendix 'L' & 'M'** respectively.
- XI. The essential requirement with regard to Hemodialysis machine, Water Treatment System and Monitoring protocols is placed as **Appendix 'N'**. It is important that service provider checks the quality of HD machines deployed in the dialysis unit and maintains the water standards meticulously to prevent any outbreak of infection.
- XII. Central venous line/ A-V Shunt / Jugular Vascular access wherever required for dialysis treatment shall be the responsibility of the service provider. However, the cost of Central Venous Line / A-V Shunt / Jugular Vascular Access is not included in the **cost per hemodialysis session** to be quoted by the bidder in their price bid. The cost of Central Venous Line / A-V Shunt / Jugular Vascular Access shall be **reimbursed** as per the CGHS Bhubaneswar 2014 (Non-NABH) rate. Similarly the cost of fistula making charges shall also be reimbursed as per CGHS Bhubaneswar 2014 (Non-NABH) rate / Rate of Gol.
- XIII. A dedicated Diesel Generator (Approx. 40 KVA) shall be provided by the concerned authority for the dialysis unit. However, the recurring cost like the diesel cost, maintenance cost of the DG Set if any shall have to be borne by the service provider.

Section -V

ELIGIBILITY CRITERIA

1. The Bidder shall be a sole provider (Company/Society/Trust). The bidder cannot be an individual or group of individuals. The bidder should be registered in India with relevant act, such as a Company (Companies Act 2013) / Partnership Firm (Indian Partnership Act 1932 / Limited Liability Partnership Act 2008), Society (Societies Registration Act 1860) or a Trust (Indian Trust Act 1882) and its amendments thereof. No bidder can place more than one bid in any form. In case of a bidder if not the manufacturer (in case of RO Water Treatment Plant), shall have to submit the manufacturer's authorization as per proforma in **Appendix 'B'**.
2. Consortium is not allowed.
3. The bidder shall have a minimum of three years of experience in carrying out similar type of assignment / service in private or public sector. In support of this, a statement regarding assignments of hemodialysis services successfully completed during last three years should be submitted as per proforma in **Appendix 'C'**. Users' certificate regarding satisfactory completion of assignments alongwith the no. of hemodialysis machines shall also to be submitted in support the information furnished in Appendix 'C'. The assignment of Govt. Depts. / Semi Govt. Depts. should be specifically brought out. (The decision of the Procurer as to whether the assignment is similar or not and whether the bidders possess adequate experience or not, shall be final and binding on the bidders.)
4. The bidder should have experience in operation & management of **dialysis facilities**, having at least a **total of 100 Haemodialysis machines** in India in any one of the three preceding financial years. This experience need be executed by the sole bidder participating in this tender.
5. The bidder should have operational Hemodialysis facility for at least 3 years prior to the submission date.
6. Bidder who has been blacklisted / debarred/ banned by any State Government / Central Govt. Organization / State Medical Corporations will not be eligible to participate in the tender during the blacklisting / debarred period. (Declaration as per **Appendix "J"**)
7. The bidder shall declare all ongoing litigations it is involved in with any government agency/state/central department
8. The bidder shall have an average annual turnover of **Rs. 10 Crores or more** in last three financial years. Information on audited annual turnover shall have to be furnished as per the format "Appendix D/2" **duly supported by audited accounts statements.**

Section - VI

TERMS AND CONDITIONS

1. Signing of Contract

The procurer shall issue the Notice for Award of Contract to the successful bidder within the bid validity period. And the successful bidder will be required to sign and submit the contract unconditionally within 15 days of receipt of such communication.

2. Modification to Contract

The contract when executed by the parties shall constitute the entire contract between the parties in connection with the jobs / services and shall be binding upon the parties. Modification, if any, to the contract shall be in writing and with the consent of the parties.

3. Performance Security

- a) The successful bidder shall furnish a performance security in the shape of demand draft / Bank Guarantee issued by a Scheduled / Nationalised Bank in favour of Bid Inviting Authority for an amount equal to **Rs. 40 Lakhs**. The Bank guarantee shall be as per proforma at "**Appendix: I**" and remain valid for a period, which is six months beyond the date of expiry of the contract. This shall be submitted within 15 days (minimum) of receiving of Notice for Award of Contract, failing which the EMD may be forfeited and the contract may be cancelled.
- b) If the service provider violates any of the terms and conditions of contract, the Performance Security shall be liable for forfeiture, wholly or partly, as decided by the Procurer and the contract may also be cancelled.
- c) The Procurer will release the Performance Security without any interest to the service provider on successful completion of contractual obligations.

4. Compliance of Minimum Wages Act and other statutory requirements

The bidder shall comply with all the provisions of Minimum Wages Act and other applicable labour laws with amendments / revision from time to time. The bidder shall also comply with all other statutory provision including but not limited to provisions regarding medical education and eligibility criteria of human resources used by the bidder for providing the services, biomedical waste management, bio-safety, occupational and environmental safety.

Legal liability of the services provided by the bidder shall remain with the service provider but in case of any death, the certificate shall be issued by the government doctor. The Service provider shall maintain confidentiality of medical records and shall make adequate arrangement for cyber security.

5. Income Tax Deduction at Source

Income tax deduction at source shall be made at the prescribed rates from the bidder's bills.

The deducted amount will be reflected in the requisite Form, which will be issued at the end of the financial year.

6. Periodicity of Payment

The payment will be made on a **monthly** basis **within 30 days** of submission of invoice through ECS for all invoices raised. The bidder will raise its invoice on completion of services during this period duly accompanied by evidences of services provided. The payment will be subject to TDS as per Income Tax Rules and other statutory deductions as per applicable laws.

The payment shall be in terms of **cost (in Rs.) per Haemodialysis Session**.

7. Damages for Mishap/Injury

The procurer shall not be responsible for damages of any kind or for any mishap/ injury/accident caused to any personnel/property of the bidder while performing duty in the procurer's / consignee's premises. All liabilities, legal or monetary, arising in that eventuality shall be borne by firm/ contractor.

The Service Provider shall assume all responsibility and liability of any and every type and of all Claims resulting from the use and operation of the Dialysis Machines and Equipments and shall indemnify and hold harmless all the stakeholders from any and all Claims of whatsoever nature resulting from the use and operation of the Dialysis Machines and Equipments by the Service Provider.

8. Termination of Contract:

The procurer may terminate the contract, if the successful bidder withdraws its bid after its acceptance or fails to submit the required Performance Securities for the initial contract and or fails to fulfil any other contractual obligations. In that event, the procurer will have the right to procure the services from next eligible bidder and the extra expenditure on this account shall be recoverable from the defaulter. The earnest money and the performance security deposited by the defaulter shall also be recovered to pay the balance amount of extra expenditure incurred by the procurer.

Prior to the termination, the Service provider will be served notice of termination explaining the reasons and will be given an opportunity to rectify the services within 30 days failing which the services will be terminated. Authority may consider a termination payment on the merit of the case.

9. Arbitration:

- a) If dispute or difference of any kind shall arise between the purchaser and the firm/ contractor in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.
- b) If the parties fail to resolve their dispute or difference by such mutual consultations within thirty days of commencement of consultations, then either the purchaser or the firm/contractor may give notice to the other party of its intention to commence arbitration, as hereinafter provided. The applicable arbitration procedure will be as per

the Arbitration and Conciliation Act, 1996 of India. In that event, the dispute or difference shall be referred to the sole arbitration of an officer to be appointed by both the parties as the arbitrator. If the arbitrator to whom the matter is initially referred is transferred or vacates his office or is unable to act for any reason, he / she shall be replaced by another person appointed by to act as Arbitrator. Such person shall be entitled to proceed with the matter from the stage at which it was left by his predecessor. The award of the provision that the Arbitrator shall give reasoned award in case the amount of claim in reference exceeds Rupees One Lac (Rs.1,00,000/-).

- c) Work under the contract shall, notwithstanding the existence of any such dispute or difference, continue during arbitration proceedings and no payment due or payable by the Purchaser or the firm / contractor shall be withheld on account of such proceedings unless such payments are the direct subject of the arbitration.
- d) Reference to arbitration shall be a condition precedent to any other action at law.
- e) Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued by Tender inviting authority or the state health societies (NHM office).

10. **Applicable Law and Jurisdiction of Court:**

The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force. The Court located at the place of issue of contract shall have jurisdiction to decide any dispute arising out of in respect of the contract. It is specifically agreed that no other Court shall have jurisdiction in the matter.

11. **Other Terms & Conditions**

- a) The Project will be awarded for a period of **5 years** and may be extendable for **next five years** based on satisfactory performance as assessed by the tender inviting authority. Service Provider will be obliged to establish, manage and operate the Project in accordance with the provisions of a Contract Agreement and terms and conditions therein. It could be cancelled at any time after providing an opportunity of hearing by the Authority, in case the contractor does not follow the rules, regulations and terms and condition of the contract.
- b) The Authority shall provide the required space (a built room) with provision of electricity & water for establishing the dialysis unit. A Possession Certificate in plain paper shall be issued while handing over the above mentioned space.
- c) **Commissioning of Dialysis Unit** : The commissioning of the dialysis facilities (location as mentioned in Appendix A) shall be carries out in two phases :

Phase I (Where the site is available as mentioned in Appendix A): The commissioning of the dialysis facilities shall be completed by the service provider **within 90 days** of signing of contract provided the built room with provision of electricity / water and the dialysis machines are provided at the dialysis centre by the concerned authority.

Phase II (Where the site will be ready after 3-4 months time as mentioned in Appendix-A) : The commissioning of the these dialysis facilities shall be completed by the service provider **within 60 days** of intimation regarding the site readiness

provided the built room with provision of electricity / water and the dialysis machines are provided at the dialysis centre by the concerned authority.

In case the authority is not at fault in providing the adequate space with electricity & water provision, a penalty of Rs. 5,000/ week/centre will be levied in case of delay in commissioning of the dialysis centre within the stipulated timeline.

- d) Service provider shall administer, manage and operate the Dialysis Machines and Equipments during the Term in accordance with (i) the latest and highest Operating Manual of the Manufacturer which will include good medical practices, investigation and all renal treatment modalities etc. as prescribed by the relevant Authorities from time to time (ii) follow all the ethical and social good practices around patient care;
- e) The service provider will train its staff and will maintain the EMR-Electronic Medical record of each dialysis session and update the requisite information on PMNDP portal. Payment shall be done after reconciliation with sessions held as per PMNDP portal.
- f) The cost per Hemodialysis Session is to be furnished as per **Appendix H**.
- g) The list of equipment to be provided by the service provider at each dialysis facility is attached at **Appendix L**
- h) One Dialysis facility would be established by the service provider at each of the locations, the details of which is attached in **appendix A**.
- i) All the pre-requisites such as civil, electrical, plumbing work, air-conditioning, computer or any other changes in the site for installation of machine will be executed by the service provider at its own cost, with due permission of the Authority. The district hospital administration will not be responsible for any loss / damage to the machine / property due to natural hazard and licensee will take adequate insurance cover at his own risk & liability for all damages arising out due to any unprecedented reasons. The service provider shall provide round the clock security services for the Dialysis facility at its own cost for the entire period of contract. The contract and terms thereof shall be governed by indemnification clause. The Electricity and Water connection will be provided by the Authority till the entry of the point of service. However internal electrification, furnishing and plumbing will be the responsibility of service provider and the service provider will make payment for the consumption of electricity by installing a **sub-meter** on actual basis.
- j) All expenses on account of man power, electricity, water and other maintenance of premises and the machine, security or any other expenses incurred in the day to day running of the machine shall be borne by the service provider. The Service Provider shall ensure that the Personnel at the Hospital Dialysis Centre are trained regularly from time to time to offer quality Dialysis treatment to the patients.
- k) The service provider shall provide for storage of soft copy and hard copy of all records at the District Hospital at its own cost. In case of change of service provider for any reason, the stored data must be transferred to the new provider for continuation of storage.

- l) The service provider shall use the Dialysis Machines and Equipments with due care and caution and shall keep and maintain the Dialysis Machines and Equipments in good order and condition (reasonable wear and tear excepted). The service provider shall ensure best quality of tests and protocols and shall submit a half yearly report of clinical audit done by a third party or as nominated by the authority. The service provider shall have to provide the Kt/v and standardised Kt/V report for each patient to the committee.
- m) Annual review of performance and observance of terms & conditions shall be carried out by a committee which shall include CDMO / CMO & Head of department of Nephrology of the Govt. Teaching hospital along with other members nominated by the authority. The report of this annual review shall form the basis for extension of the contract annually within the contract period. The service provider shall provide an access to audit/monthly reports/ bills /invoices including service logs to the Authority regarding the use of the Dialysis Machines and Equipments, number of patients treated, the fees charged etc. as required by the Authority.
- n) The service provider will have to maintain an **uptime of 90%** with maximum 7 days of downtime at a stretch of any single dialysis machine of the facility. In case the service provider fails to do so, the provider shall pay a sum of Rs.2,000/- per day beyond 7 days. If shut down extends beyond 30 days due to technical and/or administrative reasons on the part of service provider, the contract may be cancelled. The service provider shall make alternative arrangements for provision of dialysis (including free transportation of patients) in case the machine is out of order/ broken down for period greater than 24 hours. The rates at which the Authority has engaged the service provider shall not change in any case.
- o) **The authority of the concerned health facility shall make payment** to the service provider for its services on **monthly** basis through e-payment for all invoices raised for the previous month. The payment should be made within 30 days of submission of Invoice by the service provider. The Invoice should be submitted along with the Monthly Report.
- p) **A no-fee receipt** shall be provided by the service provider to every patient. A copy of all such receipts shall be submitted on a monthly basis by the service provider to the District Hospital Authority. This will form the basis of monthly payment by the procurer to the service provider for the said services. All receipts shall be subjected to a third party annual audit and the audit report submitted as part of annual work report of the service provider for that facility.
- q) The following records shall be maintained on a daily basis by the service provider:
 - 1. Daily patients register including outside as well as for patients referred by District Hospital to be separately maintained.
 - 2. Log book for record of any breakdown/shut down of the machine/facility.
- r) The service provider shall maintain line listing of patients and record the sessions in the PMNDP Portal. Log book of any breakdown/shut down of the machine/facility to be maintained.

- s) The service provider shall not sell or transfer any proprietary right or entrust to any other third party for running the facility. The service provider may however refer the test to another centre in case of breakdown/shutdown ensuring all other conditions pertaining such as services, reports, records, patient transport and safety of processes and procedures in the referred dialysis centre.
- t) The service provider shall take a third party insurance policy to cover the patients sent by the District Hospital against any mishap during patient transport, inside the dialysis facility and for consequences arising due to reporting error. Conforming to the provision of the consumer protection act shall be the sole and absolute responsibility/liability of the service provider. After the expiry of the contract agreement between the bidder and the authority, the Bidder shall vacate the space occupied and hand over the Dialysis machines and Equipments, in good and working condition to the authority, forthwith.
- u) The Authority and the service provider agree, confirm, acknowledge that during the tenure of the Agreement (between the Authority and the Service Provider) and thereafter at all point of time, the Trust (the donor agency) shall be the Sole Legal Owner and the Legal possession of the Dialysis Machines and Equipments shall exclusively vests with the Trust (the donor agency) at all point of time. Neither the Authority nor the service provider shall have any right, title, interest, claim, lien, encumbrance or charges in respect of the Dialysis Machines and Equipments.
- v) The service provider confirms and agrees that the allocation and use of the Dialysis Machine and Equipment is non-exclusive, non-assignable, non-transferable and a temporary revocable right to use the Dialysis Machine and Equipment till the tenure of the Agreement.
- w) Availability of Space, Electricity and Water shall be the responsibility of the authority. In accordance with Clause 11 (h). However, the monthly recurring bill towards electricity & water has to be borne by the service provider.
- x) The service provider shall provide a resuscitation facility (oxygen, Automated External Defibrillation (AED), suction, Ambu bag) with crash cart containing emergency medications for providing lifesaving support if required by patients within the dialysis facility.
- y) The service provider shall arrange for appropriate and adequate signage and IEC (Information- education- communication) activities for facility as decided by the authority.
- z) The service provider shall abide by all the guidelines issued by the Authority and statutory bodies. In case of violation the contract could be terminated after providing an opportunity of hearing to the service provider, at one month's notice.
- aa) The Authority shall receive Bids pursuant to this tender document in accordance with the terms set forth herein as modified, altered, amended and clarified from time to time by the Authority and all Bids shall be prepared and submitted in

accordance with such terms on or before the date specified in the tender for submission of Bids.

- bb) The Service provider shall be obligated to provide **24X7 (round the clock)** dialysis services if required to meet the work load, ensuring that no patient has a wait time of more than 24 hours from the scheduled dialysis session.
- cc) The no. of dialysis machine to be provided by the authority at each dialysis facility is mentioned at Appendix-A.
- dd) The recommended staffing pattern for each dialysis centre is mentioned at Appendix – M. In case of absence of staffs as per the recommended staffing pattern for dialysis unit, suitable substitution shall be provided by the Service Provider. The attendance of staffing in each dialysis unit shall be recorded through a biometric attendance system to be installed by the service provider. In case of absence of staffs without substitution, penalty shall be levied as per the remuneration per day of that staff calculated based on their monthly remuneration, the details of which are to be provided during signing of contract.

SECTION VII

**(Appendix, Check List of Technical Bid Envelop
&
Contract Form)**

APPENDIX - A

Location of Govt. Facilities for Hemodialysis Service in PPP Mode

Sl.	Name of the District	Name of the DHH/SDH/ CHC	Proposed Dialysis Wing (1st Phase)	Dialysis Machines (1st Phase)	Proposed Dialysis Wing (2nd Phase)	Dialysis Machines (2nd Phase)
1	Anugul	Palahara	1	4		
2	Anugul	Talcher	1	4		
3	Anugul	Athamallik			1	4
4	Balasore	Soro CHC	1	4		
5	Bolangir	Patanagar			1	4
6	Bolangir	Titlagarh			1	4
7	Baragarh	Padampur	1	4		
8	Cuttack	Athagarh	1	4		
9	Cuttack	Tigiria CHC	1	4		
10	Dhenkanal	Kamakhyanaga	1	4		
11	Dhenkanal	Hindol	1	4		
12	Ganjam	Chatrapur			1	4
13	Ganjam	Hinjilikatu			1	4
14	Ganjam	Aska			1	4
15	Kalahandi	Dharmagada	1	4		
16	Kandhamal	Baliguda	1	4		
17	Kendrapara	Pattamundai			1	4
18	Keonjhar	Anandapur	1	4		
19	Keonjhar	Champua	1	4		
20	Khurda	Khurda DHH	1	5		
21	Malkangiri	Mathili			1	4
22	Malkangiri	Chitrokonda			1	4
23	Mayurbhanj	Karanjaia	1	4		
24	Mayurbhanj	Rairangpur	1	4		
25	Mayurbhanj	Udala	1	4		
26	Nawarangpur	Umarkote	1	4		
27	Nuapada	Khariar	1	4		
28	Rayagada	Gunupur	1	4		
29	Sambalpur	Kuchinada	1	4		
30	Sambalpur	Rerakhol			1	4
31	Subarnapur	Dunguripali CHC	1	4		
32	Sundargarh	Bonaigarh	1	4		
	Total		22	89	10	40
Total Dialysis Machines				129		

MANUFACTURER'S AUTHORISATION LETTER

(To be submitted by Manufacturer of the Associated Equipment)

(To be submitted in Technical Bid Envelop for the item: **RO Plant**, in case the bidder is not the manufacturer of the RO Plant)

To

The Mission Director
National Health Mission, Odisha

Ref.: Your TE document No.-----, dated-----

Dear Sir / Madam,

We, ----- are the manufacturer of -----

----- [name of Equipment] and hereby conform that;

1. Messrs ----- (name and address of bidder) is our authorized agent for

2. Messrs ----- (name and address of the agent) have fully trained and experienced service personnel to provide the said services.

Yours faithfully,

[Signature with date, name and designation]

for and on behalf of Messrs _____

[Name & Address of the Manufacturers]

Seal

Note:

1. This letter of authorization should be on the **letterhead** of the **manufacturing firm** and should be signed by a top executive of the manufacturing firm.
2. Original letter shall be attached to the bid.

APPENDIX – C

ASSIGNMENT OF HEMODIALYSIS SERVICE SUCCESSFULLY COMPLETED DURING LAST THREE YEARS

(To be submitted in Technical Bid Envelop)

Details of No. of Hemodialysis Service in Own / PPP mode Undertaken during the last three years

Sl.	Assignment Contract No. & date	*Name of the Organization	Description of work / services provided	No. of Dialysis Machines on Operation & Management	Contract Price of assignment (Rs.)	Date of commencement of services	Date of completion/ Ongoing	** Was the assignment satisfactorily completed

Note: Attach extra sheet for above Performa if required.

*Attach Photocopies of the contract / work order of the assignments mentioned above

** Attach the users' certificates regarding satisfactory completion of assignments as mentioned above **indicating the no. of dialysis machines on operation & management.**

Signature of Authorized Signatory

Name & Designation:

Date:

Seal

Place:

PARTICULARS OF THE BIDDER

(To be submitted in Technical Bid Envelop)

1. Name:
2. Registered Address
3. Communication Address
4. Phone (Land Line / Mobile)
5. email id
6. Type of Organization : Partnership / Company / Trust / Not for Profit Organization
7. Pl. mention whether having own Dialysis Facility Centres :
8. Details of the Dialysis Facility centres in India (Own or Operation / management on PPP mode)

Sl.	Name of the Dialysis Facility Centre (Also mention whether Own or Operation / Management on PPP mode)	Location Address	No. of dialysis machine (operating & managing)	Total no. of Service Personnel	Total no. of Service Personnel

(Additional Sheets to be attached in this format if space is not sufficient)

9. Number of Service Personnel:

Name	Qualification	Experience (Similar Service)

(Additional Sheets to be attached in this format)

10. Whether the bidder has **NABL / NABH / ISO** or any other accreditation?: _ _
(If yes, attach relevant documents in technical bid).

11. Registration Nos.

- a. Registration no. of the firm
- b. EPF
- c. ESI
- d. GST
- e. PAN No.

(pl. furnish the **photocopies** of the above certificates in the technical bid envelop)

12. Copy of Income Tax Return for past three financial years

13. Bank Details of the Bidder:

The bidder shall have to furnish the Bank Details as mentioned below for return of EMD / Payment for services if any (if selected)	a. Name of the Bank :
	b. Name of the Account & Full address of the Branch concerned
	c. Account no. of the bidder :
	d. IFS Code of the Bank :

Signature of Authorized Signatory

Name & Designation:

Date:

Place:

Seal

APPENDIX –D/2

Audited Annual Turn over Statement

(In the letterhead of the Chartered Accountant)

The audited Annual Turnover for the last 3(three) financial years of M/s_____ are given below and certified that the statement is true and correct.

Sl.No.	Financial Year	Turnover in Crores (Rs.) both in figures & words
1	2019-2020	
2	2020-2021	
3	2021-2022	
4	2022-2023 (if audited)	

Date:

Signature of Auditor/ Chartered Accountant

Place:

(Name in Capital)

Seal

Membership No.:

UDIN No. :

N.B: The annual turnover statement should also be supported by copies of audited annual statement of the last three financial years / Annual Report and the turnover figures mentioned above should be highlighted there.

APPENDIX –E

Implementation Plan for this Project

(To be submitted in Technical Bid Envelop)

Brief write-up about the firm / company & their **implementation strategy** for **this project**

Note: Pl. highlight regarding how the dialysis centres at different locations (as mentioned Appendix-A) shall be established, timeline, and the operation modality etc.)

(use extra sheet if necessary or provide the detail information in a separate sheet)

**Signature of Authorized Signatory
Name & Designation:**

Date:

Place:

Seal

APPENDIX –F

Para-wise Compliance to Technical Specification

(To be submitted in Technical Bid Envelop)

- A. [Furnish **parawise compliance (Item wise)** to technical specifications of **Water Treatment System, Dialyzer, Dialysis Fluid etc.** as mentioned in **Appendix N** in a tabular form (as per the format mentioned below), where the technical specification (parawise) as per bid should be mentioned in the left column & bidder's compliance at the right with mention of page no. of the product catalogue / product data sheet].

Make :

Model No. :

Bid Specification as mentioned in Appendix – N (Para wise)	*Bidder's Compliance – Para wise	**Page No. of the technical brochure where the compliance is mentioned

(add *separate sheets* depending upon the space requirement)

- * **Leaflets / Technical Brochures / Product Data Sheets** of the Model offered **highlighting features** of the product offered **must be attached** in support of the information provided above.
- ** It is **mandatory** to mention the page no(s) in the format as mentioned above.

- B. Also attach the leaflets / brochures of other proposed equipments (ECG Machine, Defibrillator, Pulse Oxymeter, ACT Machine, Resuscitation & diagnostics equipment etc.) as per the equipment list mentioned in **Appendix L**

Signature of Authorized Signatory
Name & Designation:

Date:

Place:

Seal

Forwarding Letter for Technical Bid

(To be submitted by the bidder in their letterhead in technical bid envelop)

Date :

To

The Mission Director
National Health Mission, Odisha

Sub: Bid for provision of Services under Bid No....

Sir / Madam,

We are submitting, herewith our bid for providing Dialysis services for.....

Number of districts in the state

We are enclosing Bank Draft/Bankers Cheque No.....,
Dated.....(amount.....) towards bid document cost / fee
and Bank Draft No..... Dated..... (Amount.....) towards
Earnest Money Deposit (EMD), drawn on..... Bank in favour of <Bid
Inviting Authority>.

We agree to accept all the terms and condition stipulated in your Bid enquiry. We also agree to submit Performance Security as per ClauseNo.3 of Section VI of Bid Enquiry document.

We agree to keep our offer valid for the period stipulated in your bid document.

Enclosures:

- 1.
- 2.
- 3.
- 4.
- 5.

Signature of the bidder.....

Seal of the Bidder.....

FINANCIAL BID

(To be submitted in Financial Bid Envelop)

1. Name of the Bidder:.....
2. The bidder is expected to deliver the services for a minimum period of five years
3. The bidder has to deposit the performance security in form of Irrevocable Bank Guarantee with validity through the duration of the contract.
4. **Quote for Cost per Hemodialysis Session**

Description of Services	* Cost (in Rs.) per Hemodialysis Session
The Quote is for per Hemodialysis Session cost for all the supporting infrastructure (such as RO plant as per technical specification, equipment as mentioned in Appendix L etc. except Hemodialysis Machine), HR (qualified Nephrologists /MD, Medicine with one year of experience in Dialysis Centre for the fortnight visit, trained medical officers (MBBS), Nurses, technicians as mentioned in Appendix M), furnishing of the dialysis room with partitioning & adequate air conditioning (Split ACs), Fan & Light, biometric registration system at each dialysis centre for patient registration & dialysis session scheduling in PMNDP portal, all electricity point for each dialysis unit, all plumbing work for the water connection at each patient bed for the dialysis machine, patient semi-fowler bed (with bed sheet), dialyzer, dialysate, normal saline (0.9% w/v, 1000 ml.), tubings and all other consumables required, computer, internet connection charges, provision of online web based dashboard, operational and maintenance cost for the project including machine consumables / filters & facility for pediatric patients, AMC/CMC of the hemodialysis machine after warranty period, diesel cost for DG set, electricity expenses as per Sub-meter reading etc. as per scope of work and terms & condition	

*The bidders may quote the Cost (in Rs.) per Hemodialysis Session upto two decimal digits after the decimal point.

The prices shall be firm and inclusive of all taxes and duties presently in force.

Pl. mention the type of tax (if any) _____ & the % _____, which is included in the above price.

Signature of Authorized Signatory

Name & Designation:

Date:

Seal

Place:

Format for Performance Security in shape of Bank Guarantee

To

< Name, Designation and Office Address of Bid Inviting Authority>

WHEREAS.....(Name and address of the Service Provider) (Hereinafter called " the Service provider" has undertaken, in pursuance of contract No..... dated (Herein after "the contract") to provided Dialysis services.

AND WHEREAS it has been stipulated by you in the said contract that the service provider shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations in accordance with the contract;

AND WHEREAS we have agreed to give such a bank guarantee on behalf of the service provider;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the service provider, up to a total of..... (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the service provider to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the service provider before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the service provider shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to 6 months after the contract termination date
(indicate date)

.....

(Signature with date of the authorized officer of the Bank)

.....

Name and designation of the officer

.....

Seal, name & address of the Bank and address of the Branch

Declaration by Bidder
(To be submitted in Technical Bid Envelop)

I / We agree that we shall keep our price valid for a period of one year from the date of approval. I / We will abide by all the terms & conditions set forth in the Bid documents No. /

**I / We do hereby declare I / We have not been de- recognized / black listed by any State Govt.
/ Union Territory / Govt. of India / Govt. Organisation / Govt. Health Institutions.**

Signature of the Bidder:

Date :

Name & Address of the Firm:

Affidavit before Executive Magistrate / Notary Public in **Rs.100.00** stamp paper.

Records for Procedure

Dialysis centre shall maintain a record system to provide readily available information on:

1. **Patient care**
 - a. Dialysis charts
 - b. Standing order for hemodialysis – updated quarterly
 - c. Physician's order
 - d. Completed consent form
 - e. Patient's monitoring sheet
 - f. Standing order for medication
 - g. Laboratory results
 - h. Confinements with corresponding date and name of hospital
 - i. History and physical examination
 - j. Complication list
 - k. Transfer/referral slip (for patients that will be transferred or referred to another health facility)
2. **Incident and accident (in log books)**
 - a. Complications related to dialysis procedure
 - b. Complications related to vascular access
 - c. Complications related to disease process
 - d. Dialysis adequacy of patients on thrice weekly treatments
 - e. Outcomes
 - f. Staff/patient's hepatitis status
3. **Staff and patient vaccination and antibody titer status as applicable**
 - a. Hepatitis B (double dose) – 0, 1,2,6 months
 - b. Influenza – annually
 - c. Pneumococcal – every 5 years
4. **Water treatment**
 - a. Bacteriological
 - b. Endotoxin
 - c. Chemical
5. **Facility and equipment maintenance schedule**
 - a. Preventive maintenance
 - b. Corrective measures

Equipment List

Emergency equipment: The following equipment should be provided for by the Service Provider:

S. No	Name of Equipment
1	RO Plant (Dual Water Treatment System)
2	Resuscitation equipment including Laryngoscope, Endotracheal tubes, Suction equipment, Xylocaine spray, Oropharyngeal and Nasopharyngeal airways, Ambu Bag- Adult & Paediatric (neonatal if indicated)
3	Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs
4	Suction Apparatus
5	Defibrillator with accessories
6	Equipment for dressing/bandaging/suturing
7	Basic diagnostic equipment : Blood Pressure Apparatus, Stethoscope, Weighing Machine, Thermometer
8	ECG Machine
9	Pulse Oximeter
10	Nebulizer with accessories
11	Dialyzer Reprocessing Unit
12	ACT machine
13	Cardiac monitors
14	Vein finder
15	Refrigerator
16	All required consumables for adult and paediatric patients

STAFFING

It is recommended to have the following minimum standards and staffing pattern for the Dialysis Unit.

- 1 Qualified Nephrologists / MD, Medicine with one year of experience in Dialysis Centre (Public / Private) and performing one visit every fortnight and clinical review for all patients.
- 2 Medical Officers (on duty) – One doctor (MBBS) per shift for a maximum of 10 machines. 3 Dialysis technicians/ nurses: One technician for every 3 machines and one dedicated for dialysis machine for patients with blood borne infections per shift
- 3 Dietician (optional)
- 4 Sweepers: 1 for every five machine per shift
5. Hospital Attendant: 1 for every five machines per shift

Specification

RO Plant (Water Treatment System) & Associated Systems (Dialyzer, Dialysate etc.)

A. HD machine: To be provided by the Authority

- Dialysis Machine with NIBP & TDMS Hardware
- Open System
- Transportation & Installation of Dialysis Machine at the Hospital
- Comprehensive Warranty: **3 years**

B. HD machine: Storage Requirement

The Service Provider shall place the Dialysis Machines (to be provided by the authority) and Equipments within the Hospital in a designated part of the Hospital as per the Operating Manual of the Manufacturer and shall ensure that it shall not store any dangerous, inflammable or explosive material materials or articles or things near the Dialysis Machines and Equipments by reason whereof any insurance effected by any insurer or warranty given by the Manufacturer on or in relation to the said Dialysis Machines and Equipments may be rendered void or voidable and the service provider shall strictly comply with the recommendations of the Manufacturer, the insurers and/or the Manufacturer in relation to storing and keeping the Dialysis Machines and Equipments in the Hospital. The Service Provider shall strictly comply with instructions of the Manufacture for maintaining, using, operating & preserving the Dialysis Machines and Equipments.

C. Monitoring and Evaluation of HD machine

1. Conductivity of the final dialysate being delivered to the dialyzer should be checked before every treatment. According to manufacturers' instructions, the conductivity should be checked with an independent reference meter which is known to be properly calibrated. Conductivity must be within the manufacturer's stated specifications. The frequency of checking with independent reference meter should be as per manufacturer's guideline and also every time the machine is calibrated and repaired.
2. When used, the pH of bicarbonate dialysate should also be confirmed before each treatment. If the pH is below 6.5 or above 7.5, dialysis should not be started, even when conductivity within limits acceptable. The pH can be checked with a similar pH meter.
3. Temperature should also be within the manufacturer's specifications. Temperature may be checked with an independent reference meter or with a reference thermometer.

4. Absence of residual germicide should be verified on all delivery systems connected to a single water treatment "loop" before dialysis begins. Such testing must be performed with an assay known to detect the minimum standard level.
5. A test of proper functioning of the air/foam detector should be performed before dialysis is initiated. This test should be a direct test of function of the alarm, causing interruption of the blood pump and actuation of the blood line clamp, either by introducing air into the venous level detector or by removing the tubing so that air is sensed by the detector as recommended by the device manufacturer.
6. The blood detector must be checked for proper armed status according to the method recommended by the manufacturer.
7. The user should perform applicable tests of the UF control system as prescribed by the manufacturer.
8. All other alarms must be tested according to the manufacturer's instructions for use before every treatment including low and high conductivity alarm, low and high temperature alarm, dialysate pressure alarm, water pressure alarm, etc. Documentation of that testing should be performed. If the particular delivery system is equipped with a "self-alarm check" mode, it is important that the user understand that, most often, it is a check of the electronic circuitry, and not a confirmation of some of the vital functions of specific alarms.
9. Observation of dialysate flow should be made while the machine is in a "dialyzing" mode. Absence of dialysate flow should be confirmed when the machine is in "bypass" mode actuated by both manual setting of the machine to bypass or via any of the alarm functions that will cause the machine to enter a bypass mode.
10. The automatic "self-test" should be performed if this facility is available prior to each HD treatment to confirm proper performance of operative and protective functions of the machine and should never be bypassed.

Recommendation for once monthly evaluation and monitoring:

11. Periodic Microbiological monitoring: water for production of dialysate and actual dialysate proportioned and exiting the dialyzer should be monitored for bacterial levels on no less than a monthly basis. Microbiological monitoring is performed to establish ongoing validation of proper disinfection protocols. The sampling should be done at the termination of dialysis at the point where dialysate exits the dialyzer. Results for total microbial counts in dialysis water or dialysis fluid, should be less than 100 CFU/mL as per ISO 23500/AAMI 2020/BIS 17646 standard.
12. Assessing trends: Pertinent information, i.e., bacterial levels, conductivity and pH readings, etc., should be logged on a chart across a page so that readings can be examined and compared over an extended period of time. This tool makes it possible to compare current readings to those taken during the past several days/weeks/months.

D. Dialyzer (filter) specifications:

The hollow fiber dialyzer forms the central component of dialysis deliver system, where in actual

process of transfer of solutes and water occurs across a semi-permeable membrane. A large array of dialyzers is available for clinical use with several permutations and combinations based on biocompatibility, flux and surface area of the dialyzer. Most often a single type of dialyzer may be sufficient in most patients in a dialysis unit. However, some patients may have specific needs and may require change in the dialyzer specifications. Hence, dialyzers with specifications other than that generally used in the dialysis unit may also be routinely stocked or should be made available at a short notice when the need arises.

E. Recommendations for dialyzer use in HD:

1. Biocompatible, synthetic (e.g., Polysulfone, Polyacrylonitrile, Polymethyl Methacrylate) or modified cellulose membrane (e.g. cellulose acetate) should be preferred over unmodified
2. Cellulose membranes (e.g., Cupraphan). Cupraphane membranes should only be used when patient is intolerant to other biocompatible membranes.
3. Either low flux or high flux biocompatible membrane may be used for regular HD.
4. An allergic reaction to a specific dialyzer is rarely encountered in some patients. In such situation, the particular dialyzer should be avoided and this should be specifically written in bold letters on the dialysis folder of the patient to prevent its inadvertent use.
5. Dialyzer may be use for **NOT more than 10 times or till the bundle volume is > 80% of original capacity** and in such cases reused only for the same patient after due sterilization **using dialyzer reprocessing unit**. Dialyzer should not be reused for sero-positive cases on isolated machine and in such case, single use dialyzer shall be used.
5. Blood line, Transducer Protectors, IV sets, Catheters any other disposables **should not be reused**.

F. Dialysis fluid specifications:

Dialysate, or dialysis fluid, is a non-sterile aqueous solution with an electrolyte composition near that of normal extracellular fluid. Its electrolyte composition is designed to correct the metabolic imbalance that occurs as a result of azotemia. Dialysate concentrates are manufactured commercially in liquid or powder form. The chemicals present in the dialysate have access, via the dialyzer, to the bloodstream of patients undergoing dialysis. Hence, the proper concentration of all of these chemicals as well as the quality of the concentrate and the water used to dilute the concentrate is critical. The following is to be ensured:

1. Electrolyte content of dialysate includes sodium, potassium, chloride, magnesium, calcium, glucose (optional), and bicarbonate as a buffer. The concentration of HD solutions should be such that after dilution to the stated volume the final concentrations of the ions expressed as mmol/L are usually in the following ranges: Sodium 135-145, 40 Potassium 0-4, Calcium 1.0-2.0, Magnesium 0.25-1.0, bicarbonate (32-40, Chloride 95-110. 42; Sodium concentration may be adjusted to levels outside the range of 135-140 mmol/L by HD machines with variable sodium capabilities only when prescribed by physician in charge.

2. Commercially produced concentrates are classified as medical devices and should be approved for clinical use by appropriate authority. The dialysate should contain bicarbonate as the buffer.
3. Water used to prepare the dialysate must have a bacteriological colony count of 100 CFU/ml as per AAMI 139959:2014 / ISO 23500: 2019 / BIS 17646. Bacteriological and fungal growth in the dialysate shall be checked at least once monthly preferably fortnightly (depending upon the raw water condition) (as per Standard Treatment Guidelines for hemodialysis, Indian Society of Nephrology). The colony count in dialysate samples collected at the termination of dialysis a) in a single pass system or b) in a re-circulating single pass system at the periphery of the re-circulating chamber containing the dialyzer should be 100 CFU/ml as per AAMI 139959:2014 / ISO 23500: 2019 / BIS 17646. Dialysate containing glucose at 100- 200 mg/dl concentration should be used.

G. Recommendations for storing and mixing dialysis concentrate:

1. Store and dispense dialysate concentrates as though they were drugs. Ensure that all personnel in the facility are aware of the types of dialysate concentrates available, even if currently only one type is being used.
2. Develop a policy, management, and storage system that will effectively control the mixing and dispensing of all concentrates. Storing concentrates according to type, composition, and proportioning ratios should reduce the risk of mismatching concentrates. Prohibit access to storage areas and allow only authorized, specially trained personnel to mix and dispense concentrates. The concentrate should be prepared / consumed on the same day and there should not be overnight storage to prevent bacterial colonization in the bicarbonate concentrate.
3. Double-check and record concentrate formulas on the patient's record. Consider a procedure for countersigning patient and storage records. Do not dispense concentrates from large containers into smaller ones without a "keyed" dispensing system. Whenever possible, purchase concentrates in single-treatment (2½-4 gallon) containers (optional).
4. Always dispose of concentrates remaining from the previous treatment. Do not pour remaining concentrate into another container or use in the next treatment. Replace empty or partially full containers with full ones. Whenever possible, standardize equipment so that only one bicarbonate concentrate system is used.

H. Water Treatment System:

1. **Dual water treatment system** is mandatory which consists of pre-treatment system and main RO system.
2. Pre-treatment should consist of:
 - Filtration for suspended particles
 - Activated carbon filtration
 - Softener or deionizer
3. Each water treatment system includes reverse osmosis membranes.

4. The water treatment system components are arranged and maintained so that bacterial and chemical contaminant level in the product water does not exceed the standards for Haemodialysis water quality as stated in AAMI 139959:2014 / ISO 23500: 2019 / BIS 17646.
5. Monitoring-
 - a) Chemical purity: Online conductivity meters are mandatory after deionizers & reverse osmosis. There should be visible & audible alarm for improper conductivity in the dialysis technician's station. The alarm should lead to stoppage of water beyond reverse osmosis. The water should re-start only after adequate conductivity is achieved. Once in 3 months treated water sample must be sent for detailed chemical analysis to an independent laboratory having adequate instrumentation for testing as per AAMI 139959:2014 / ISO 23500: 2019 / BIS 17646 standards. The results should be mandatory part of the record system.
 - b) Microbiological purity: This should be checked at least once monthly preferably fortnightly (depending upon the raw water condition) to achieve the standards as per AAMI 139959:2014 / ISO 23500: 2019 / BIS 17646 standards. It is strongly recommended that pour plate method on nutrient poor medium should be used for cultures of treated water.
 - c) Endotoxin levels: should be checked at least once monthly preferably fortnightly (depending upon the raw water condition) to achieve the standard as per AAMI 139959:2014 / ISO 23500: 2019 / BIS 17646 standards.

Maximum allowable levels for total viable microbial count (TVC) and endotoxins in dialysis water, in standard and ultrapure dialysis fluid (dialysate) and online prepared substitution fluid.

Fluid category	Application	TVC (CFU/ml)	Endotoxin (EU/ml)
Dialysis Water	Basis for all fluid preparation used in water treatment system	< 100 (Action level 50)	< 0.25 (Action level 0.125)
Standard dialysis Fluid	Maximum acceptable quality for routine HD used in HD concentrates	< 100 (Action level 50)	< 0.5 (Action level 0.25)
Ultrapure Dialysis Fluid	Recommended for routine HD - used in dialysate ultra filters	< 0.1	< 0.03
Online prepared substitution fluid	HF and HDF: priming solution, bolus administration - used in dialysis machines	Sterile	Non-pyrogenic

6. Sterilization- it is recommended that each component of the water treatment system must be thoroughly cleaned & sterilized as per the manufacturer's recommendation. The process of sterilization should be carried out once in every 15 days. After sterilization it is essential that the sterilant is completely removed before the treated water is used for dialysis.
7. Proper function of water treatment system is continuously monitored during patient treatment and be guarded by audible or visual alarm that can be heard or seen in the dialysis treatment area in case performance of the water treatment system drops below specific parameters.

8. A log should be maintained documenting the performance of the water treatment system components and indicating the maintenance done on each component:

Component	Monitoring parameter	Maintenance Required	Recommended frequency
Depth Filter	Pressure drop across filter	Backwashing & Rinsing	Twice a week and daily during the monsoon or when water extra suspended particles/impurities
Activated carbon filter	Chlorine in product water	Changing of Charcoal	If > 0.1 ug/ml
Softner	Hardness	Regeneration	Failure to achieve 10-fold decrease
Membrane Filters	Pressure drop across filter	Change of filter	>25%
Reverse osmosis membranes	Inlet, reject and permeate pressures & flow conductivity	Increase in inlet pressure >25% or decrease in permeate flow by 25% - increase by 50% from baseline	Cleaning of membranes offline Cleaning of membranes offline or replacement
Deioniser	Conductivity or resistivity	<1mega ohm or > 0.5 micro ohms	Regeneration with acid and alkali
Storage tank and pipeline	Bacterial	>50% increase over baseline	Cleaning and disinfection

9. Procedure guidelines for Disinfection of Reverse Osmosis Machine and Loop as recommended by the manufacturer are in place.
10. No Hemodialysis procedure is performed during disinfection of the water treatment system and the loop.
11. Microbiological testing of the treated water from the water treatment system and the loop is done regularly and preferably monthly.
12. For dialysis unit performing HDF, testing of treated water for endotoxin at regular interval is needed.
13. Written record and results of microbiological and chemical testing of water are in place and reviewed. Corrective action is recorded if indicated.

I. Reuse of Haemodialyzers and related devices

1. Procedure guidelines for dialyzer reprocessing are in place. Dialyzers should be reprocessed & sterilized using a dialyzer re-processing machine and not done manually.
2. Testing for presence of disinfectant in the reprocessed dialyzer before rinsing and absence of disinfectant after rinsing are performed and documented.
3. Each dialyzer is clearly labelled and identified to be re-used by the same patient.

4. Routine disinfection of active and backup dialysis machines are performed according to defined protocol, i.e. HD Machine shall be disinfected after every dialysis session with 20 minutes of Citric Acid to avoid cross contamination. Also end of the day, 1 hour of Citric and thermal disinfection shall be done to all HD machines. The same shall be documented.

J. Other Activities for patient care and staff working in the dialysis unit

1. Blood chemistry and haematocrit (or hemoglobin) of each dialysis patients are checked at regular interval (preferably every month) to ensure patient's well being and viral markers be tested every 3 months (HIV/HBsAg/HCV) iPTH (intact Parathyroid hormone) and vitamin-D should be done every 6 monthly.
2. Contingency plan or procedures are available in case of equipment failure, power outages, or fire so that the patient health or safety can be ensured.
3. Drill for CPR and emergency conditions outlined are performed regularly.
4. All staff including janitorial staff is educated with clear instruction on handling blood spillage on equipment and the floor.
5. All blood stained surface shall be soaked and cleaned with 1:100sodium hypochlorite if the surface is compatible with this type of chemical treatment.
6. All new dialysis patients or patients who return to the dialysis unit after treatment from high- or unknown-risk areas are tested for HbsAg and Anti-HCV etc.
7. HBsAg/HCV-positive patient should be treated in a segregated area with designated Hemodialysis machines.
8. Carrier of HCV receives hemodialysis using designated machines.
9. Patient with unknown viral status is dialyzed using designated hemodialysis machines until the status is known.

CHECK LIST

(To be submitted in *Technical Bid Envelop*)

The documents have to be arranged serially as per the order mentioned in checklist for ease of scrutiny.

Sl. No	Item	Whether included Yes / No	Page No.
1	Format (Check List)		
2	Bid Document Cost of Rs.5,900/- as DD		
3	The Earnest Money Deposit(s) of Rs. 10 Lakhs as DD		
4	Appendix –E (Forwarding Letter for Technical Bid)		
5	Appendix –D (Particulars of the Bidder)		
6	Appendix-E (Brief write-up about the firm / company & their implementation strategy for this project)		
7	Appendix–C (Assignments of similar nature successfully completed during the last three years)		
8	Copies of the Contract / Work Order in support of the information provided in Appendix – C		
9	Copies of the User certificate from the organization (mentioning the no. of dialysis machines operational) where the hemodialysis services had been executed as mentioned in Appendix-C		
10	Appendix - J (Declaration Affidavit on Stamp Paper)		
11	Copies of the annual audited statement / Annual Report for 2019-20, 2020-21, 2021-22 or 2020-21, 2021-22, 2022-23 (If audited)		
12	Manufacturer's Authorization Letter in Appendix – B		
13	Appendix–F (Para-wise Compliance to Technical Specification of Water Treatment Plant as stated in Appendix - N)		
14	Leaflets / Technical Brochures / Product Data Sheets of the Model offered (for Water treatment plant & other equipment like Defibrillator, ECG Machine, Cardiac Monitor, ACT Machine, Basic diagnostic & resuscitation equipment as mentioned in Equipment list at Appendix - L		
15	Copies of the Income Tax Return for past three financial years		
16	Copy of the Registration Certificate of the Firm		
17	Copy of the EPF Certificate		
18	Copy of the ESI Certificate		
19	Copy of the GST registration certificate		
21	Copy of NABL/NABH/ISO certification if any		
22	Copy of PAN		

CONTRACT FORMAT

Contract Form for Providing Dialysis Facilities

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(Address of the Bid Inviting Authority/Office issuing the contract)

CM Contract No._____ **dated**_____

This is in continuation to this office's Notification for Award of contract No dated .

Name & address of the Service Provider:

Reference: (i) Bid Enquiry Document No Datedand subsequent Amendment No, dated (if any), issued by the Bid Inviting Authority (ii) Service provider's Bid No Datedand subsequent communication(s) No

Dated (if any), exchanged between the service provider and the procurer in connection with this bid.

THIS AGREEMENT made the Day of 2023 between (name of Bid inviting authority) (hereinafter called the **Procurer**) of one part and (name of Service Provider) (Hereinafter called the **Service Provider**) of the other part:

WHEREAS the Procurer is desirous that certain services should be provided by the Service Provider, viz. (brief description of services) and the Procurer has accepted a bid submitted by the Service Provider for the Services for the sum of (Contract price in words and figures) (Hereinafter called the Contract Price),

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. The following documents shall be deemed to form part of and be read and constructed as integral part of this Agreement, viz.:
 - (i) Terms and Conditions of the RFP;
 - (ii) Location and Description of Equipment;
 - (iii) Job Description;
 - (iv) Manufacturer's Authorisation Form (if applicable to this bid);
 - (v) Procurer's Notification of Award.
2. In consideration of the payments to be made by the Procurer the Service Provider hereby covenants to provide the Dialysis Services for the specified facilities in conformity in all respects with the provisions of the Contract.

3. The Procurer hereby covenants to pay the Service Provider in consideration of the, services the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed in the Contract.
4. The bank guarantee valid till _____(fill amount) shall be furnished in the prescribed format given in the TE document, within a period of 15 (fifteen) days of issue of Notice for Award of Contract failing which the EMD shall be forfeited.
5. Payment terms: The payment will be made against the bills raised to the Procurer by the Provider on monthly basis after satisfactory completion of said period, duly certified by the designated official. The payment will be made in Indian Rupees.
6. Paying authority: _____(name of the Procurer i.e. Office, Authority)

(Signature, name and address of authorised official)

For and on behalf of _____

Received and accepted this contract

(Signature, name and address of the service provider's executive duly authorised to sign on behalf of the Provider)

For and on behalf of _____

(Name and
address of the Provider)
(Seal of the provider)

Date: _____

Place: _____