Pariwar Kalyan Bhawan, Sheikhpura, Patna-14

# GOVERNEMNT OF BIHAR. **DEPARTMENT OF HEALTH**

Notice Inviting Tender(NIT) Reference No.:- 2/SHSB/PPP(DIALYSIS)/2017 Dt. 03/04/2017

# **NOTICE INVITING TENDER**

For Setting up & operationalizing 24X7 Dialysis Units through Public Private Partnership (PPP) mode in 14 Government District Hospitals (DHs) i.e. Begusarai, Jehanabad, Kaimur, Katihar, Khagaria, Kishanganj, Munger, Nawada, Purnea, Rohtas, Saharsa, Saran, Sitamarhi & Vaishali in the state of Bihar.

# **ACRONYMS**

	Association for the Advancement of Medical						
AAMI	Instrumentation						
ACLS	Advance Cardiac Life Support (ACLS)						
ACT	Activated Clotting Time Machine						
AV	Atrioventricular						
AY	Atrioventricular Assessment Year						
BAS	Bihar State Administrative Services						
BG	Bank Guarantee						
BMET	Bio-Medical Equipment Technician						
CE	Conformité Européenne						
CMO	Chief Medical Officer						
DH	District Hospitals						
DM	Diabetes Mellitus						
DNB	Diplomate of National Board						
ECG	•						
EMD	Electrocardiogram  Farnest Money Deposit						
EPF	Earnest Money Deposit						
EPF	Employee Provident Fund						
	Erythropoietin						
ESI	Employee State Insurance						
FBV	Fiber bundle volume						
FDA	Food and Drug Administration						
FY	Financial Year						
HD	Hemodialysis						
ITB	Instructions to Bidders						
ITR	Income Tax Returns						
KPIs	Key Performance Indicators						
Lol	Letter of Intent						
MAFs	Manufacturers' Authorization Form						
NHM	National Health Mission						
NIT	Notice Inviting Tenders						
OEM	Original Equipment Manufacturer						
PAN	Permanent Account Number						
PoA	Power of Attorney						
PPP	Public Private Partnership						
RFP	Request for Proposal						
RFQ	Request for Quotation						
RO	Reverse Osmosis						
RoC	Registrar of Companies						
SHSB	State Health Society Bihar						
SOP	Standard Operating Procedures						
SoW	Scope of Work						
STG	Standard Treatment Guidelines						
TDS	Tax Deducted at Source						
TIA	Tender Inviting Authority						
VAT	Value Added Tax						

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# **NOTICE INVITING TENDERS**

- 1. The Executive Director, State Health Society, Bihar (SHSB), Patna invites sealed tenders from eligible & qualified organizations for setting up & operationalizing 24X7 Dialysis Units through Public Private Partnership (PPP) mode in 14 Government District Hospitals (DHs) in Bihar for the period of 5 years from the date of agreement.
- 2. State Health Society, Bihar (SHSB) under Department of Health, Govt. of Bihar is implementing the National Health Mission (NHM) to improve the availability and access of quality health care for people of Bihar. SHSB intends to provide specialized dialysis facilities in 14 Government District Hospitals (DHs) i.e. Begusarai, Jehanabad, Kaimur, Katihar, Khagaria, Kishanganj, Munger, Nawada, Purnea, Rohtas, Saharsa, Saran, Sitamarhi and Vaishali through Public Private Partnership (PPP) Project. The key objective is to provide access to high quality Hemodialysis at competitive rate under PPP mode to the people of Bihar.
- 3. The Service Provider shall be responsible for Development (where "Development" means financing, design, build, equip, operate, maintain & manage) of dialysis centres in the hospitals identified by SHSB. The contract with the successful Private Partner will be done by SHSB but day-to-day execution of the contract will be done by the concerned District Health Society in which District dialysis unit is to be set up.
- 4. The Bidder cannot bid for an individual District Hospitals or a group of District Hospitals, but has to bid taking into consideration all the 14 District Hospitals.
- 5. Each Hemodialysis Unit shall have five (4+1) machines.
- 6. Single stage bidding process will be followed to decide the selected bidder. Bids will be evaluated in two steps, as per the evaluation process outlined in Para **9 to 11** in **Section II**.

#### 7. Schedule of Events

SI no	Description	Schedule		
1	Pre-tender Meeting (Date & Time)	12.04.17 (Wednesday) at 3.00 pm		
2	Pre-Tender Meeting Venue	Conference Hall,SHSB, Patna		
3	Closing Date and Time of Receipt of Tender	05.05.17 (Friday) at 3.00 pm		
4	Time, Date and Venue of Opening of	05.05.17 (Friday) at 4.00 pm,		
	Technical Tender/Bid	Conference Hall, SHSB, Patna		
5	Time, Date and Venue of Opening of	Will be informed later		
	Financial Tender/Bid			

Note – i) Interested tenderers may obtain further information about this requirement from the office of State Health Society, Bihar.

ii) No any tender will be accepted after closing date and time in any circumstances.

- 8. Tenderer may also download the tender enquiry documents (a complete set of document is available on website) from the web site <a href="www.statehealthsocietybihar.org">www.statehealthsocietybihar.org</a> and submit its tender by using the downloaded document. The technical bid, should accompany a non-refundable tender fee of Rs 5,000/- (Rupees Five thousand only) in the form of Demand Draft from any scheduled Bank in favour of State Health Society, Bihar, payable at Patna.
- 9. All prospective tenderers may attend the Pre-Tender meeting. The venue, date and time are indicated in Schedule of Events as in Para 7 above.
- 10. The tenders may be sent to The Executive Director, State Health Society, Bihar, Pariwar Kalyan Bhawan, Sheikhpura, Patna-800014 by Registered Post/ Speed Post must reach the above said address on or before the closing date & time indicated in **Para 7** above, failing which the tenders will be treated as late tender and would be summarily rejected.
- 11. In the event of any of the above mentioned dates being declared as a holiday/ closed day for the State Health Society, Bihar the tenders will be received/opened on the next working day at the scheduled time.
- 12. All Tenders must be accompanied by Non-refundable tender fee and EMD as mentioned. Tenders without tender fee and EMD shall be rejected.
- 13. SHSB reserves the right to accept or reject any or all tender or change the terms and condition of NIT or cancel the NIT without assigning any reasons at any stage and time.
- 14. For further enquiry and information, please contact to the following officers during office hours 9:30 AM to 6:00 PM-
  - I. Sri Ravish Kishore, BAS, Sr. Deputy Collector, SHSB 9473197729
  - II. Sri Avinash Kumar Pandey, State Programme Manager, SHSB 9470003016
- 15. All further notifications/amendments, if any shall be posted on <a href="https://www.statehealthsocietybihar.org">www.statehealthsocietybihar.org</a>. No separate communication shall be made to bidders.

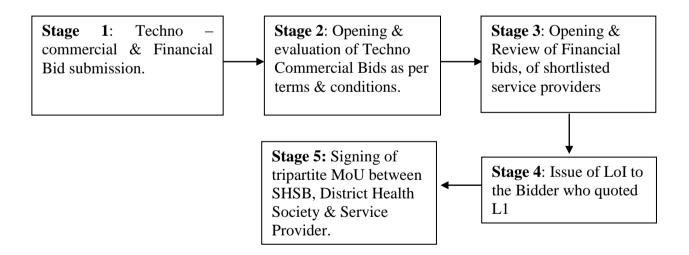
Executive Director
State Health Society, Bihar

# **INSTRUCTIONS TO BIDDER (ITB)**

#### 1. General Instructions

- a) The bidder should prepare and submit its offer as per instructions given in this section.
- b) Before preparing the tender and submitting the same to the Tender Inviting Authority (TIA), the bidder should read and examine all the terms & conditions, instructions, checklist etc. contained in the Tender Documents. Failure to provide required information or to comply with the instructions incorporated in these Tender Documents may result in rejection of tender(s) submitted by bidders.
- c) The tenders must be complete with all documents in hard copies only. The tenders submitted by Fax or Email will not be entertained.
- d) The tenders which are for only a portion of the components of the job /service shall not be accepted. (The tenders /bids should be for all components of the job /service.)
- e) 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.
- f) The tenders (technical and financial) shall be submitted (with a forwarding letter as per **Appendix 'E'**) before the last date of submission. Late tenders / bids shall not be considered.

#### g) Stages of tendering:



#### 2. Inspection of Site and Equipment

The interested bidder may inspect the locations where the services are to be rendered during 10.00 AM TO 5.00 PM on all working days till last date of sale of tender as given in the tender schedule. The Executive Director, State Health Society Bihar shall not be liable for any expenditure incurred in such inspection or in the preparation of the bid(s).

#### 3. Tendering Expense

The bidder shall bear all costs and expenditure incurred and/or to be incurred by it in connection with its tender including preparation, mailing and submission of its tender and subsequently processing the same. The Tender Inviting Authority will, in no case be responsible or liable for any such cost, expenditure etc. regardless of the conduct or outcome of the tendering process.

#### 4. Language of the tender

The tender submitted by the bidder and documents relating to the tender shall be written in the English language. However, the language of any printed literature furnished by the bidder in connection with its tender may be written in any other language provided the same is accompanied by an English translation and, for purposes of interpretation of the tender, the English translation shall prevail.

#### 5. Amendments to Tender Documents

- a) At any time prior to the deadline for submission of tenders, the Tender Inviting Authority may, for any reason deemed fit by it, modify the Tender Documents by issuing suitable amendment(s) to it.
- b) Such an amendment will be notified on www.statehealthsocietybihar.org and the same shall be binding to all prospective Bidders.
- c) Any bidder who has downloaded the tender document should watch for amendment, if any, issued on the above website and Tender Inviting Authority will not issue separate communication to them. Tender Inviting Authority shall not be responsible in any manner if prospective Bidders miss any notifications placed on above mentioned website.

# 6. Pre-Tender Meeting

I. In order to provide response to any doubt regarding terms and conditions, scope of work and any other matter given in the tender document, a pre-tender meeting has been scheduled to be held in the office of Tender Inviting authority as per details given hereunder:

**Date & Time:** 12/04/2017 (Wednesday) at 3.00 pm

Venue: Conference Hall, State Health Society, Bihar, Pariwar Kalyan

Bhawan, Sheikhpura, Patna

Contact I. Sri Ravish Kishore, BAS, Sr. Deputy Collector, SHSB, Mobile -

persons: 9473197729

II. Sri Avinash Kumar Pandey, State Programme Manager, SHSB,

Mobile – 9470003016

II. During the pre-tender meeting, the clarification sought by representative of prospective bidders shall be responded appropriately. However, they shall clarify and will be asked to submit their written request by close of office next day. The Tender Inviting Authority (TIA) shall upload written response to such requests for clarifications, without identifying its source. In case required, amendments, in terms of Para 5 above shall be issued, which shall be binding on all prospective bidders.

#### 7. Clarifications to Tender Documents

- I. A prospective bidder requiring any clarification regarding terms & conditions, technical specifications etc. given in the Tender Documents may submit written request for clarifications to Sri Ravish Kishore, BAS, Sr. Deputy Collector by post/email ID: dxserviceshs@gmail.com within 1 (one) day of date of pre-tender meeting.
- II. All the prospective bidders will be notified of response to clarifications only through website www.statehealthsocietybihar.org. Any bidder who has downloaded the tender document should watch for clarifications, if any, issued on the above mentioned website and Tender Inviting Authority will not issue separate communication to them.
- III. Tender Inviting Authority shall not be responsible in any manner if a prospective bidder fails to notice any notifications placed on above mentioned website.

#### 8. Earnest Money Deposit (EMD)

- a) The tender shall be accompanied by Earnest Money Deposit (EMD) of 14,00,000/- (Fourteen Lakhs only) for all the 14 District hospitals in the shape of Demand Draft from any Schedule Bank in favour of State Health Society, Bihar payable at Patna.
- b) It may be noted that no bidder is exempt from deposit of EMD. Tenders 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) Earnest money is required to protect the Tender Inviting Authority against the risk of the Bidder's conduct, which would warrant the forfeiture of the EMD. The EMD of a bidder may be forfeited without prejudice to other rights of the SHSB, if the bidder withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to notice that the information /documents furnished in its tender 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 SHSB, if it fails to furnish the required performance security within the specified period.

### 9. Preparation of Tender

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

- I. The **first envelope** shall be marked in bold letter as **"TECHNOCOMMERCIAL BID"** which shall be sent with forwarding letter**("Appendix-E")** and shall include the following:
  - 1) Non-refundable tender fee of Rs. 5,000/- (Rupees Five Thousand only) in the form of Demand Draft of any Scheduled Bank drawn in favour of the State Health Society, Bihar payable at Patna
  - 2) Earnest Money Deposit (EMD) furnished in accordance with above "Para 8";
  - 3) Original tender document duly stamped and signed in each page along with the "Forwarding Letter for Technical Bid" confirming the performance of the assignment as per Technical Bid i.e. "Appendix E".
  - 4) Particulars of the bidder as per "Appendix-D"
  - 5) Self-attested copy of audited accounts statement i.e. Profit & Loss Account, Balance Sheet, Income & Expenditure statement and other related financial statements along with all Appendix s for the last 3 financial years (FY) 2013-14, 2014-15 and 2015-16.
  - 6) Copy of the Income Tax Returns (ITR) acknowledgement for three assessment years (AY) i.e. 2014-15, 2015-16 and 2016-17.
  - 7) Authorization Letter for signing of proposal in favour of signatory to tender documents as per "Appendix B.2".
  - 8) Self-attested copy of the certificate of registration of CST, VAT, EPF, ESI & Service tax issued by the appropriate authority valid as on date of submission of tender documents must be submitted, **if applicable**.
  - 9) A duly notarized declaration from the bidder in the format given in the "Appendix-H" to the effect that the firm has neither been declared as defaulter or black-listed or declared ineligible or ongoing litigation is pending etc by any competent authority of Government of India OR Government of any State or Society of any state.
  - 10) Checklist as per format given in "Appendix-N" in Section VII.

In addition to the above documents,

- a) The tender of the Authorized Agent shall include the manufactures authorization letter as per performa given in "Appendix –B.3".
- b) The tender of others (i.e. those who are neither manufactures nor authorized agents) shall include a statement regarding similar services performed by them in last three years and user's certificate regarding satisfactory completion of such jobs 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. No bidder can place more than one bid in any form in the state.

IV. The Bidder cannot bid for an individual District Hospitals or a group of District Hospitals, but has to give a single bid taking into consideration all the 14 District Hospitals as a single unit.

#### 10. Tender Submission

- 1. The two envelopes containing both technical and the financial bid shall be put in a bigger envelope, which shall be sealed and superscripted with "TENDER NAME "Notice Inviting Tender for Setting up & operationalizing 24X7 Dialysis Units through Public Private Partnership mode in 14 Government District Hospitals (DHs)"
- The offer shall contain no interlineations or overwriting except as necessary to correct errors, in which cases such correction must be initialed by the authorized person or persons signing the tender. In case of discrepancy in the quoted prices, the price written in words will be taken as valid.
- 3. The Bidders shall submit their tenders as per schedule indicated in Notice Inviting Tenders (NIT) and any amendments made in due date for submission of bids by SHSB.
- 4. Tender Documents are invited in two bids System i.e. "TECHNOCOMMERCIAL BID" -- Envelope-A" and "FINANCIAL BID" Envelope-B.
- 5. The Techno commercial bids and financial bids shall either be typed or written in indelible ink and the same shall be signed by the bidder or by a person(s) who has been duly authorized to sign. The Authorization Letter shall also be furnished along with the tender as per "Appendix B.1".
- 6. All the pages of the tender shall be duly signed at the appropriate places as indicated in the Tender Documents and all other pages of the tender including printed literature, if any shall also be signed by the same person(s) signing the tender. The tender shall not contain any eraser or whitener or overwriting, except as necessary to correct any error made by the bidder and, if there is any such correction; the same shall be initialed by the person(s) signing the tender. However, no correction in financial bid shall be allowed even if with the signature of the person signing the bid.
- 7. The bidder has to seal the Technical and Financial bids in separate envelops duly superscribed, sealed and both these envelopes should then to be put in a bigger outer envelope, which should also be sealed and duly superscribed. The outer as well as inner envelops should have complete address of bidder as well as Tender Inviting Authority.
- 8. If the outer envelope is not sealed and marked properly as above, the Tender Inviting Authority will not assume any responsibility for its misplacement, premature opening, late opening etc.

#### 11. Tender opening

- I. The Tender Inviting Authority will open the tenders at the date and time as indicated in the NIT. In case the specified date of tender opening falls on / is subsequently declared a holiday or closed day for the Tender Inviting Authority, the tenders will be opened at the appointed time and place on the next working day.
- II. Authorized representatives of the bidders, who have submitted tenders on time may attend the tender opening provided they bring with them letters of authority from the bidders.
- III. The "Technical Bid (Envelope-A)" shall be opened at the first instance, at the prescribed time and date as indicated in NIT. These Bids shall be scrutinized and evaluated by the designated committee with reference to parameters prescribed in the Tender Document. "Financial Bid (Envelope-B)" of only the technically responsive acceptable offers (as decided in the first stage) shall be opened for further scrutiny. The prices offered will be read out by tender opening official(s).

### **EVALUATION OF TENDERS**

#### 1. Scrutiny of Tenders

The tenders 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 Tender Enquiry Documents. 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 purchaser as to whether the bidder is eligible and qualified or not and weather 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. Infirmity/Non-Conformity

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

# 3. Discrepancies in Prices

- 1) If there is a discrepancy between the amount expressed in words and figures, the amount in words shall prevail.
- 2) If, as per the judgment of the Tender Inviting Authority, there is any such arithmetical discrepancy in a tender, the same will be suitably conveyed to the bidder by speed post/e-mail. If the bidder does not agree to the observation of the Tender Inviting Authority, the tender is liable to be ignored.

#### 4. Bidder's capability to perform the contract

The Tender Inviting Authority, through the above process of tender scrutiny and evaluation will determine to its satisfaction whether the bidder, whose tender has been determined as the lowest evaluated responsive bidder, is eligible, qualified and capable in all respects to perform the contract satisfactorily. In such conditions, decision of the SHSB shall be final and binding on the bidders.

#### 5. Contacting the Tender Inviting Authority

- I. From the time of submission of tender to the time of awarding the contract, if a bidder needs to contact the Tender Inviting Authority for any reason relating to its tender, it should do so only in writing.
- II. In case a bidder attempts to influence the Tender Inviting Authority in the Tender Inviting Authority's decision on scrutiny, comparison & evaluation of tenders and awarding the

contract, the tender of the bidder shall be liable for rejection and it may also lead to forfeiture of EMD in addition to appropriate administrative and coercive actions being taken against that bidder, as deemed fit by the Tender Inviting Authority.

#### 6. Bid Clarification

- I. To facilitate evaluation of Proposals, the Authority may, at its sole discretion, seek clarifications in writing from any Bidder regarding its Proposal. Notwithstanding anything contained in the NIT, the Authority reserves the right not to take into consideration any such clarifications sought for evaluation of the Proposal.
- II. At any point in time during the bidding process, if required by the Authority, it is the Bidders' responsibility to provide required evidence of their eligibility as per the terms of the NIT, to the satisfaction of the Authority. The Authority or appointed advisers can verify the facts and figures quoted in the proposal. The Authority reserves the right to conduct detailed due diligence of the information provided by the Bidders for qualification and financial evaluation. If no response is received by this date, the SHSB shall evaluate the offer as per available information.

#### 7. Fraud and Corrupt Practices

- I. The Applicants and their respective officers, employees, agents and advisers shall observe the highest standard of ethics during the Selection Process. Notwithstanding anything to the contrary contained herein, the SHSB may reject an Application without being liable in any manner whatsoever to the Applicant if it determines that the Applicant has, directly or indirectly or through an agent, engaged in corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice in the Selection Process.
- II. Without prejudice to the rights of the SHSB hereinabove, if an Applicant is found by the SHSB to have directly or indirectly or through an agent, engaged or indulged in any corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice during the Selection Process, such Applicant shall not be eligible to participate in any tender or RFP issued by the SHSB during a period of 5 (Five) years from the date such Applicant is found by the SHSB to have directly or indirectly or through an agent, engaged or indulged in any corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice, as the case may be and it may also lead to forfeiture of EMD deposited by such bidder.
- III. For the purposes of this Clause, the following terms shall have the meaning hereinafter respectively assigned to them:
  - (a) "Corrupt practice" means (i) the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence the actions of any person connected with the Selection Process (for avoidance of doubt, offering of employment to, or employing, or engaging in any manner whatsoever, directly or indirectly, any official of the SHSB who is or has been associated in any manner, directly or indirectly, with the Selection Process.

- (b) "Fraudulent practice" means a misrepresentation or omission of facts or suppression of facts or disclosure of incomplete facts, in order to influence the Selection Process.
- (c) "Coercive practice" means impairing or harming or threatening to impair or harm, directly or indirectly, any person or property to influence any person's participation or action in the Selection Process.
- (d) "Undesirable practice" means (i) establishing contact with any person connected with or employed or engaged by the SHSB with the objective of canvassing, lobbying or in any manner influencing or attempting to influence the Selection Process; or (ii) having a Conflict of Interest, and
- (e) "Restrictive practice" means forming a cartel or arriving at any understanding or arrangement among Applicants with the objective of restricting or manipulating a full and fair competition in the Selection Process.

#### 8. Award of Contract

- I. The Tender Inviting Authority reserves the right to accept in part or in full any tender or reject any tender(s) without assigning any reason or to cancel the tendering process and reject all tenders at any time prior to award of contract, without incurring any liability, whatsoever to the affected bidder(s).
- II. The bidder shall within 7 days of issue of the Letter of Intent (LoI), give his acceptance.
- III. The final selection of the agency shall be as per the Least Cost Selection (LCS) method, and the contract will be awarded to the bidder/service provider whose financial bid is the lowest (L1), provided the bidder meets the eligibility criteria as per **Section V**.
- IV. The Tender Inviting Authority reserves the right at the time of Contract award and/or during validity of contract, to increase or decrease the scope of services without any change in unit price or other terms and conditions.
- V. The Tender Inviting Authority will notify the successful bidder(s) in writing by issuing a Letter of Intent (LoI), that its tender has been accepted, briefly indicating there in the essential details like description of services and corresponding prices accepted.
- VI. The successful bidder must furnish to the Tender Inviting Authority the required performance security within 15 days along with the contract agreement from the date of issue of LoI, failing which the EMD will be forfeited and the award will be cancelled and bidder will be blacklisted. Relevant details about the performance security have been provided under **Section VI Para 13**. The Notification of Award shall constitute the formation of the Contract.
- VII. The contract agreement will be a tripartite agreement between State Health Society, Bihar, concerned District Health Society (DHS) and the selected service provider. The stamp duty, if any, payable on the Agreement will be borne by the selected service provider/bidder.

# **SCOPE OF THE WORK**

- 1. The Service Provider shall be responsible for operationalization of *Dialysis* facility at district hospital to the patients referred by doctors of Government Hospitals. Referred cases of other than Government Hospitals may be accepted with the permission of Superintendent of the concerned District Hospital when adequate referred patients of Government Hospitals are not available to meet the capacity of the unit.
- 2. Ownership status of all movable assets created from the investments made by the Service Provider shall remain with the Service Provider.
- 3. The service provider would be allotted a space of 600 sq ft.(Within the building/ Open space within the premises of the concerned District Hospital with a capacity to run 5 dialysis machines (@ 120 sq. ft. per machine) free of cost and the service provider shall make complete arrangements to make the dialysis facility operational and provide round the clock services(24X7) (should factor all required infrastructure, including renovation, modification of infrastructure, HR like trained Nephrologists/M.D Medicine, Medical officers, Nurses, technicians etc.), supportive infrastructure, dialyzer and all other consumables etc., operational and maintenance cost for the project. The space of 600 sq.ft., as mentioned above, is exclusively for Dialysis machines (5 Nos.). Adequate space for other purposes may be provided separately as per availability and requirement. A Possession Certificate in plain paper shall be issued by the concerned District Hospital while handing over the above mentioned space.
- 4. All the pre-requisites such as interiors, civil, piping, electrical, 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 District Hospital. The district hospital administration will not be responsible for any loss/ damage to the machine/property due to natural hazard and the service provider/ agency 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.
- 5. Water and electricity charges will be paid by the Service Provider to hospital administration/concerned department as per Government rules. The hospital administration will provide authorization for separate electricity & water connection to Private partner. The Private partner must arrange separate connection from BSPHCL/BSEB for electricity, and PHED, Bihar for water supply at his own cost.
- 6. The decision to refer a patient for dialysis in District/ hospital should originate from a qualified nephrologist/ M.D Medicine in a Government hospital. In all cases, the diagnostic tests (Urea, Creatinine, Potassium, complete bio-chemistry & hematology profile) before and after the dialysis should be done through the free diagnostic program OR governments own laboratory. Incorrect laboratory tests may lead to wrong referral for dialysis hence due precautions would be taken to refer a patient for dialysis and laboratory reports before and after the dialysis cycle should be recorded. The Dialysis unit/facility must have a minimum of

- 4 Dialysis machines plus one dedicated machine for infective cases (Hepatitis B, Hepatitis C, HIV etc.). However, the service provider would have to increase the no. of machines, in the facility in the future, subject to load availability and decisions by SHSB.
- 7. Service to the patients referred by Government Hospitals or Non-Government Hospitals shall be provided at contracted rate only for full package. No additional charge is allowed in any shape. The payment will be made by the patients themselves. However, no amount will be charged from the patients, under Free Patients Category as decided by SHSB, and reimbursement of such service charge shall be made by the concerned District Health Society(DHS).
- 8. The doctor of the dialysis facility provided by the service provider shall facilitate Govt. doctors to issue the death certificate in case of death of any patient while the dialysis process is in progress or immediately after the dialysis procedure, if the death is within the facility.
- 9. The facilities such as observation rooms, recovery rooms among other should be developed within the premises of the Hemodialysis centre and provided on the cost of Service Provider.
- 10. An indicative list of the minimum staff to be deputed is given in **Section VI Terms & Conditions Clause**4 as shown in **"Appendix K"**.
- 11. All machinery & equipment's, Air Conditioning, RO unit and materials including consumables, Dialyzers etc. needed for Dialysis, has to be procured by the service provider to provide uninterrupted service. No refurbished, second hand or used equipment's shall be installed. An indicative specification of equipment's is given in "Appendix J & L". The bidder will be required to furnish certificate that the equipment's are "FRESH NEW" issued by the Original Equipment Manufacturer (OEM) at the time of installation.
- 12. Any deficiency in services due to deficiency in manpower or equipment or due to material quality will be the sole responsibility of the service provider.
- 13. Running cost of dialysis facilities, staff salary is to be borne by the service provider.
- 14. Responsible for Capacity building of doctors and staff of the hospital on providing dialysis service by the Service Provider.
- 15. Service Provider will be responsible for inventory management of consumables to provide the service.
- 16. Service Provider will be responsible for providing Emergency care for Dialysis patients- 24X7.
- 17. Service Provider **shall facilitate in** making arrangements to shift the patient to other centres, for patients who suddenly deteriorate during Dialysis and cannot be treated within the hospital.
- 18. Service Provider will be responsible for making alternate arrangements in the event of breakdown of their services at their own cost.
- 19. Service Provider will be responsible for maintaining all records both medical and non-medical as well as medico legal records, as prescribed under the provisions of law
- 20. Service Provider will 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.
- 21. Service Provider will submit required reports and duty roster to the Hospital administration
- 22. Service Provider will use the space provided only for the purpose of dialysis service to the patients.
- 23. Service Provider will Issue Identity cards, uniforms to their staff, workers and patients.
- 24. Service Provider will maintain dress code for the workers.

- 25. Service Provider will be responsible for Insurance cover/annual maintenance contract for equipment's or other facilities connected with services.
- 26. Service Provider will be responsible for any permits in case required, shall be the responsibility of bidder.
- 27. Service Provider will be responsible for Software used should be compatible with hospital software.
- 28. Services of Nephrologists, Physician/Dialysis Doctor, Dialysis Technician, Nurses/Para Medical Staff, Ward Boy/Attendant, Sweeper etc. will be provided by the service provider on their own cost.
- 29. Service Provider will provide dashboard for monitoring of service delivery with due diligence to patient privacy for administrative Staff. Treating Nephrologist should have complete access to the dashboard.
- 30. Service Provider will be responsible for procurement of RO plant and its maintenance
- 31. The service provider will provide 24 hours Generator backup during power failure, for which a silent generator sufficient to run the Dialysis unit/centre has to be purchased and installed at an appropriate place. All costs associated with the installation & operation of generator shall be borne by the service provider.
- 32. Service Provider will be responsible for regular maintenance of equipment's and quality checking of materials/ consumables/ process for quality hemodialysis and develop a quality manual as per good industry practice.
- 33. Service Provider will be responsible for Wastes generated by the hemodialysis facility should be considered infectious & handled accordingly. These solids wastes should be disposed of properly, in an incinerator or sanitary landfill, according to and regulations governing medical waste disposal (Bio- Medical Waste Management Rules, 2016). The concerned District Health Society will facilitate in co-ordinating between the existing common Bio-Medical Waste Treatment facility and the selected Dialysis service Provider. However, the charges of Bio-Medical services would be borne and paid by the Dialysis Service Provider.
- 34. Service provider would install a latest version of any licensed hospital management application software. Software should be capable of generating invoice, manage patient data/test results/ history, Inventory Management and generate reports.
- 35. Security of the Dialysis Unit or other equipments of unit will be the responsibility of the service provider.
- 36. SMS based appointment system for all patients enrolled for services could be provided by Service Provider on their own cost.
- 37. The service provider will have to maintain an uptime of 90% annually with maximum 7 days of downtime at a stretch of any single dialysis machine of the facility.
- 38. The service provider will be responsible for make alternative arrangements for provision of dialysis (including free transportation of patients at alternate place) 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.
- 39. The following records shall be maintained on a daily basis by the service provider:
  - (i) Daily patients register including outside as well as for patients referred by District Hospital to be separately maintained.
  - (ii) Log book for record of any breakdown/shut down of the machine/facility.
- 40. 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 center 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 center.
- 41. Availability of Electricity, water, **oxygen cylinder/ oxygen concentrator** and all other required amenities including waiting area for patient & patient attendant shall be the responsibility of the service provider.
- 42. The service provider shall provide a resuscitation room with crash cart for providing lifesaving support if required by patients within the dialysis facility.
- 43. Service Provider shall arrange for appropriate and adequate signage and IEC (Information-education-communication) activities for facility as decided by the authority.
- 44. 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 contractor, at one month's notice. Dispute resolution shall be as per **Section VI Terms & Conditions Clause 20.**
- 45. In addition to above, service provider shall be required to carry out incidental works and services as required.
- 46. Services to be provided under the Rate Contract Package:
- a) All the obligations of the service provider/firm under this service contract shall include all service activities and commitments as listed above. The details of various services required at different locations and type of facilities is given in **Appendix 'A'**.
- b) The details of the Rate Contract Package will include the following:
  - 1) Provide Hemo Dialysis Service for one session with Dialyzer and all consumables like AV Blood line, AV Fistula Needles, heparin, normal saline, dialysis fluid, needles, syringes, IV sets, gloves, cotton etc.,
  - 2) Dialyzer
  - 3) Provide essential medications like Erythropoietin (EPO), Iron Sucrose etc.,
  - 4) Provide required clinical diagnostic services, (Note: The Financial Bid will not include the cost of AV Fistula making, Single/Double/Triple Lumen catheter.)
- 47. The agency will directly charge and receive the amount from the patients as per rate contract. However, no amount is to be charged from the patients, under "Free Patients Category" as decided by SHSB. The concerned District Health Society (DHS) will pay the agency at the contracted rate for such referred patients under" Free Patients Category" by the doctors of district hospital, for which service is provided by the agency. The agency will have to submit the bill for such free patients as per Section VI Terms & Conditions Clause 7.

# **ELIGIBILITY CRITERIA**

- 1) This invitation is open to all organizations (Proprietorship Firms, Partnership Firms, Limited Liability Partnership Firms, Companies registered under Companies Act, 1956/2013 or Societies Act, Trusts, Societies registered under respective Act & Jurisdiction in India) who fulfill the eligibility & qualification criteria specified hereunder. (The bidder can't be an individual or group of individuals & Consortium is not allowed)
- 2) The bidder shall declare all ongoing litigations it is involved in with any government agency/state/central department.
- 3) The eligibility criteria and Supporting Documents to be submitted by the bidders are as follows:-

follows:-							
SI.	Eligibility criteria for Bidders	Supporting Documents					
(1)	The Bidder should be an established firm under Proprietorship, Partnership Firms, Limited Liability Partnership Firms, Companies registered under Companies Act, 1956/2013 or Societies Act, Trusts, Societies registered under respective Act & Jurisdiction in India	Copy of the Certificate of Incorporation issued by the Registrar of Companies/ Registrar of Societies/official having jurisdiction in case of a trust/ other appropriate authority whichever is applicable					
(11)	The bidder must have minimum turnover of Rs. 5.00 Crores per annum in each of the last three financial years (FY 2013-14, FY 2014-15 & FY 2015-16).	Audited Balance sheet & Profit & Loss Account & other related documents for FY (FY 2013-14, FY 2014-15 & FY 2015-16).					
(111)	The bidder must provide self attested scanned copies for (i) PAN Card along with income tax returns of three assessment years AY 2014-15, AY 2015-16 & AY 2016-17, and (ii) Service Tax Registration Certificate and (iii) Sales Tax/VAT certificate, if applicable.	Self-attested copies of  1) PAN Card  2) Service Tax  Registration Certificate  3) Sales tax or VAT  Certificate  4) Copy of Income Tax  Return filed and submitted by the bidder for three assessment years AY 2014-15, AY 2015-16 &  AY 2016-17.  5) The latest copy of Service Tax returns & VAT returns submitted by the bidder as on 31.03.2016.					

SI.	Eligibility criteria for Bidders	Supporting Documents		
(IV)	The Bidder shall have a minimum of three years of experience in carrying out similar type of assignment / service in private or public sector. (The assignment of Govt. Depts. / Semi Govt. Depts. should be specifically brought out. (The decision of the SHSB 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.))	<ol> <li>Statement regarding assignments of similar nature successfully completed/running/in-operation during last three years should be submitted as per proforma in "Appendix 'C'".</li> <li>Users' certificate regarding satisfactory completion of assignments should also be submitted.</li> </ol>		
(V)	The bidder should have the experience of Operating & managed dialysis facilities, having at least a total of 50 Hemodialysis machines, and that the facilities should have been in operation for at least 3 years prior to the submission date.	Copy of work order or experience certificate from the employer during the F.Y. 2013-14, 2014-15 & 2015-16		
(VI)	<ul> <li>(i) Blacklisted / banned / convicted by any court of law for any criminal or civil offences/ declared ineligible by any entity of any State Government or Govt. of India or any local Self-Government body or public undertaking in India for participation in future bids for unsatisfactory part performance, corrupt, fraudulent or any other unethical business practices or for any other reason during the past 5 years, from the last date of submission of bids.</li> <li>(ii) No criminal case or vigilance case related to cheating, forgery, Criminal breach of trust, theft and prevention of Corruption Act is pending at the level of a competent authority.</li> <li>(iii) No investigation by any statutory body / Govt. investigating Agency of any state Govt./ Central Govt. is undertaken or pending against the bidder for the charge having nature of criminal/economic offence/fraud. Please refer Appendix H.</li> <li>(iv) The bidder shall declare all ongoing litigations, it is involved in with any Government Agency/State.</li> </ul>	Affidavit sworn before Public Notary/Executive Magistrate as per "Appendix H".		

The bidders who fulfill the above eligibility criteria will qualify the technical bid, and all the financial bids of all the technically qualified bidders will be opened.

# **TERMS AND CONDITIONS**

#### 1. Use of contract documents and information

- 1.1 The Service Provider shall not, without the Tender Inviting Authority's prior written consent, disclose the contract or any provision thereof or any information furnished by or on behalf of the Tender Inviting Authority in connection therewith, to any person other than the person(s) employed by the Service Provider in the performance of the contract emanating from this Tender Document. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for the purposes of such performance for this contract.
- 1.2 Further, the Service Provider shall not, without the Tender Inviting Authority's prior written consent, make use of any document or information mentioned in sub-clause 1.1 above except for the sole purpose of performing this contract.
- 1.3 Except the contract issued to the Service Provider, each and every other document mentioned in sub-clause 1.1 above shall remain the property of the Tender Inviting Authority and, if advised by the Tender Inviting Authority, all copies of all such documents shall be returned to the Tender Inviting Authority on completion of the Service Provider's performance and obligations under this contract.

### 2. Intellectual Property Rights

The Service Provider shall, at all times, indemnify and keep indemnified the Tender Inviting Authority, free of cost, against all claims which may arise in respect of goods & services to be provided by the Service Provider under the contract for infringement of any intellectual property rights or any other right protected by patent, registration of designs or trademarks. In the event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against the Tender Inviting Authority, the Tender Inviting Authority shall notify the Service Provider of the same and the Service Provider shall, at his own expenses take care of the same for settlement without any liability to the Tender Inviting Authority.

#### 3. Insurance

- 3.1 The Service Provider shall be responsible for insuring all the machines, plant, equipment, furniture, etc. for accident, theft, damage, burglary etc.
- 3.2 The SHSB 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 SHSB's / consignee's premises. All liabilities, legal or monetary, arising in that eventuality shall be borne by firm/ agency.

#### 4. Proposed Human Resources:

- 4.1 The Service provider acknowledges that it will be providing round the clock uninterrupted services and shall appoint and recruit manpower and impart adequate training to the manpower for performance of all obligations, in accordance with the terms, conditions, and covenants set forth in the NIT for the operation, maintenance and management of dialysis Units, and the Project facilities.
- 4.2 The manpower appointed or hired for the operation of the Dialysis units as per **Appendix K: Staffing** and the project facilities shall be the employees of the service provider and that the State Health Society Bihar, or the District Health Society will not be liable for any acts of commission/omission vis-à-vis the manpower appointed or hired by the service provider.
- 4.3 The bidder shall also comply with all other statutory provisions 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 facility.
- 4.4 The service provider shall be responsible to comply with all the provisions of Minimum Wages Act and other applicable labour legislation in respect of the manpower appointed or hired by the service provider in respect of execution and implementation of the project and shall indemnify and keep indemnified the Authority for any claim, action or demand whatsoever in that regard. It will be the sole responsibility of the Service Provider to abide by the provisions of the following acts as to the manpower appointed or hired for performance of this contract:
  - I. Employment of Children Act
  - II. Workmen Compensation Act
  - III. Employment of labour/Contract Labour Act
  - IV. Industrial Employment Act
  - V. Contract Labour abolition & regulation Act 1970
  - VI. Minimum Wages Act
  - VII. Employee Provident Fund Act
  - VIII. ESI Act
    - IX. Any other Act or Legislation, which may govern the nature of the contract and/or being issued by Government from time to time regarding manpower/employment.

# 5. Project Duration

- 5.1 The Project will be awarded for a period of 5 years from the date of agreement and may be extended for another one or more years on the terms & conditions mutually agreed by the service provider and SHSB.
- 5.2 The Service Provider will be obliged to establish, manage and operate the Project in accordance with the provisions of the Contract Agreement and terms and conditions therein.

### 6. Standard Operating Procedures

The service provider will develop Standard Operating Procedures (SOP) and share with State Nodal person. The SOP must include the following:

- 6.1 Plant & machinery should include regular repairing, periodic repairing schedule, defined time period for each services, scheduled maintenance work etc. Refer "Appendix I".
- 6.2 Human Resources should clearly define roles, responsibilities, training, working hours, etc.
- 6.3 Devising and practicing a safety plan to ensure safety of patient adopting adequate safety standards.
- 6.4 Implementing a quality control programme for providing quality service

All SOPs must also include measurable indicators which will be verified by SHSB or its authorized representative as and when required. SOPs will be used for monitoring purpose by the client. The selected service provider will have to submit training plan, job description and terms of reference for each position in manpower to SHSB.

### 7. Payments

- 7.1 The payment will be made on monthly basis to the agency by the concerned District Health Society, against the invoices raised for the services provided to the patients under "Free Patients Category" as decided by SHSB.
- 7.2 The service provider will raise its invoices on completion of services during the month and the invoices must be submitted to respective District Health Society till 7th of the next month 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.
- 7.3 The payments will be made through RTGS/NEFT by 20<sup>th</sup> of the month, after necessary verifications & deducting penalties (if any). In case the payment is delayed beyond 20<sup>th</sup> of the month, after receipt of claims with relevant documentary evidences as accepted by the concerned officials, a nominal interest of 4%(per annum) shall be paid to the service provider on the admitted bill amount from expiry of mandated 20<sup>th</sup> day of the month of period till the actual date of receipt of payment by the service provider.
- 7.4 However, the agency must directly charge and receive the amount (As per the quoted cost per Hemodialysis cycle from the patients) who are not covered by "Free Patients Category" as decided by SHSB.
- 7.5 The prices (cost per Hemodialysis cycle from the patients) quoted shall remain for the duration of the contract with 3% escalation on the quoted financial bid (all inclusive rate for the full package service) per annum with respect to preceding year, as per approval from SHSB.

### 8. Performance Review, Incentives & Penalty provisions.

- 8.1 Agency performance would be evaluated based upon identified Key Performance Indicators (KPIs) listed in "Appendix M"
- 8.2 The parameters will be used to assess the performance of the Service Provider and penalty will be applied as and when required.
- 8.3 The penalties would be imposed for each occurrences as per details mentioned in the sub-identified Key Performance Indicators (KPIs) listed in "Appendix –M". However, maximum penalty would be limited to 10% of total payments due for the month against the invoice raised

#### 9. Start of the services

The service provider shall commission and start the 24X7 Dialysis facility across all the facilities (14 DHs) within 90 days of the signing of the contract, otherwise a penalty of 10% amount of Performance Security/Bank Guarantee for delay of every 30 days may be imposed and deducted from the Performance Security/Bank Guarantee submitted by the Service Provider as decided by the SHSB.

If service provider fails to start the services beyond 180 days, the contract may be terminated and the selected service provider may be blacklisted and might result in forfeiture of performance security/bank guarantee to which, the selected agency shall have no claims. However, if the delay in commissioning and start of 24X7 Dialysis service is due to genuine reasons and there is no negligence on the part of the agency, the SHSB shall consider the matter on submission of written application by the agency and shall pass appropriate order regarding reducing /waiving the penalty.

### 10. Assignment

The Service Provider shall not assign, either in whole or in part, its contractual duties, responsibilities and obligations to perform the contract, except with the Tender Inviting Authority's prior written permission.

#### 11. Sub Contracts

Sub-letting/Sub-contracting of the contract would not be allowed under any circumstances and contract may be terminated in case the service provider sublets or sub-contracts its liabilities/responsibilities/obligation to other. Penal action may also be taken against the service provider. Notwithstanding the aforesaid, the Service Provider has a right to subcontract the services as mentioned below:

- 1) Development of infrastructure for all dialysis centers includes; Any Civil Work; which includes, Demolition of existing walls or construction, Painting, Carpentry which includes, Furniture's, which may be necessary for the dialysis centre, Plumbing, Electrical Connections, Electrical Fixtures, Air Conditioning of the Treatment Rooms, Flooring etc.
- 2) House-keeping Services of all the dialysis centers
- 3) Laboratory and other Diagnosis Services may be outsourced to renowned laboratory providing best standard reports

- 4) Bio-medical waste, collection, disposal, and incineration, may be outsourced to Bio-Waste Management agencies approved by SHSB following the State Pollution Control Board Protocols & regulations governing medical waste disposal rules as mentioned in Bio- Medical Waste Management Rules, 2016.
- 5) Annual Maintenance Contracts for Air-conditioners, Reverse Osmosis Plants, Dialyzer Reprocessing Machines, Hemodialysis Machines and Other medical and general equipment's at the dialysis centre.
- 6) Ambulance Facility to transport patients from Hospital to nearby Nursing Home/Hospital in case of emergency.

Emergency services for patients requiring such services during Hemodialysis.

In addition, if the service provider is desirous of subletting/subcontracting any services in addition to those listed above, it shall make a request in writing to the SHSB & the SHSB may permit the same to the Service Provider after considering the request.

#### 12. 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. In future, If SHSB decides to allot the work related to other districts beyond the above mentioned 14 hospitals, the separate contract will be signed on determined rate with the mutual consent of both the parties.

#### 13. Performance Security

- a) The successful bidder shall have to furnish a performance security in the shape of a Demand Draft/Bank Guarantee issued by a scheduled Bank in favour of Tender Inviting Authority for an amount of Rs. 5,00,000/- (Five lacs only) for each hospital. The Bank guarantee shall be as per proforma at "Appendix: G" 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 of receiving of Notice for Award of Contract, failing which the EMD may be forfeited and the contract may be cancelled.
- b) If the firm / contractor violate any of the terms and conditions of contract, the Performance Security shall be liable for forfeiture, wholly or partly, as decided by the SHSB and the contract may also be cancelled.
- c) The SHSB will release the Performance Security without any interest to the firm / contractor on successful completion of contractual obligations.

#### 14. 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.

#### **15.**Termination of Contract

- I. Any bidder found to be involved in fraudulent practices (misrepresentation or omission of facts or suppression/hiding of facts or disclosure of incomplete facts), in order to secure eligibility to the bidding process during the submission of bid or after release of Letter of Intent(LoI) or agreement formalization, shall be liable for punitive action amounting to blacklisting of the bidder upto 5 (five) years including the forfeiture of concerned EMD (Bid Security) and/or Performance Security also.
- II. The Tender Inviting Authority, without prejudice to any other contractual rights and remedies available to it, may, by written notice of default sent to the Service Provider, terminate the contract in whole or in part, if the Service Provider or (its Sub-contractor if any) fails to perform services as specified in the present contract or any other contractual obligations within the time period specified in the contract and the firm shall also be blacklisted, consequently the performance security shall also be forfeited.
- III. In the event the Tender Inviting Authority terminates the contract in whole or in part, the Tender Inviting Authority may carry out risk purchase of services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the Service Provider shall be liable to the Tender Inviting Authority/ Paying Authority for the extra expenditure, if any, incurred by the Tender Inviting Authority/Paying Authority for arranging such services.
- IV. Unless otherwise instructed by the Tender Inviting Authority, the Service Provider shall continue to perform the contract to the extent not terminated.

### 16. Termination for Insolvency

If the Service Provider becomes bankrupt or otherwise insolvent, it will inform to the Tender Inviting Authority with the 30 days written notice to terminate the contract. The Tender Inviting Authority reserves the right to terminate, without any compensation, whatsoever, to the Service Provider, and the Tender Inviting Authority may forfeit the performance security.

#### 17. Termination by Mutual Consent

In the event the Tender Inviting Authority & Service Provider mutually agrees to the terminate the contract, either party shall give 30 days written notice to the other party and after the consent of both parties agreement may be terminated without any Legal or Financial Obligation on any Party to the contract.

#### 18. Force Majeure

- I. Notwithstanding the provisions contained in clauses 15 and 16 the Service Provider shall not be liable for imposition of any such sanction so long the delay and/or failure of the Service Provider in fulfilling its obligations under the contract is the result of an event of Force Majeure.
- II. For purposes of this clause, Force Majeure means an event beyond the control of the Service Provider and not involving the Service Provider's fault or negligence and which is not foreseeable and not brought about at the instance of , the party claiming to be affected by such event and which has caused the non performance or delay in performance. Such events may include wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires,

floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees, lockouts excluding by its management, and freight embargoes.

- III. If a Force Majeure situation arises, the Service Provider shall promptly notify the Tender Inviting Authority in writing of such conditions and the cause thereof within twenty one days of occurrence of such event. Unless otherwise directed by the Tender Inviting Authority in writing, the Agency shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.
- IV. If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of Force Majeure for a period exceeding sixty days, either party may at its option terminate the contract without any financial repercussion on either side.
- V. In case due to a Force Majeure event the Tender Inviting Authority is unable to fulfil its contractual commitment and responsibility, the Tender Inviting Authority will notify the Service Provider accordingly and subsequent actions taken on similar lines described in above sub-paragraphs

#### 19. Notices

Notice, if any, relating to the contract given by one party to the other, shall be sent in writing or by e-mail or facsimile or post. The addresses of the parties for exchanging such notices will be the addresses as incorporated in the contract.

#### 20. Arbitration

- I. If dispute or difference of any kind shall arise between the SHSB and the firm/agency in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.
- II. If the Parties fail to resolve their disputes or differences by such mutual consultations within thirty (30) days of commencement of consultations ("Initial Period"), then either Party may give notice to the other Party of its intention to commence arbitration ("Notice of Arbitration"), as hereinafter provided. In that event, the disputes or differences shall be referred to a sole arbitrator to be jointly appointed by the Parties.
- III. In the event the Parties do not agree to the appointment of a sole arbitrator within thirty (30) days from the date of receipt of the Notice of Arbitration by the other Party, the matter shall be referred to a panel of three (3) arbitrators ("Panel") to be appointed within thirty (30) calendar days from the expiry of the Initial Period.
- IV. Both Parties to the dispute (that is the Party instituting the arbitration proceeding and the respondent Party) shall appoint one (1) arbitrator each to the Panel and the two (2) arbitrators so appointed by the Parties shall together appoint the third arbitrator to the Panel, who shall be the presiding arbitrator of the Panel.

- V. If the Parties fail to constitute the Panel as stated above, the Panel shall be appointed in accordance with the provisions of the Arbitration and Conciliation Act, 1996 (As amended from time to time).
- VI. The venue of arbitration shall be Patna.
- VII. The award of the panel of Arbitrator shall be final and binding on the Parties. The arbitration shall be conducted in accordance with the provisions of the Arbitration and Conciliation Act, 1996 (As amended from time to time)

# 21. Applicable Law

The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force.

# 22. Third Party Assessment

Tender Inviting Authority, at their own cost, may conduct third party assessment of services rendered and conduct of Agency during project period. The Agency will be informed about such assessment. Tender inviting authority may take action on the basis of findings of third party assessment. Third party assessment may be done on yearly basis or as & when felt necessary by SHSB.

#### 23. Other Terms & Conditions

- 1. Technology Up gradation: The machine shall be suitably upgraded by the service provider under following conditions:
- a) Review by a board appointed by Authority upon assessing the need for a technology up gradation. Such reviews should not be made in less than one year.
- b) Upon declaration of any national or international guideline accepted by the Government prohibiting the use of earlier (currently installed) technology
- c) After completion of 2 contract periods each not less than 5 years, the entire Equipment machinery shall be replaced.
- 2. The service provider shall provide for storage of soft copy and hard copy of all records at the concerned Hospitals 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.
- 3. 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.
- 4. The service provider shall maintain confidentiality of medical records and shall make adequate arrangements for cyber security on their own cost.

5.	After closure of the contract agreement between the service provider and the authority, the
	service provider shall vacate the space occupied, if provided by the authority, within a period
	of 60 days.

**Executive Director State Health Society Bihar** 

# **APPENDIX-A**

# **LOCATION OF FACILITY AND FACILITY WISE DESCRIPTION OF SERVICES REQUIRED**

Sl. No.	Name of District Hospital	No. of Dialysis Machines required for General Patients	No. of Dialysis Machines extra required for Infective cases such as Hepatitis B, Hepatitis C, HIV etc.	Land/space to be provided by the correspondin g District Hospital (Yes/No)
1	Sadar Hospital, Begusarai	4 (Four)	1 (One)	YES
2	Sadar Hospital, Jehanabad	4 (Four)	1 (One)	YES
3	Sadar Hospital, Kaimur	4 (Four)	1 (One)	YES
4	Sadar Hospital, Katihar	4 (Four)	1 (One)	YES
5	Sadar Hospital, Khagaria	4 (Four)	1 (One)	YES
6	Sadar Hospital, Kishanganj	4 (Four)	1 (One)	YES
7	Sadar Hospital, Munger	4 (Four)	1 (One)	YES
8	Sadar Hospital, Nawada	4 (Four)	1 (One)	YES
9	Sadar Hospital, Purnea	4 (Four)	1 (One)	YES
10	Sadar Hospital, Rohtas	4 (Four)	1 (One)	YES
11	Sadar Hospital, Saharsa	4 (Four)	1 (One)	YES
12	Sadar Hospital, Saran	4 (Four)	1 (One)	YES
13	Sadar Hospital, Vaishali	4 (Four)	1 (One)	YES
14	Sadar Hospital, Sitamarhi	4 (Four)	1 (One)	YES
	Total	56 (Fifty Six)	14 (Fourteen)	

# **BIDDER'S AUTHORISATION LETTER**

(To be submitted by authorized agent)

То	
The Executive Director	
State Health Society, Bihar	
Dear Sir,	
	are the Service Provider of
	(name of services(s) and hereby confirm that;
	(name and address of the agent) is our
authorized agents for	
	(name and address of the agent) have fully trained and nel to provide the said services.
	Yours faithfully,
	[Signature with date, name and designation]
Fo	or and on behalf of Messrs
	[Name & Address of the Service Provider]

#### Note:

- 1. This letter of authorization should be on the letterhead of the firm and should be signed by a top officer of the firm.
- 2. Original letter shall be attached to the tender.

# **AUTHORIZATION LETTER FOR SIGNING OF PROPOSAL**

# $\begin{array}{c} (On\ Non-judicial\ stamp\ paper\ of\ Rs\ 100\ duly\ attested\ by\ notary\ public) \\ POWER\ OF\ ATTORNEY \end{array}$

Know all men by these present, we	(name and address of the registered
office of the Single Entity) do hereby constitute	e, appoint and authorize Mr. / Ms
R/o(name and address of residence) who	o is presently employed with us and holding the
position of	as our authorized representative, to do in our
name and on our behalf, all such acts, deed	ds and things necessary in connection with or
incidental to the bid of the consortium consist	ting of, and (please
state the name and address of the mem	bers of the consortium) for "Setting up &
operationalizing 24X7 Dialysis Units through	Public Private Partnership (PPP) mode in 14
Government District Hospitals (DHs) i.e. Be	gusarai, Jehanabad, Kaimur, Katihar, Khagaria,
Kishanganj, Munger, Nawada, Purnea, Rohta	s, Saharsa, Saran, Sitamarhi & Vaishali in the
state of Bihar." (the "Project"), including signing	g and submission of all documents and providing
information / responses to State Health Societ	ry Bihar (SHSB), representing us in all matters in
connection with our bid for the said Project.	
We hereby agree to ratify all acts, deeds and th	nings lawfully done by our said attorney pursuant
to this Power of Attorney and that all acts, deed	ls and things done by our aforesaid attorney shall
and shall always be deemed to have been done	by us.
This Power of Attorney shall be effective, bindi	ng, and operative till
if not revoked earlier or as long as the said Atto Whichever is earlier	
(Name, Title and Address of the Authorized Address)	d representative) (Signature) (Name, Title and
(Signature)	
(Name, Title and Address)	

### FORMAT OF MANUFACTURER'S AUTHORIZATION FORM

This is Non Exclusive and OEM may authorize more than one bidder

Manufacturers'/Producers' Authorization Form- For Dialysis Machines, Dialyzer Reprocessor, Defibrillator, Dialysis Chair and Water Treatment Plant.

"This form has to be provided by the OEMs separately for each of the products proposed. For Example if an OEM is providing 3 different products then OEM has to issue product wise separate Manufacturers Authorization Forms (i.e. 3 MAF)"

No. & Date:

To: OEM Authorization Letter

Dear Sir: Ref:

Your NIT Ref: [\*] dated [\*]

We hereby extend our full guarantee and warranty for the Solution, Products and services offered by the above firm against this Bid Invitation.

We hereby declare that we are not insolvent, in receivership, bankrupt or being wound up, our affairs are not being administered by a court or a judicial officer, our business activities have not been suspended and we are not the subject of legal proceedings for any of the foregoing. We also undertake to provide any or all of the following materials, notifications, and information pertaining to the Products manufactured or distributed by the Supplier:

- a. Such Products as the may opt to purchase from the Supplier, provided, that this option shall not relieve the Supplier of any warranty obligations under the Contract; and
- b. In the event of termination of production of such Products:
- i. Advance notification to the Authority of the pending termination, in sufficient time to permit the Authority to procure needed requirements; and
- ii. Following such termination, furnishing at no cost to the Authority, the blueprints, design documents, operations manuals, standards, source codes and specifications of the Products, if requested.

We duly authorize the said firm to act on our behalf in fulfilling all installations, Technical support and maintenance obligations required by the contract. We do agree to provide only New Equipment and we will not provide any Refurbished equipment against this project. We will provide necessary Test Certificates and date of manufacturing for the product. Yours faithfully,

(Name)
(Name of Producers)

Note: This letter of authority should be on the letterhead of the manufacturer and should be signed by a person competent and having the power of attorney to bind the manufacturer. The Bidder in its Bid should include it.

# **ASSIGNMENT OF SIMILAR NATURE SUCCESSFULLY COMPLETED**

# **DURING LAST THREE YEARS (2013-14, 2014-15 & 2015-16)**

1. Attach users' certificates (in original) regarding satisfactory completion of assignments.
Note: Attach extra sheet for above Performa if required.
Signature
Name

[Signature with date, name and designation]

Sr.No	Assignment contract No &date	Description of work services provided	Contract price of assignment	Date of commencement	Date of completion	Was assignment satisfactorily completed	Address of organization with Phone No. where assignment done
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

For and on behalf of Messrs \_\_\_\_\_

[Name & Address of the Service Provider]

# PARTICULARS OF THE BIDDER'S ORGANISATION

(To be submitted by all tenderers / bidders)

	ame gistered Addro one/Fax/Mail						
-	. Type of Organization : Prop./Partnership/Company/Trust/Not for Profit Organization						
5. Ac	ldress of the	office of Services Pr	ovider in the State:				
6.	Details of e	mployees :					
	Name	Designation	Qualification	Experience (Similar Service)	Contact No. & Email ID		
7. W			BH/ISO or any other a tached with techno co				
8. Re	gistration. N	os.					
	(a) EPF						
	(b) ESI						
	(c) Sales Ta (d) VAT	1X					
	(e) Service	Tax					
	(f) PAN No						
	<ul> <li>(g) Audited Accounts Statement i.e Profit &amp; Loss Accounts Balance Sheet along with all Appendix s for past three financial years i.e. 2013-14, 2014-15 and 2015-16</li> <li>(h) Copy of Income Tax Return for three Assessment Years i.e. 2014-15, 2015-16 and</li> </ul>						
	2016-17		ii ioi tiilee Assessiii	ent rears i.e. 2014-1	13, 2013-10 and		
			dder regarding existin	g Dialysis services			
9. Br			npany. (use extra she	•			
Signa	ture of Bidde	ers					
	Date: Name						
Place	:			Office Seal			

# **FORWARDING LETTER FOR TECHNICAL BID**

(To be submitted by all tenderers / bidders in their letter head)

	Date:
To,	
The Executive Director,	
State Health Society, Bihar	
Sub: Tender for providing services of Dialysis.	
Sir,	
We are submitting, herewith our tender for providing Dialysis services for number of districts in the state.	r
We are enclosing Receipt No or Bank Draft Dated	Amount) ur of State Health iry. We also agree
4. We agree to keep our offer valid for the period stipulated in your notice invi	ting tender.
Enclosures:	
1.	
2.	
3.	
4.	
5.	
Signature of the Tend	lerer
Seal of the Tendere	

## **FINANCIAL BID**

1.	Name	of the	Tenderer:
----	------	--------	-----------

- 2. The Quote is for per cycle cost of Hemodialysis and factors all the infrastructure, HR (trained & qualified Nephrologist/ M.D Medicine, Medical Officers, Nurses, Technicians, supportive infrastructure, Dialyzer, all consumables like AV Blood line, AV Fistula Needles, heparin, normal saline, dialysis fluid, needles, syringes, IV sets, gloves, cotton etc.), essential medications like Erythropoietin (EPO), Iron Sucrose, required clinical diagnostic services, monthly kidney profile report of the patient, operational and maintenance cost for the project.
- 3. The bidder is expected to deliver the services for a minimum period of five years from the date of agreement.

The cost per Hemodialysis cycle Rs/-				
(in words Rs)				
The prices shall be firm and inclusive of all taxes and duties presently in force.				
Note: Financial Bid has to be submitted for all the hospitals as single rate. No bid for partial no. of hospitals would be allowed. The Financial Bid will not include the cost of AV Fistula making, Single/Double/Triple Lumen catheter.				
Signature				
Name				

## **PROFORMA FOR BANK GUARANTEE FOR PERFORMANCE SECURITY**

То

The Executive Director,
State Health Society, Bihar
Pariwar Kalyan Bhawan
Sheikhpura, Patna-14
WHEREAS(Name and address of the Service Provider) (Hereinafter called "the Service provider" has undertaken, in pursuance of LoI vide Memo No
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
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 remain in force for a period of six months beyond the close of all the contractual obligations under this contract i.e. up to( 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**

I / We ...... agree that we shall keep our price valid for a period of five years from the date of signing of contract. I / We will abide by all the terms & conditions set forth in the tender.

- (A) I / We do hereby declare I / we have not been de- recognized / black listed by any State Govt. / Union Territory / Govt. of India / Govt. Organization / Govt. Health Institutions or convicted by any court of law for any criminal or civil offences & declared ineligible for participation in future bids for unsatisfactory part performance, corrupt, fraudulent or any other unethical business practices or for any other reason during the past 5 years, from the last date of submission of bids, and
- (B) No criminal case or vigilance case related to cheating, forgery, Criminal breach of trust, theft and prevention of Corruption Act is pending at the level of a competent authority, and
- (C) No investigation by any statutory body / Govt. investigating Agency of any state Govt./ Central Govt. is undertaken or pending against the bidder for the charge having nature of criminal/economic offence/fraud, and
- (D) There is no any ongoing litigations, in which we are involved in with any Government Agency/State.

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**

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

(A) Detient com-	- D'alada da ata		
(A) 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)		
(B) Incident and accident	a. Complications related to dialysis procedure		
(in logbooks)	b. Complications related to vascular access		
	c. Complications related to disease process		
	d. Dialysis adequacy of patients on thrice weakly		
	treatments		
	e. Outcomes		
	f. Staff/patient's hepatitis status		
(C)Staff and patient	a. Hepatitis B (double dose) – 0, 1,2,6 months		
vaccination	b. Influenza – annually		
	c. Pneumococcal – every 5 years		
(D) Water treatment	a. Bacteriological		
	b. Endotoxin		
	c. Chemical		
(E) Facility and	a. Preventive maintenance		
equipment maintenance	b. Corrective measures		
schedule			
(F) Manpower Attendance	a. Electronic and Manual record of maintenance of all staff		
& training	deployed at a facility		
	b. Record of the training conducted by the Service		
	Providers.		

## (B) Format for Weekly Check Report

SI.	Parameter	Remark- In case of No
no		please specify
1	Dialysis machine and dialyzer reprocessors are	Yes/No – Serial No. of
	functional	machines to be recorded
2	Water quality as per AAMI	Yes/No – Record the
		deficiency
3	Availability of Doctor & Monitoring by	Yes/No – Record the
	Nephrologist	deficiency
4	Availability of nursing staffs	Yes/No – Record the
		deficiency
5	Availability of Technicians	Yes/No – Record the
		deficiency
6	Reuse of Dialyzer ( Max 5 times or till 75% of	Yes/No – Record the
	fibre volume)	deficiency
7	Dialyzer procedure time > 4 hrs	Yes/No – Record the
		deficiency
8	Availability of BMET	Yes/No – Record the
		deficiency
9	Availability of Power back-up	Yes/No – Record the
		deficiency
10	Cleanliness of Dry Storage Area	Yes/No – Record the
		deficiency
11	Availability of waiting chairs	Yes/No – Record the
		deficiency

Comments and recommendations of Nodal Officer

Signature of representative of Service Provider

Signature of representative/Nodal Officer of Hospital

## (C) Format for Monthly Monitoring Report (To be submitted along with Invoice)

SI.	Parameter	Complied	Remarks	
No				
1.	No of Dialysis machine and dialyzer	Yes/No	Serial No. of machines	
	down for more than 48 hours		to be recorded	
2.	Water quality as per AAMI	Yes/No	Record the deficiency	
3.	Patient clinical record maintenance			
	pre & post	Yes/No	Record the deficiency	
	(Blood Urea, Creatinine, Sodium &	103/140	record the denoichey	
	Potassium)			
4.	Treatment as per STG & monitoring			
	by Nephrologist for each patient	Yes/No	Record the deficiency	
	personally at least once a month ( to	1 00,110	record the denoichey	
	maintain records)			
5.	Availability of Power back-up	Yes/No	Record the deficiency	
6.	Dialysis process timings more than 4	Yes/No	Record the deficiency	
	hours		•	
7.	Display of schedule at Nursing Station	Yes/No	Record the deficiency	
8.	No legs of Bed/chairs broken and all	Yes/No	Record the deficiency	
	mattresses in working condition			
9.	Total no. of patients treated in the			
	month			
10.	No. of patients under "Free category"			
	as decided by SHSB in the month			
11.	Total no. of dialysis sessions			
	conducted in the month			
12.	No. of dialysis sessions conducted for			
	patients under "Free Category" as			
	decided by SHSB in the month			
13.	Total no. of new patients registered in			
	the month			
14.	No. of new patients registered in the			
	month			

Recommendations & comments and recommendations of Nodal Officer:

Signature of representative of Service Provider

Signature of representative/Nodal Officer of Hospital

## **EQUIPMENT & CONSUMABLES LIST**

## (A) EQUIPMENT

**Emergency equipment:** The following equipment should be provided for by the service provider:

Sl.No.	Name of Equipment		
1	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction		
	equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag-		
	Adult & Paediatric (neonatal if indicated)		
2	Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs		
3	Suction Apparatus		
4	Defibrillator with accessories		
5	Equipment for dressing/bandaging/suturing		
6	Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope,, weighing		
	machine, thermometer		
7	ECG Machine		
8	Pulse Oximeter		
9	Nebulizer with accessories		
10	Dialyser reprocessing unit		
11	Activated clotting time(ACT) machine		
12	Cardiac monitors		
13	Vein finder		
14	All required consumables for adult and pediatric patients		

## (B) CONSUMABLES

Sl.No.	Name of Equipment			
1	Hollow Fibre Polysulfone Dialyzer (Artificial Kidney) – These should be reused as per			
	recommended guidelines. On an average a dialyzer should be used between 6-10			
	times, before it is discarded (If FBV <80%)			
2	AV Blood Line -To be discarded after single use			
3	AV Fistula Needles - To be discarded after single use			
4	Low molecular weight heparin			
5	Normal Saline			
6	Dialysis fluids			
7	Disposables such as needles, syringes, IV sets, gloves, cotton etc.			
8	Medications like			
	Erythropoietin (EPO)			
	> Iron Sucrose			

#### **STAFFING**

1. It is proposed to have the minimum staff–pattern for a proposed dialysis unit, with 5 dialysis units (4 Dialysis machines for General patients & 1 required for Infective cases such as Hepatitis B, Hepatitis C, and HIV etc.)

Shift. No.	Physician/ Dialysis Doctors	Dialysis Technician	Hospital Attendant	Nurses or Paramedical staff	Sweepers
Shift-1	1	1	1	1	1
Shift-2	1	1	1	1	1
Shiflt-3	1	1	1	1	1
Total	3	3	3	3	3

- 2. Apart from the same, a minimum of 3 Nephrologists will be required, assuming 1 Nephrologist per 5 facilities, and also adequate availability must be ascertained of the Dietician and Bio-Medical Engineer across the facilities.
- 3. These numbers can be changed as per actual load and case delivery.
- 4. The bids are to be submitted considering the no. of required manpower as above. The above list of key personnel is minimum and it is obligatory for Service provider to hire/employ other necessary clinical & non-clinical staff for running the Hemodialysis Unit as per the good industry practices/applicable statuary guidelines. The no. of required manpower may be revised during course of implementation of contract as per requirement of case load. The shift-timings are also indicative, and may be changed as per convenience of the Agency after approval from SHSB.

SI. No	Descriptio n	Min. Qual. & Exp.	Minimum Number Required	Key Responsibilities
1	Nephrolo gist	DM or DNB in Nephrology / MD with Special training in nephrology from a recognized centre with minimum 2 years of experience	1 for 5 facilities	Responsible for overall functioning of the unit. Primary responsibility will include:  1. Perform review of all patient charts.  2. Provide 24-hour consultation and back up care to all patients  3. Carry out periodic review of water quality and infection control measures.  4. Periodically evaluate the performance of dialysis, doctors, technicians, and nurses.  5. Be responsible for enforcement of patient care and safety rules and regulations.  6. Act as liaison between the hospital management, statutory bodies, dialysis staff, and patients.

				7. Protect patient rights.  8. Be in charge of periodic performance audit.  She/he should sit with the team and discuss all issues of concern. The unit should maintain a record of performance parameters, including but not limited to: proportion of patients with arteriovenous fistula (AV) fistula, treatment compliance rates, infection rates categorized by site, organism and sensitivity, nutrition, rehabilitation status, 2comorbidity management, c3linically important events, Dropouts and outcomes.
2	Physician / Dialysis Doctor	MBBS with minimum 1 years of experience in critical care and also be certified in Advance Cardiac Life Support (ACLS)	3 for each facility (1 per shift)	<ol> <li>To be involved in day to day patient management.</li> <li>Before starting dialysis: Assess hemodynamic status, indication of dialysis, vascular access, and any co-morbid illness.</li> <li>During dialysis: Overall direct monitoring including dialysis prescription, care of vascular access, adequacy of flow, complications, and maintain liaison with and follow Instruction of the nephrologists.</li> <li>At the time of closure: Check access site, hemodynamic status, any complication, and give specific instruction if needed.</li> <li>For in-patients: assess the patient at least once in the ward after dialysis.</li> <li>Accompany the patient to the ward, if critically ill.</li> <li>Handle/supervise/guide supporting staff in cardiopulmonary resuscitation.</li> <li>Have working knowledge of the dialysis machine, water treatment plant, ventilator, defibrillator, and other gadgets in the dialysis unit.</li> <li>Act as the team leader during the day to day functioning of the unit.</li> <li>Ensure implementation of all guidelines.</li> <li>Look after the safety and security of the supporting staff.</li> <li>Take regular teaching sessions for the dialysis staff.</li> </ol>

				1
3	Dialysis Technician	One year or longer certificate course in Dialysis Technology(a fter high school) certified by a government authority with 3 years of experience	3 for each facility (1 per shift)	<ol> <li>Performing all aspects of the dialysis procedure as per prescription.</li> <li>Conducting discharge assessment.</li> <li>Following instructions of the dialysis doctors.</li> <li>Conveying to the dialysis doctor any new event/change in patient status and recommending changes in the treatment based on the current needs of the patient.</li> <li>Facilitating communication between the patient and patient's family on one side and the treating team on the other.</li> <li>Keeping an inventory of items in the unit.</li> <li>Providing oversight and direction to the trainee technicians/nurses.</li> <li>Participating in continuous quality improvement activities.</li> <li>Entry and maintenance of records of all patients and produce them for medical auditing</li> </ol>
4	Nurses	Grade A nurses with 6 month experience in a dialysis unit.	3 for each facility (1 per shift)	<ol> <li>Performing all aspects of the dialysis procedure as per prescription.</li> <li>Conducting discharge assessment.</li> <li>Following instructions of the dialysis doctors.</li> <li>Conveying to the dialysis doctor any new event/change in patient status and recommending changes in the treatment based on the current needs of the patient.</li> <li>Facilitating communication between the patient and patient's family on one side and the treating team on the other.</li> <li>Keeping an inventory of items in the unit.</li> <li>Providing oversight and direction to the trainee technicians/nurses.</li> <li>Participating in continuous quality improvement activities.</li> <li>Entry and maintenance of records of all patients and produce them for medical auditing.</li> </ol>
5	Ward Boys/ Attendant	Literate with 1 years of hospital experience	3 for each facility (1 per shift)	Perform the function of helper and assist the medical staff/patients in performing various activities in dialysis unit
6	Sweeper		3 for each facility (1 per shift)	

#### HEMODIALYSIS MACHINE & ASSOCIATED SYSTEMS

#### A. HD machine: Mandatory

- 1. Blood pump to achieve a unidirectional flow up to 400ml/min
- 2. Heparin pump
- 3. Arterial line and venous line pressure monitors
- 4. Functional air bubble detector
- 5. Mixing proportion of unit with bicarbonate dialysis facility, rate of Dialysate delivery from 300 to 500 ml/min or more.
- 6. Conductivity meter
- 7. Functional blood leak detector
- 8. Dialysate temperature regulator that has a range of temperature 35 to 39°C
- 9. Volumetric UF control
- 10. Safety devices functioning alarms, venous blood camp
- 11. Dialysate Filter
- 12. The HD machine should be FDA approved or European CE marked.

#### **B. HD machine: Optional**

- 1. On line blood volume monitor
- 2. On line urea clearance
- 3. Sodium profiling of dialysate
- 4. Single needle dialysis facility
- 5. Hemodiafiltration
- 6. Optical detector

#### 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 specifics. 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 an 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.

#### D. Recommendation for once monthly evaluation and monitoring:

- 11. Periodic (Monthly) 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 shall not exceed 2,000 colony forming units per ml.
- 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.

#### E. 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.

#### F. Recommendations for dialyzer use in HD:

- 1. Biocompatible, synthetic (e.g., polysulfone, polyacrilonitrile, polymethylmethacrylate) or modified cellulose membrane (e.g., cellulose acetate) should be preferred over unmodified
- 2. Cellulose membranes (e.g., cuphraphan). Cupraphane membranes should only be used when patient is intolerant to other bio-compatible 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 used for NOT more than 10 times or till the bundle volume is >70% 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.
- 6. Blood line, Transducer Protectors, IV sets, Catheters any other disposables should NOT be reused.

#### **G.** 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 uremia. 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 (or acetate) 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.
- 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
   The final diluted dialysate should be analyzed every 6 months, with every new batch of
  dialysate and after each major servicing/ repair of dialysis machine.
- 3. The final diluted dialysate should be analyzed every 6 months, with every new batch of dialysate and after each major servicing/repair of dialysis machine.
- 4. Water used to prepare the dialysate must have a bacteriological colony count of less than 200 CFU/ml. Bacteriological analysis of the dialysate shall be carried out at least 2 monthly, preferably every 15 days. 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 shall be less than 2000 colony-forming units/ml. Dialysate containing glucose at 100- 200 mg/dl concentration should be used.

#### H. 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.
- 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.

_	<u>CHNICAL SPECIFICATION OF HAEMODIALYSIS MACHINE</u> HEMODIALYSIS UNIT SHOULD BE MICROPROCESSOR CONTROLLED	AND CADABLE OF
	HEMODIALISIS UNIT SHOULD BE MICKOPROCESSOR CONTROLLED  VIDING THE FEATURES:	AND CAPABLE OF
1.1	ACETATE & BICARBONATE DIALYSIS	
1.2	VOLUMETRIC ULTRA FILTRATION (UF)	
1.3	VARIABLE SODIUM & BICARBONATE	
1.4	SINGLE AND DOUBLE NEEDLE TREATMENT	
1.5	ADJUSTMENT DIALYSATE FLOW	
1.6	PROFILLING OF SODIUM BICARBONATE AND UF	
1.7	ISOLATED UF	
1.8	HAEMODIA FILTRATION (OPTIONAL)	
TECH	CHNICAL SPECIFICATION	
1	BLOOD CIRCUIT	
1.1	VASCULAR ACCESS	
1.1.1	SINGLE NEEDLE, SINGLE PUMP/SINGLE NEEDLE, DOUBLE PUMP	
1.2	BLOOD PUMP	
1.2.1	RANGE SHOULD BE BETWEEN O AND 20 TO 500ML/MIN. WITH AC	CCURACY OF +/- 15
1.2.2	THE PUMP SHOULD BE EASY AND SAFE TO THREAD THE BLOOD	TUBING
	AN EMERGENCY HAND CRANK SHOULD BE PROVIDED TO TURN AND THE PATIENT WHEN ELECTRICAL POWER IS LOST. T ROTATION IS LIMITED VISUALLY INDICATED TO PREVENT IN	THE DIRECTION OF
1.2.3		
1.3	HEPARIN PUMP  INFUSION RATE SHOULD BE APPROX .0/0 5-10ML/H WITH	A ACCUDACY OF
1.3.2		A ACCURACT OF
1.3.2	POSITIVE AND NEGATIVE EXTRACORPORIAL CIRCUIT PRESSURE	E SHOULD NOT
1.3.3	STOP TIME; HEPARINIZATION STOP TIME (BEFORE END OF TREA' 9.59 HR	TMENT) 0.00-
1.3.4	ACCUMULATED HEPARIN VOLUME SHOULD VE PROGRAMMABL	.E.
1.4	PRESSURE ,MONITORING AND ALARMS	

	VENOUS PRESSURE MONITORING RANGE SHOULD BE APPROX. 700 TO 750 MM HG		
1.4.1			
	VENOUS PRESSURE ALARM		
	HIGH AND LOW VENOUS PRESSURE ALARMS ALARM SETTING SHALL BE NON		
1.4.2	OVERLAPPING AND WITHIN RANGE OF THE PRESSURE MORE.		
	ARTERIAL PRESSURE MONITORING		
1.4.3	IT SHOULD VE APPROX. 700 TO 750 MM HG		
	THE ALARM LIMITS AROUND VENOUS PRESSURE AND TMP SHOULD BE		
	AUTOMATICALLY CALIBERATED. ADJUST TO PRESET LIMIT AT A TOUCH OF		
1.4.4	BUTTONS.		
1.5	AIR DETECTION		
	SENSITIVITY; AN ALARM SHOULD VE HIVEN FOR>0.5ML AIR PER MINUTE AT		
1.5.1	AFLOW 300ML/MIN		
1.50	ON DETECTION OF EXCESSIVE AIR THE BLOOD PUMP SHALL BE STOPPED AND AN		
1.5.2	AUDIO ALAFRM ACTIVATED.		
2	DIALYSATE CIRCUIT		
2.1	TREATMENTS FACILITIES		
2.1.1	IT SHOULD BE CAPABLE TO PROVIDE ACETATE AND BICARBONATE DIALYSIS		
	IT SHOULD HAVE THE FACILITY OF ADJUSTABLE VARIABLE BICARBONATE		
2.1.2	CONCENTRATION		
	IT SHOULD HAVE THE FACILITY OF ADJUSTABLE VARIABLE SODIUM		
2.1.3	CONCENTRATION		
2.1.4	IT SHOULD HAVE VOLUMEMETRIC ULTRA FILTRATION CONTROL		
	IT SHOULD HAVE THE FACILITY OF USER PRESETABLE INDEPENDENT ISOIATED		
2.1.5	ULTRA FILTERATION.		
2.2	CONDUCTIVITY CONTROL AND ALARMS		
	THE DIALYSIS CONDUCTIVITY SHOULD BE ADJUSTED BY SETTING THE SODIUM		
	FOR ACUTE DIALYSIS MODE, AND SODIUM WITH BICARBONATE FOR		
2.2.1	BICARBONATE DIALYSIS MODE.		
	THE SET CONDUCTIVITY SHOULD BE AUTOMATICLLY REGULATED BY THE CONC.		
2.2.2	VARIATION.		
222	IN ACETATE DIALYSIS, SODIUM CONDUCTIVITY/ CONCENTRATION SHOULD BE		
2.2.3	ADJUSTABLE.		
224	IN THE BICARBONATE DIALYSIS, SODIUM /BICARB CONCENTRATION SHOULD BE		
2.2.4	ADVANCED DICAPRONATE DIALVEIS		
2.3	ADVANCED BICARBONATE DIALYSIS		
	THE MACHINE SHOULD BE CAPABLE OF ON-LINE PREPARATION OF BICARBONATE		
2.4	DIALYSIS FILTER. A CARTRIDGE OF DRY POWER BY USING R.O WATER		
2.4	DIALYSIS FLOW RATE.  IT SHOULD BE APPROX. 300TO 700 ML/MIN. ACCURATE TO WITHIN+- 10ML/MIN.		
	TEMPERATURE CONTROLAND ALARMS.		
	CONTROL RANGE SHOULD BE BETWEEN APPROX.+30.0CTO +-40.0		
	BLOOD LEAK DETECTION		
	DETECTION METHOD SHOULD BE		
	INFRARED LIGHT DETECTOR; MICROPROCESSOR CONTROLLED REPEATED		
2.7	FUNCTION CHECK		
2.7	ULTRA FILTRATION (UF) CONTROL		
2.7.1	VOLUMETRIC CONTROL		
	CONTROL RANGE SHOULD BE BETWEEN APPROX. 0.00-4 LITRES PER HOUR GIVEN		
	BY TREATMENT TIME UF VOLUME SHOULD BE ADJUSTABLE ACCURACY SHOULD		
2.7.2	BE BETWEEN + 50ML /H OR+1%.		
2.7.3	PRESET ABLE ISOLATED ULTRA FILTRATION		
	THE ACQUIRED UF VOLUME AND THE TIME FOR ISOLATED ULTRA FILTRATION		
	TREATMENT PRESET ABLE SO THAT THE DESIRABLE UF RATE AND UF VOLUME		

	CAN DE AUTOMATICA CONTROLLED MONTROLED AND ACMENTE DURING THE
	CAN BE AUTOMATIC A CONTROLLED, MONITORED AND ACHIEVED DURING THE
	ISOLATED ULTRA FILTRATON MODE.
3.	TABLE FOR THE PARAMETER RECORDES
	THE HAEMODIALYSIS MACHINE SHOULD PROVIDE A GRAPHIC INFORMATION
3.1	DISPLAY AND / OR INSTANTANEOUSLY.
	THE FOLLOWING PARAMETERS IN FORMS OF BAR-GRAPH, NO. AND TEXT
3.1.1	BAR-GRAPH.
3.1.1.1	VENOUS PRESSURE
3.1.1.2	HIGH & LOW LIMITS FOR VENOUS PRESSURE
3.1.1.3	PRESENT BLOOD FLOW
3.1.1.4	ACTUAL BLOOD FLOW
3.1.1.5	BLOOD FLOW GUARD
3.1.1.6	PRESET DIALYSATE TEMPERATUE
3.1.1.7	ACTUAL DIALYSATE TEMPRATUE
3.1.1.8	HIGH & LOW LIMIT OF DIALYSIS TEMPRATURE
3.1.1.9	PRESET DIALYSIS CONDUCTIVITY
3.1.1.10	ACTUAL DIALYSIS CONDUCTIVITY
3.1.1.11	HIGH & LOW LIMITS OF DIALYSIS CONDUCTIVITY
3.11.12	MEASURED TMP.
3.1113	HIGH& LOW LIMIT OF TMP.
3.11.14	PRESET PATIENT WEIGHT LOSS
3.1.1.15	REMOVED OF VOLUME
3.1.1.16	CALCULATED OF RATE
3.1.1.17	ACTUAL UF RATE
3.1.1.18	REMAINING TREATMENT TIME
3.1.2	NUMBER AND /OR TEXT INFORMATION
3.1.2.1	VENOUS PRESSURE
3.1.2.2	HIGH AND LOW LIMIT OF VENOUS PRESSURE
3.1.2.3	PRESET BLOOD FLOW
3.1.2.4	ACTUAL BLOOD FLOW
3.1.2.5	BLOOD FLOW GUARD.
3.1.2.6	PRESET DIALYSATE TEMPERATURE
3.1.2.7	ACTUAL DIALYSATE TEMPERATURE
3.1.2.8	HIGH AND LOW LIMIT FOR TEMPRATURE
3.1.2.9	PRESENT DIALYSATE CONDUCTINITY
3.1.2.10	ACTUAL; DIALYSATE CONDUCTIVITY
3.1.2.11	HIGH AND LOW LIMIT OF DIALYSATE CONDUCTIVITY
3.1.2.12	MEASURED TMP
3.1.2.13	HIGH AND LOW LIMITS OF TMP
3.1.2.14	PRESET WEIGHT LOSE
3.1.2.15	REMOVED UF VOLUME
3.1.2.16	CALCULATED UF RATE
3.1.2.17	ACTUAL UF RTAE
3.1.2.18	SINGLE NEEDLE DATA
3.1.2.19	REMAINING TREATMENT TIME
3.1.2.20	HEPARIN INFUSION RATE, STEPPED TIME AND ACCUMULATED VOLUME.
3.1.2.21	ATTENTION ALARM IN INFORMATION IN TEXT FORMAT
3.1.2.22	TECHNICAL ALARM INFORMATION IN TEXT FORMAT (THE ABOVE MENTIONED
	DATA S ON LCD/ CRT MONITOR MAY ALSO BE ACCEPTIC)
4.	SAFETY
	THE MACHINE SHOULD AUTOMATICALLY PERFORM A COMPLETE FUNCTIONAL
4.1	AND SAFETY TEST AT EACH START UP
4.2	THE MACHINE SHOULD COMPLIES WITH THE FOLLOWING INTERNATIONAL
	THE ATTEMPT OF COME BED WITH THE COME WITH THE WITH

	STANDARD
	IEC 601-1 AND IS PROTECTED AGAINST ELECTRICAL SHOCK ACCORDING TO
4.2.1	CLASSIFICATION
	ICE 601-2-16 PARTICULAR REQUIREMENT FOR HEAMODIALYSIS EQUIPMENT
4.2.2	DISINFECTION AND CLEANING
5.1	FACILITY OF CHEMICAL AMD HEAT DISINFECT ION MUST BE AVAILABLE
	SODIUM HYPOCHLORITE FORMALDEHYDE OXALIC ACID2% AND PARACETIC ACID
5.2	SHOULD BE AVAILABLE IN THE CHEMICAL DISINFECTIONS PROGRAMME.
	AUTO- HEATING DISINFECTIONSAS WELL AS WITH CITRIC ACID (20%) AND AUTO -
	RINSING & DRAIN SHOULD BE PRESET AUTOMATIC START OF MACHIN FOR HEAT
5.3	DISIFNFECTION AND RINSING IN PRESET TIME.

#### I. Water Treatment System:

#### **General requirements:**

- 1. Dual water treatment system is mandatory.
- 2. Each water treatment system includes reverse osmosis membranes.
- 3. 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 Hemodialysis water quality.
- 4. 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.
- 5. Written logs of the operation of the water treatment system for each treatment day are in place.
- 6. Procedure guidelines for Disinfection of Reverse Osmosis Machine and Loop as recommended by the manufacturer are in place.
- 7. No Hemodialysis procedure is performed during disinfection of the water treatment system and the loop.
- 8. Microbiological testing of the treated water from the water treatment system and the loop is done regularly and preferably monthly.
- 9. For dialysis unit performing HDF, testing of treated water for endotoxin at regular interval is needed.
- 10. Written record and results of microbiological and chemical testing of water are in place and reviewed. Corrective action is recorded if indicated.

# Equipment Technical Specifications for Water Treatment System (R O system) for <u>hemodialysis</u> <u>Machines:</u>

- 1 Description of Function
- 1.1 Water Treatment systems is required to produce pure water for dialysis.
- 2 Operational Requirements
- 2.1 The system should be sufficient for online operation of 6 to 8 machines with pure water capacity of 800 900 litres per hour.

#### **3 Technical Specifications**

3.1 The system should comprise of pre treatment modules such as sand filter, activated carbon filter, water softener, 5-micron particulate filter and deionizer before the reverse osmosis unit

and post R.O Bacterial Filters (1 micron) and UV light Disinfection for yielding high purity water.

- 3.2 All pre treatment modules should have programmable back wash and regeneration facility. These stages should be designed to handle water flow of 800 900 litres/hour.
- 3.3 R.O. Unit should be compact in sleek cabinet, housing two or more R.O. membranes of equal output connected in parallel for being used alternately every two- three hours by automated valves, a high pressure pump and bypass mechanism. The control unit should be microprocessor/ microcontroller controlled. A 5-micron filter should protect the membrane.
- 3.4 The entire unit should have adequate monitoring of input and output water conductivity, feed water pressure and rejection flow rate.
- 3.5 The system should have protection alarm against low feed water, high output conductivity and high temperature of pump motor.
- 3.6 The system should include online water distribution to 6 to 8 machines in loop so that the unused water may be fed back to treatment unit, thus saving on water rejection.
- 3.7 The unit should have programmable and automatic rinsing/flushing facility, at regular intervals, when system is not in use, to prevent drying of filter media and R.O. Membrane.
- 3.8 The system should have programmable disinfection /de-calcification facility using commonly available disinfection / decalcification chemicals.
- 3.9 The system should accept feed water with TDS up to 1500 mg/litre and hardness up to 1 dH with 0.5% rejection of TDS & hardness and 99% rejection of bacteria and endotoxins.
- 3.10 The unit should be designed for maximum saving of raw water, with efficiency of 60-70%.
- 3.11The water distribution loop, booster pump and storage water tank should be made up of PVC (High quality). Storage water tank should have capacity of at least2000 litres with water level controller, outlet valves and easy cleaning provisions.

#### 4 System Configuration Accessories, spares and consumables

- 4.1 System as specified-
- 4.2 The Service Provider should provide a system on a turnkey basis including all civil and electrical works including two booster pumps in parallel for providing water delivery. The Service Provider should inspect the site for this purpose.
- 4.3 The Service Provider should supply adequate filter cartridges, media or resins to last for at least 3 years. The Service Provider may visit the site and check the water quality.
- 4.4 The Service Provider should provide preventive maintenance which includes chemical checks, bacterial and pyrogen checks periodically during the warranty period.
- 4.5 In the case, when the facility is established in the District Hospital, the hospital will provide vacant space, water outlets and electrical points as specified by the Service Provider. Other plumbing works and civil works will have to be undertaken by the bidder. Service Provider should ensure that there is no environmental damage of any kind takes place.

#### 4.6 Power Supply

Power input: 220-240V/ 50 Hz AC Single phase or 380-400V AC 50 Hz Three phase fitted with appropriate Indian plugs and sockets.

4.7 Output water quality should match AAMI (Association for the advancement of Medical Instrumentation) standards for Hemodialysis Water( Al < 0.01 mg/L; Ca < 2 mg/L; BACTERIA < 200 CFU/ml)

#### Should be CE / UL or BIS approved product.

The service provider should have the necessary equipment's recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

User/Technical/Maintenance manuals to be supplied in English.

Certificate of calibration and inspection.

List of Equipment's available for providing calibration and routine Preventive Maintenance Support. as per manufacturer documentation in service/technical manual.

User list to be provided with performance certificate.

The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%.

The unit shall be capable of operating continuously in ambient temperature of 10 - 40deg C and relative humidity of 15-90%

#### J. Reuse of Haemodialyzers and related devices

- 1. Procedure guidelines for dialyzer reprocessing are in place.
- 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 labeled 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.

#### K. Other Activities for patient care

- 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 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 healthy or safety can be ensured.
- 3. Drill for CPR and emergency conditions outlined are performed regularly.

- 4. Routine disinfection of active and backup dialysis machines are performed according to defined protocol. Documentation of absence of residual disinfectants is required for machines using chemical disinfectant.
- 5. Samples of dialysate from machines chosen at random are cultured monthly. Microbial count shall not exceed 200 colony forming units per millilitre (cfu/ml) for HD and shall not exceed 10 1 cfu/ml for online HDF before IV infusion into the patient's circulation. Periodic testing of inorganic contaminant is performed.
- 6. Repair, maintenance and microbiological testing results of the hemodialysis machine are recorded with corrective actions where indicated.
- 7. All staff including janitorial staff is educated with clear instruction on handling blood spillage on equipment and the floor.
- 8. All blood stained surface shall be soaked and cleaned with 1:100 sodium hypochlorite if the surface is compatible with this type of chemical treatment.
- 9. 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.
- 10. HBsAg/HCV-positive patient should be treat in a segregated area with designated Hemodialysis machines.
- 11. Carrier of HCV receives hemodialysis using designated machines.
- 12. Patient with unknown viral status is dialyzed using designated hemodialysis machines until the status is known.

#### **KEY PERFORMANCE INDICATORS & PENALTY CLAUSES**

## Section A: KEY PERFORMANCE INDICATORS (KPIs)

- 1. The service provider will have to maintain an uptime of 90% annually with maximum 7 days of downtime at a stretch of any single dialysis machine of the facility.
- 2. The dialyzer will be used for one time only for all HIV, hepatitis-B and hepatitis-C cases.
- 3. Hollow Fibre Polysulfone Dialyzer (Artificial Kidney) These should be reused as per recommended guidelines. On an average a dialyzer should be used between 6-10 times, before it is discarded (If FBV<80%).
- 4. Presence of Doctors/Nurses/Technician, in each shift
- 5. The private partner would ensure disinfection of all machines using formalin or heat disinfection at least once in a week. The method of disinfection may vary according to recommendation by the manufacturer/OEM.
- 6. The private partner would ensure Chemical disinfection followed by water rinsing after each dialysis procedure.
- 7. The private partner would arrange for regular cleaning/sweeping of the Hemodialysis unit either through own staff or outsourced arrangement.
- 8. The private partner would ensure aseptic precautions to minimize procedure related infections.
- 9. The private partner would ensure disposal of bio medical waste as per stipulated regulations of Pollution Control Board & regulations governing medical waste disposal (Bio- Medical Waste Management & Handling) Rules, 2016).
- 10. All patient entry data would be performed by the private partner through the proposed software and would give access to the government as per "Appendix I".
- 11. The patient data and financial data would be shared by Private Partner and Government to agree on the total dialysis procedures performed during a period.
- 12. The patient registered on a particular day would be attended on the same day provided any idle machine is available.
- 13. If all machines are pre booked for the day, the incoming patient would be allocated next earliest available slot, which should not be more than three (3) days from day of registration.
- 14. If no slot is provided to a registered patient within next consecutive three (3) days, this would be termed as denial of service and treated as non-conformance to the standards.

#### **Section B: PENALTY CLAUSES**

Clause	Penalty
<ol> <li>Failure to maintain an uptime of 90% annually with maximum 7 days of downtime at a stretch of any single dialysis machine of the facility.</li> </ol>	3% of the Performance security <b>X</b> No. of facilities reporting/month
2) Absence of Doctors/Nurses/ Hospital Attendant/Technician/ Sweeper in each shift	Rs. 1000 per day/shift - Doctor Rs. 500 per day/shift - Nurses, Hospital Attendant, Technician & Sweeper
3) Failure to ensure disposal of bio medical waste as per stipulated regulations of Pollution Control Board & regulations governing medical waste disposal (Bio-Medical Waste Management Rules, 2016).	2% of the Performance security X No. of facilities reporting/month
4) Failure to commission and start the 24X7 Dialysis facility across all the facilities (14	10% amount of Performance Security/Bank Guarantee for delay of

DHs) within 90 days of the signing of the	every 30 days may be imposed and
contract.	deducted from the Performance
	Security/Bank Guarantee as decided by
	the SHSB.

Note: The above service level indicators are minimum and it is obligatory for Concessionaire to provide efficient service delivery to all the stakeholders in the Hemodialysis Unit as per the good industry practices / applicable statutory guidelines.

## **CHECKLIST FOR BIDDERS**

Sno	Documents to be submitted	Submission Status (Yes/No)	Page Nos in the bid	Remarks if any
1.	Bidder's Authorization Letter			
2.	PoA for signing of proposal			
3.	Manufacturer's Authorization Form(MAF) for			
I.	1) Dialysis Machines			
I.	2) Dialyzer Re-processor			
II.	3) Defibrillator			
III.	4) Dialysis Chair			
IV.	5) Water Treatment Plant			
4.	Form Assignment of similar nature successfully completed			
	Private/public sector in India, as per			
	span of years			
	2) Private/public sector in the state of			
	Bihar, as per span of years			
	3) Operating & managing dialysis facilities			
	having at least a minimum of 50			
	hemodialysis machines			
5.	Form Particulars of the Bidder's company			
6.	Forwarding Letter for Technical Bid			
7.	Financial Bid			
8.	Earnest Money Deposit in the form of DD of any Scheduled Bank in favour of the Executive Director, State Health Society Bihar, payable at Patna			
9.	Declaration of Bidder for not being de- recognized or black listed			
10.	Original tender doc dully signed and stamped on each page			
11.	Self-attested Copy of the Certificate of Incorporation issued by the Registrar of Companies/ Registrar of Societies/official having jurisdiction in case of a trust or other appropriate authority whichever is applicable			
12.	Audited Balance sheet and Profit & Loss			
	Account for last three Financial Years(FY)			
I.	1) FY 2013-14			
II.	2) FY 2014-15			
III.	3) FY 2015-16			

13.	Self-attested copy of the ITR for last three		
	Assessment Years(AY)		
l.	1) FY 2014-15		
II.	2) FY 2015-16		
III.	3) FY 2016-17		
14.	Copies of: PAN card, Service Tax		
	Registration Certificate, Sales Tax or VAT		
	certificate		
15.	The latest copy of VAT returns submitted by		
	the bidder as on 31.03.2016		
16.	The latest copy of Service Tax returns		
	submitted by the bidder as on 31.03.2016		

#### Note:

- 1. All pages of the tender should be manual page numbered & indexed.
- 2. The Bidder may go through the checklist & ensure that all the documents/confirmations listed above are enclosed in the tender & no column is left blank. If any column is not applicable, it may be filled up as NA.
- 3. Wherever necessary & applicable, the bidder shall enclose certified copy as documentary proof/evidence to substantiate the corresponding statement.
- 4. In case a bidder furnishes a wrong or evasive answer against any of the question/issues mentioned in the Checklist, its tender will be liable to be ignored.
- 5. It is the responsibility of the bidder to go through the Tender document to ensure furnishing all required documents in addition to above, if any.

218114141 0111441011244 218114101J.	
Seal with Designation:	
Place:	
Date:	

**(For SHSB Use Only)** – *To be filled during opening of applications* 

Verified the above mentioned documents and found them to be in order at respective page nos. except those as under

1.

2.

3.

Signature of Authorized Signatory:

Signature of Authorized Signatory:

Designation:

Place and Date: