



**REQUEST FOR QUALIFICATION (RFQ) CUM
REQUEST FOR PROPOSAL (RFP)**

**For
Selection of Hemodialysis Unit Service Provider (HDU-SP)
in 18 District Hospitals in other than Divisional
Headquarters in Uttar Pradesh**

Part III: Schedules to Draft Agreement

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1 Background

a) Introduction

The Department of Medical & Health under the Government of Uttar Pradesh proposes to provide dialysis facilities at few of its hospitals. The key objective is to provide access to high quality Haemo-Dialysis free of cost to the entire population of Uttar Pradesh .

The Department of Medical & Health , Government of Uttar Pradesh (the “**Authority**”) has decided to undertake development and operation/maintenance of these dialysis facilities (the “**Project**”). The Project comprises of setting up of Haemo-Dialysis facilities at the hospitals identified by the Authority for which concession would be granted to the selected Bidder for Development-transferback of the Haemo-Dialysis facilities.

b) Current Scenario and Needs Assessment

End Stage Renal Disease (ESRD, the complete, or almost complete failure of the kidneys to function) affect around 250 people/million population every year.

Given the state’s current population of ~ 200 million and an ESRD incidence rate of 229/million, it is estimated that ~13,000 patients are diagnosed with ESRD every year. Given that typical life expectancy of patients on dialysis is 3.5 years, this means ~45,700 patients at any point of time need dialysis services. After taking into consideration increase in requirement due to patient inflow from outside the state for dialysis services and reduction due to patients on Peritoneal Dialysis etc, it is estimated that the state needs to provide for Haemo-dialysis for ~37,000 patients at any point of time. This would mean a requirement of over 4100 dialysis machines to meet the demand.

Uttar Pradesh currently has an estimated 470 machines to cater to this demand. In order to bridge the gap, the Authority plans to set up 180 (One Hundred and Eighty) Haemo-Dialysis machines on a PPP basis. DoMH plans to start with 18 Regional Hospitals with intent to develop similar facilities in PPP Mode.

c) Government of Uttar Pradesh (GoUP)’s Strategy

The over-riding objective of the policy is to utilize the technical, financial and management resources available in the private sector for strengthening the quality of services being provided through the public healthcare network.

GoUP has decided to provide space (free of cost) in 18 District Level Hospitals located in other tahn divisional head quarters to let Service Providers having expertise in managing Dialysis units establish, operate and maintain Haemodialysis units and provide free treatment facilities to all the patients requiring maintenance dialysis to lead quality life and also to serve as bridge for requirement of kidney transplant.

2 Objectives

The Service Provider is required to provide maintenance dialysis services to all the patients referred to it by the Medical Superintendent of respective Regional Hospitals. Patient has to register himself once in the OPD and will be referred to Dialysis unit for further treatment.

The key considerations are:

- a) To reduce out of pocket recurring expenses for the patients suffering from ESRD (End Stage Renal Disease).
- b) To provide affordable quality, dialysis *and allied* facilities in various government hospital services.
- c) To provide universal access to Dialysis facilities for the patients suffering from ESRD.
- d) To provide state-of-the-art Haemodialysis equipment and ancillary equipment required for smooth operations of Haemodialysis Centre and allied services to Government of Uttar Pradesh.
- e) To provide free of charges services to all patients. .
- f) System will be laid out for taking new and continuous patients by the Authority which are binding to HDU-SP
- g) To provide hassle free services - The patient has to register only first time and not every time when he/she is coming to undergo the haemodialysis procedure. A prefix schedule will be defined and will be available on the department's website and patients can view the same and get the information about their respective schedule. In case the beds are not available (fully occupied), it will be responsibility of designated Hospital Authority to sequentially prepare a waitlist of the patients and get them admitted once the beds are available.

3 Activities to be performed by the Service Provider (Scope of Work)

The Service Provider will provide the Services as defined in Schedule-A (Description of Services). The Services would broadly consist of the following:

- a) Private partner would setup advanced haemodialysis and allied facilities at the hospitals identified under the project including (1) Machines (2) Manpower (3) Consumables required to conduct the services defined in Schedule A(Description of Services) and as per Specifications Annexure-I (4) Running and maintenance of the centre for entire duration of the tender.
- b) Private partner to provide affordable services at pre-determined rates. Entire services across the identified hospitals to be managed by the private partner concessionaire
- c) A 24- h our Dialysis helpline for man aging and coordinating the services to be provided by the private partner (detailed scope to be laid out in the RFP document).
- d) Dialysis services – The private player will also set up and provide dialysis helpline services,

- e) Private partner to operate and maintain these centres as per the requirement specifications laid out in the RFP document.
- f) Compliance to various Acts- It will be the sole responsibility of the Service Provider to abide by the provisions of the following acts as to the workers engaged by him for performance of this contract:
 - Employment of Children Act.
 - Workmen compensation Act.
 - Employment of Labour/ Contract Labour Act.
 - Industrial Employment Act.
 - Contract Labour abolition and regulation Act 1970.
 - Minimum Wages Act.
 - Employee Provident Fund Act.
 - ESI Act
 - Any other Act or Legislation, which may govern the nature of the contract and/ or being issued by Govt. from time to time.

4 Commencement of Work and Liquidated Damages for delayed commencement

- The Service Provider is required to start the Haemodialysis services at respective hospitals within 60 Days for Two Hospitals of the Cluster and within 120 days in balance Hospitals of the Cluster. from the date of award/ date of communication of acceptance of the contract. In case it is found the Haemodialysis services at respective hospitals has not been taken up within stipulated time from the date of acceptance contract or issue of the Work Order the Project at its sole discretion may levy Liquidity Damages and on non-compliance may cancel the work order and forfeit the performance security as per the provisions laid out in the bidding documents.
- The Service Provider is required to post his authorized representative at the site of the work all the time, who shall receive the instructions from the contract signing authority from time to time. All such instructions received by the authorized representative on behalf of the Service Provider shall be deemed to have been received by the Service Provider within the scope of this work order.

5 Monitoring, Evaluation and Reporting –

The following Annexures define the Monitoring, Evaluation and Reporting:

Annexure- II- Essential Monitoring Criteria-

Annexure- III- Daily Monitoring Check List-

Annexure-IV- Weekly Review List -

Annexure-V-Patient Feedback Review Sheet-

Annexure-VI- Weighted Average Score Calculation-

Annexure-VII- Quarterly Audit Sheet-

Annexure- VIII- Internal Audit Sheet-

- Any problem encountered on daily basis which means that services are not complying with the required standards shall be recorded as a comment in the format attached in Annexure III and reported to the Dialysis staff or supervisor or authorized representative of service provider and the staff has to rectify the problem in accordance with – 48 Hours and if not rectified within the timeframe this will be recorded in the Annexure-IV- Weekly Review Sheet where there will be ZERO Score Marking.
- If any patient send his/her complaint regarding Dialysis in the hospital through IVR or SMS service or written application , a notification shall be sent to the supervisor through his/her mobile and after taking necessary actions the supervisor has to notify back within 24 Hours and the same shall be recorded for monitoring purposes: A time log book will be maintained at the office of contract signing authority and a copy of the same shall be maintained by the site supervisor of the Service provider. In case of failure to resolve the issue within 24 Hours there will be ZERO Score Marking in Patient Feedback Review Sheet- Annexure-V.
- Nodal Officers- All the invoices, reports etc. needs to be certified by the Nodal officers who will be Chief Medical Superintendent of the hospital concerned. In his absence, the Medical Superintendent or any Medical Officer as assigned by the Chief Medical Superintendent may sign the documents.
- Each of the Service Provider should have to submit the Invoice along with a monthly report Comprising of Annexure-VI and reasons of deficiency and non-compliances to the DoMH within 7(seven) working days of the next month.
- Members and Technical Experts from the Health & Family Welfare Department may visit the Service Provider concerned at any time with/without notice. There will be an Annual Review as per provisions and the opinions and recommendations of the Review Committee will be considered during the renewal of the agreement.
- The designated hospital staff of respective centre of the hospital shall fill the weekly review sheet mentioned in Annexure IV by marking the response in a scale of 0-5 (whether the services are complying to the standards or not) against TEN elements/criteria. The duly filled review sheet shall be signed by assigned hospital staff (by whom sheet will be filled), counter signed by the contract signing authority and the site supervisor or assigned personnel of service provider. All monitoring reporting formats and notifications should be linked to the Control room MIS whenever it is installed and the cost of maintaining this module will be borne by the Authority
- On monthly basis, the authorized representative assigned by the Authority or contract signing authority shall collect all the reports and notifications and payments shall be reimbursed according to that as mentioned in Part-II- Article-7 (Consideration for Payment).
- An internal audit shall be conducted on random basis during each quarter for all schedules by the authority assigned by the Authority. The auditor shall decide the compliance of each element using the service standards and requirements (Essential Monitoring Criteria-Annexure II) and record it as either acceptable (score 1) or unacceptable (score 0). Review elements comprise 10 elements (Annexure

VII).

- A third party audit shall also be conducted on random basis after every six months to understand the community perception of dialysis services in the hospital. Random checks of critical parameters will be conducted by the third party. (Annexure-VIII).
- The recommendations of Third Party as well as Internal Audits will be communicated and the Service Provider will need to rectify the deficiency within 30 days failing which the payments of the Service Provider will not be released. If the deficiency is not rectified within 60 days the Service Provider will be issued a Termination notice and the Contract will be terminated within 30 days from the date of intimation of Termination.

6 Dispute

- In the event of any dispute or difference arising between the parties relating or concerning to interpretation of the contract or any alleged breach thereof or
- any matter relating to this contract, the same shall be settled by the parties as far as possible by mutual discussions and consultation between themselves, whether the same has arisen during the subsistence of this contract or thereafter.
- In the event of any dispute of differences arising in connection with this contract whether during the subsistence of the contract or thereafter not being settled in aforesaid manner, an arbitrator shall be appointed by both parties together, whose decision shall be final and binding on both the parties. The proceeding before the arbitrator would be governed by the provision of the ARBITRATION AND CONCILIATION ACT, 1996.
- The Courts of Lucknow shall have exclusive jurisdiction in all matters arising out of this contract.
- No Party shall be allowed to be represented by lawyer during any investigation, enquiry appeal or and other proceeding at the Project.
- The service provider may seek to make minor modifications in the Terms and conditions of the contract with the written consent of the Authority without affecting the basic nature of this contract. The Authority may not accede to any such modifications if found unreasonable or such modifications that may alter the basic nature of the contract.
- The work of Service Provider will be inspected by contract signing authority or an officer nominated by the Authority. In case of default financial penalty for each such default shall be imposed as appropriate.

7 Stamp Duty

Stamp duty leviable on agreement to be executed between the Authority and Service Provider shall be borne by the Service Provider.

8 Termination of the Agreement-

The Termination of the contract will be as per CI 1.18 Article 18- in Part-II- Draft Agreements and as per following provisions:

- After giving opportunity of being heard to the Service Provider, Project may terminate/ cancel the agreement on the following grounds:
 - ✓ Breach of any or all terms and conditions of agreement.
 - ✓ Non-performance or unsatisfactory performance of work.
- The project reserves the right to terminate the contract without assigning any reason by giving a notice of three months. The Service Provider will have to serve a notice of three months, if he wishes to terminate the contract, failing which his performance security would be forfeited.
- Refer for specific Termination provisions.

9 Renewal of the Contract

As per timeframe provisions in BDS the renewal of the contract will be based on the Internal Audit and third party review.

10 Annexure I: Specifications

10.1 Haemodialysis area

The Service Provider will be made available with the space for setting up the Haemodialysis unit and water at the input of the Space. The Service Provider will provide the internal connections for electricity as well as Water –Treated as well as Non Treated. The HDU-SP will have to bear all the cost for Electricity connection, water supply as well as its consumption

The Haemodialysis area will have the following features -

- Each Dialysis machine will have at least 8 x 7 ft. (approx..) Space.
- Cardiac resuscitation equipment should be available and could be easily wheeled on all four sides of the patient.
- Facilities for non-invasive blood pressure monitoring of all patients and ECG monitoring of select patients are needed.
- Each machine area should be easily observed from the nursing station which should be included in this area.
- Nursing station should have enough space for adequate number of nurses /technicians depending on the number of dialysis machines
- Head end of each bed should have stable electrical supply (at least 3 outlet of 5/15 amps), oxygen &vacuum outlet, treated water inlet & drainage facilities.
- Air conditioning to achieve 70° F to 72° F temperatures & 55 to 60% humidity.
- Areas for dialyzing patients having viral diseases (HBV/HCV) and HIV should be separated from those patients not having any viral infections. These spaces should have independent drainage, independent water supply, independent air handling & separate personnel facilities.
- An indicative Layout structure of Dialysis unit is attached for reference. However the same will be finalized mutually between the designated hospital authority (MS/CMS/Director of the associated Hospital) and Service Provider before commencement of work. The layout structure of all theHemo dialysis unit should be universal.
-

10.2 Preparation, Work and Storage Area

The preparation, work and storage areas should have the following:

- Independent area is needed for reprocessing the dialyzers. This should have a work bench with sink having side board & drainage. The work bench should be supplied with treated as well as untreated water which are separately marked. Two sinks for the work bench should be provided. The space should be sufficient for at least two persons working simultaneously.
- This preparation area should be physically separate for processing dialyzers from viral infection patients versus those not having any viral infection.

For both areas stable electrical supply & drainage is needed for the work bench. There should be space for dialyzer reprocessing machine(s) in this area.

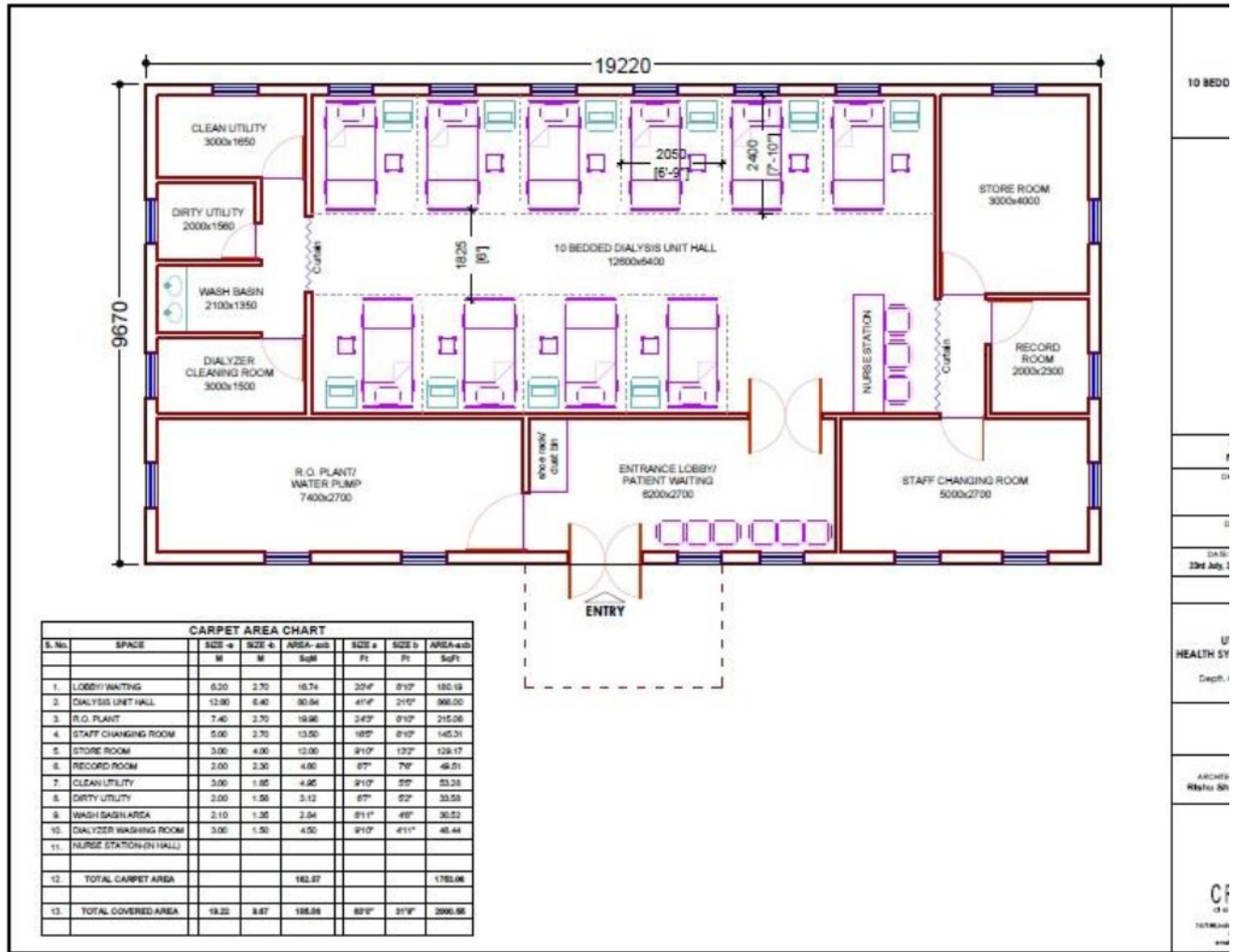
1. There should be two storage areas, one for storage of new supplies and one for reprocessed dialyzers. The principle of dry storage area is to be able to store 1 months supply of dialyzers, tubing, Haemodialysis concentrate solutions, IV fluids. However the bidders will ensure all time availability of items and Hemodialysis should not suffer because of this. It should also have space for stationery, linen etc. The wet storage is for reprocessed dialyzers & tubing. The dry storage area should be separate from the wet storage.
2. A clean room with a work bench is needed for preparation of sterile trays for dialysis Start-up kit & for preparation of injections & storage of emergency equipment.
3. This area should have a designated place for keeping wheelchair /trolleys for transporting
4. Patients & weighing scale. There should be an area for dirty utility. This area should be located in such a way that personnel and material need not come from dirty utility to clean area of dialysis.
5. There should be changing room for Doctors, nurses & technicians
6. Each patient is generally accompanied by two individuals; hence, a specially designed area for their stay and some relaxation should be provided. Patients waiting to go on dialysis & those who have recently completed dialysis could also utilize the same area.
7. Storage facility (lockers) should be provided for individual patients belongings which should be prepared in the patient waiting room.
8. There should be space for a water treatment unit

General Conditions

The general conditions should have the following -

- Air conditioning: All Haemodialysis machine areas, consultants & technicians/nurses rooms should have air conditioning. Treatment areas should have temperature 70°F & 55 to 60% humidity. Relative's waiting / recreation area & reception should be well ventilated with fans or may have air conditioning.
- Electricity: Stable voltage continuous supply is required. Online UPS is recommended. It should have a backup for at least 30 minutes. The power capacity of the UPS should be able to support all functions of the dialysis machine. The electrical supply should be stable & uninterrupted, preferably a pure sine wave both voltage and frequency regulated. The use of electrical surge protectors is necessary to protect dialysis machine's electronics. Adequate capacity generator is recommended.
- Plumbing & drainage:
- All treated water pipelines should be stainless steel grade 316 or medical grade PVC. There should be minimum bends & blind loops should be avoided.
- All drainage should be connected directly to the main drainage line. There should be no bends or blind loops.
- The bidders will be required to keep two oxygen cylinders and two suction machines.
- The ambience should be cheerful looking in terms of colour used. It should be brightly lit so that examination of patient or if procedures are required there is no difficulty. There should be a facility to dim the lighting.

- The system for record keeping should be preferably electronic for patient as well as unit records. Depending on the authority & function of the person using it, the records system should be accessible by username and password protection. There should be protection of privacy of the patients.
- All consumables should have FDA/CE/BIS approved standard.



10.3 HDU-SP Staff

Proposed Minimum standards for personnel in Dialysis Facility

1. OUTLINE: It is mandatory to have the following minimum staff-pattern for a proposed Dialysis unit:

- a) Nephrologist (only 1 per cluster)
- b) Contract Manager (only 1 per cluster)
- b) Dialysis doctors
- c) Dialysis technicians.
- d) Biomedical Engineering Technicians (BMET)
- e) Dialysis nurses
- f) Medical social worker
- g) Sweepers

2. PARTICULARS: Above category (a to e) of staff should satisfy the following:

- a) Training
- b) Job description / responsibilities (Dos and Don'ts)
- c) Appraisal / Auditing
- d) Updating

Medical Social Worker should satisfy the details as defined under Job Description.

Details of Personnel Specifications:

S/N	Staff Group	Particulars	Descriptions
1	Nephrologist (1 Per cluster)	Training	1. DM/ DNB in Nephrology 2. MD with special training in nephrology (at least 2 yrs.)
		Job Descriptions	1. Visit the dialysis centre at least once a week .The SP can appoint as many nephrologist they wish whether full time or part time but they will have to ensure that they visit once every week. Also it needs to ensure that each patient is assessed at least once in 30 days 2. Responsible for overall supervision of the unit 3. Assess the patients; decide about specific dialysis prescriptions: evaluate the co morbid illnesses and advice regarding supporting medicines; takenote of the initial / inter / post dialysis events, and consider specificrecommendations. 4. Review the water quality, infection control measures and day to day functioning at regular intervals. 5. Judge the practices of the dialysis doctors, technicians and nurses from time to time. 6. Provide 24 hour consultation and backup care to all the patients. 7. Monthly review of all in center dialysis patients.

S/N	Staff Group	Particulars	Descriptions
			<p>8. Enforcement of rules and regulations relative to the level of patient care and safety.</p> <p>9. Maintenance of an ongoing liaison between the hospital authority, statutory bodies, dialysis staff and the patients.</p> <p>10. Protecting the rights of the patient's vis-à-vis the staff.</p> <p>11. Supervise the in house teaching program.</p>
		Auditing / Appraisal	There will be a system of dialysis audit. At least once a month the team should meet and discuss the matter. The facts should be shared with the hospital authorities and statutory bodies.
		Updating	To attend National Level Conference at least once a year.
2	Contract Manager (1 Per cluster)	Training	Any graduate with PG Diploma in Finance / Materials Management / Marketing Management / CA with experience of 5 years in managing contracts / procurement functions / project management
		Job Description	<p>1. To be involved in day to day management of inventory</p> <p>2. Raising invoicing as per contract documentations</p> <p>3. To address all the contract obligations</p> <p>4. Day to Day liaison on contract clarifications with stakeholders.</p>
		Appraisal auditing	Shall coordinate all internal as well as external audit and shall address all audit issues
		Updating	Shall keep himself updated on all financial asnd contracting obligations
3	Dialysis Doctors for round the clock services (8 hourly). Patient: Doctor ratio 10:1	Training	<p>Registered M.B.B.S. degree with one year experience certificate in Dialysis Unit.</p> <p>1. At least one year house job in internal medicine / allied specialty</p> <p>2. Experience in central line access</p> <p>3. Experience in critical care management</p> <p>4. Certified in advanced cardiac life support (ACLS)</p> <p>5. Experience in pediatric patient management – desirable</p>
		Job Description	<p>1. To be involved in day to day patient management.</p> <p>2. Assess the patient before starting dialysis :</p> <ul style="list-style-type: none"> - hemodynamic status - indication of dialysis - vascular access - recent surgery - co morbid illness - bleeding manifestations <p>3. Be involved in patient care during dialysis :</p> <ul style="list-style-type: none"> - making access - adequacy of flow - follow instruction of the nephrologist - deciding about any modification in dialysis prescription in

S/N	Staff Group	Particulars	Descriptions
			<p>consultation with the nephrologist</p> <ul style="list-style-type: none"> - monitoring the patient during dialysis - managing complications during dialysis - will coordinate with dialysis technicians and dialysis nurses <p>4. Assess the patient at the time of closure :</p> <ul style="list-style-type: none"> - access site - hemodynamic status - any complication - any specific instruction to (a) the ward nurse (b) the relatives <p>5. Assess the patient at least once in the ward after dialysis</p> <p>6. Accompany the patient to the ward, if critically ill</p> <p>7. Handle/ supervise / guide the supporting staff in CPR if situation arises.</p> <p>8. Have working knowledge of the dialysis machine, water treatment plant, Ventilator, defibrillator and other gadgets and equipment of the dialysis unit.</p> <p>9. Be the team leader of the day to day dialysis procedure and on one hand will keep in touch with the nephrologist on the other hand will disseminate the information thus gathered to the subordinate staff in order to implement the guidelines fixed by the hospital authority and the nephrologist.</p> <p>10. Look after the safety and security of the supporting staff.</p> <p>11. Will take regular teaching sessions meant for the dialysis staff.</p>
		Appraisal auditing	Same as Nephrologist
		Updating	Attend national level conferences Haemodialysis Society / PDSI at least once in 2 years
4	Dialysis Technicians Patient: Technician =3:1	Training	<p>1. Have passed at least two year certificate course in dialysis technique (after 12th standard) certified by a Govt. authority or have sufficient hands on experience.</p> <p>2. The training curriculum should include :</p> <p>3. Fundamentals of renal anatomy and physiology, principle of dialysis</p> <p>4. Water quality, water treatment, water distribution</p> <p>5. The dialysis machine: connectology, upkeep of machines.</p> <p>6. Care of vascular access- Pre and Post Dialysis</p> <p>7. Dialyzers and tubings including cleaning and</p>

S/N	Staff Group	Particulars	Descriptions
			<p>preservation.</p> <p>8. Anticoagulation</p> <p>9. Dialysate : composition & ingredients</p> <p>10. Common complications of dialysis: How to manage them at bedside.</p> <p>11. Basic evaluation of a patient before during and after dialysis.</p> <p>12. Infection control and safety. Disinfection.</p> <p>13. Reuse of dialyzers</p> <p>14. Cannulation (vascular access) : the broad principles</p> <p>15. Special expertise in critical care dialysis (CRRT/ SLED) and paediatric patient management.</p> <p>16. ABC of peritoneal dialysis.</p>
		Job Description	<p>1. All those which they have been trained in</p> <p>2. Conducting discharge assessment</p> <p>3. Keeping an inventory of the medicines and disposables</p> <p>4. Following instructions of the dialysis doctors.</p> <p>5. Conducting assessment of a patient when indicated</p> <p>6. Facilitating communication between the patient and patient's family on one side and the treating team on the other.</p> <p>7. Providing oversight and direction to the junior dialysis technicians</p> <p>8. Participating in continuous quality improvement activities.</p>
		Auditing Appraisal	They should maintain registers for individual patients and enter the data of each patient, which will be subjected to medical auditing from time to time.
		Updating	Must attend update sessions meant for dialysis technicians at least once a year.
5	Biomedical Engineering Technician 1 Technician (should be available for 24 hour on call services)	Training & Certification	<p>Diploma in Biomedical/Electronics engineering/ Certified by Health Sector Skill Council/NCVT with at least 2 Years of experience in maintaining Dialysis Machines and associated RO Plants.</p> <p>Should have functional knowledge of Dialysis Machines working and troubleshooting.</p>
		Job description	<p>Breakdown and preventive maintenance.</p> <p>Co-ordinating with the company engineers.</p> <p>Spares and accessories inventory management</p> <p>Co-ordinating with Technicians, Nurses and Doctors.</p>
		Audit	Should maintain equipment history including installation, maintenance and calibration history and monitor vendor performance as well as inventory levels of essential spares.
		Up-gradations	Shall attend training at least once a year at vendor's

S/N	Staff Group	Particulars	Descriptions
			premises and update on the latest development in dialysis machines as well as water treatment.
6	Dialysis Nurses- Patient: Nurse = 3:1	Training	GNM + 6 month exposure in a dialysis unit. Should be registered with the local Nursing Council.
		Job Description	<ol style="list-style-type: none"> 1. Conducting admission assessment 2. Conducting discharge assessment 3. Keeping an inventory of the medicines and disposables 4. Following instructions of the dialysis doctors. 5. Conducting assessment of a patient when indicated 6. Recommending changes in the treatment based on the current needs of the patient 7. Facilitating communication between the patient and patient's family on one side and the treating team on the other. 8. Cooperate with and provide oversight and direction to the dialysis technicians 9. Participating in continuous quality improvement activities.
		Auditing and Updating	Same as Dialysis Technician.
7	Medical Social Worker	Job Descriptions.	<ol style="list-style-type: none"> 1. Psychosocial evaluations 2. Case work counselling of patients and family 3. Group work 4. Information and referral 5. Team care planning and collaboration 6. Facilitating community agency referral
8	Sweepers- Both male and female at a time for round the clock service (8 hourly basis)	Job Descriptions.	As per the existing norms and standards of any critical care unit



Equipment: The following equipment should be available in each unit-

Sr.No	Name of Equipment	Minimum No. required
1	Haemodialysis Machines	10
2	Dialyzer Pre-processors	02
3	Dialysis Chair/ Bed	10
4	Defibrillator with ECG Machine	01
5	Emergency Patient Transfer Trolley	02
6	Ambu Bag-	02

7	Weighing Machines	02
8	Computer with Printer	01
9	Water Treatment Plant-1000 litres / hour	01
10	Bins as per Waste Management Codes	03
11	Minor Surgical Tools- SET	02
12	Digital Multimeter	01
13	UPS for 30 Minutes back up.(Battery back-up for 20-30 minutes to run the machine with Extracorporeal circuit. Also clarified that Machines having battery back up of 20 minutes or more will not be required to provide UPS.) and Generator with load capacity sufficient to run the Dialysis Unit.	01
14	Dressing Set- 10 per shift	30

10.4 EQUIPMENT SPECIFICATIONS-

- A. There will be a tolerance of 5% on all numerical values of all specified parameters.**
- B. All equipment and RO System should be US FDA OR European CE approved irrespective of whether specified or not.**

01.Specifications for Haemodialysis Machine

ECRI Code: 11-218

1 Description of Function

SI	Description
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- | | |
|-----|---|
| 1.1 | Haemodialysis is a method for removing waste products such as potassium and urea, as well as free water from the blood when the kidneys are incapable of this (i.e. in renal failure). It is a form of renal dialysis and is therefore a renal replacement therapy. |
|-----|---|

2 Operational Requirements

SI	Description
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- | | |
|-----|--|
| 2.1 | Machine should have facility for Acetate, Bicarbonate, Sequential dialysis (Isolated UF) |
| 2.2 | Upgradable to future software developments and can be linked with Patient Data Management System |
| 2.3 | The blood pump should run even in the absence of water or dialysate flow. |

3 Technical Specifications

Sl	Description
3.1	Should have facility for conventional and High flux dialysis.
3.2	The Machine to have one bacterial filter(Pyrogen Filters) at the water inlet only. The filter to be replaced as recommended by the manufacturer.
3.3	Battery back-up for 20-30 minutes to run the machine with Extracorporeal circuit.
3.4	Should have Na, and UF profiling
3.5	Dialysate temperatures selectable between 35 degrees C to 39 deg. C
3.6	Variable conductivity setting between 12 to 15
3.7	Should have variable dialysate flow 300/ 350-800 ml/min.
3.8	Should have facility to show trends curve of all parameter for 15-20 minutes
3.9	Heparin pump with syringe sizes up to 20/30 ml with pump flow rate from 1-10 ml/hr(0.1 ml increments)
3.10	Stroke pressure operated short term single needle dialysis
3.11	Ultrafiltration 0.1 to 2.5 litres/hr. The in and out fluid circuit must be separated so that there is no chance of contamination in the event of membrane rupture.
3.12	Treatment parameter should be displayed by graph and digitally both
3.13	Should have integrated heat and chemical disinfection facility.
3.14	Should have accurate feedback control conductivity mixing technique.
3.15	Should have drain facility.
3.16	Should have accurate UF control by flow measurement technique.
3.17	Extra facilities like Blood Volume sensor, Bicarb Select technique and online clearance kt/V.
3.18	All important data should be pre-setted so that machine can be used anytime without feeding data every time
3.19	Should have automatic self test facility
3.20	Should have auto ON/OFF Facility
3.21	Should have Colour TFT/LCD Display with minimum 10" Screen.
3.22	Easy to service, trouble shoot and calibrate

- 3.23 Machine can be connected to computer to feed all data and trouble shoot whenever any problem
- 3.24 Blood pump rate from 20/30-500 ml/min adaptable to standard A-V bloodlines.
- 3.25 Ability to monitor pulse rate and NIBP with graphic and tabulated trends.
- 3.26 Audio visual alarms on limit violation of conductivity, blood leak, air leak, transmembrane pressure alarms,, Dialysis temperature alarm, dialysis can empty alarm, end of disinfection alarm, bypass alarm and blood pump stop alarm
- 3.27 Alarm for reverse Ultrafiltration.
- 3.28 Machine should have real time monitoring for clearance of adequacy of dialysis during treatment. Machine should have KT/V monitor and display clearance, plasma, sodium, current KT/V and time required to achieve target KT/V.
- 3.29 Machine should have mixing for Bicarb Solution using dry bicarbonate cartridge.

4 System Configuration Accessories, spares and consumables

SI	Description
4.1	System as specified
4.2	All consumables required for installation and standardization of system to be given free of cost.
4.3	To be supplied free of cost Bacterial filters– 2 sets extra , 100 polysulfone 1 m2 dialyzers and tubings

5 Environmental factors

SI	Description
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0 - 50deg C and relative humidity of 15-90%
5.2	The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%

6 Power Supply

SI	Description
6.1	Power input to be 220-240VAC, 50Hz fitted with Indian plug
6.2	UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up for the entire unit

7 Standards, Safety and Training

SI	Description
7.1	Should be FDA or CE(Notified Body) Certified product
7.2	Manufacturer/Supplier should have ISO certification for quality standards.
7.3	Shall comply with IEC 60601-2-16 SAFETY requirements of medical electric equipment part2- particular requirements for the safety of Haemodialysis equipment.
7.4	Comprehensive warranty for 2 years and 5 years AMC after warranty
7.5	Comprehensive training for lab staff and support services till familiarity with the system.
7.6	Should have local service facility .The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

8 Documentation

SI	Description
8.1	User/Technical/Maintenance manuals to be supplied in English.
8.2	Certificate of calibration and inspection from factory with date of manufacturing.
8.3	List of Equipment available for providing calibration and routine Preventive Maintenance Support as per manufacturer documentation in service/technical manual.
8.4	List of important spare parts and accessories with their part number and costing.
8.5	Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out

02. Equipment Specifications for Dialyzer Re-processor

UNSPSC Code: 42161615

ECRI Code: 16-108

1 Description of Function

SI	Description
----	-------------

- 1.1 Dialyzer re processors are systems which cleans the dialyzer for reuse and reduce overall dialysis expenses.

2 Operational Requirements

SI	Descriptions
2.1	Should have fully automatic operation. In built dedicated software should operate without external computer. Should have connectivity with other reprocessors or external computers, if needed.
2.2	Option of semiautomatic operation for customized cleaning.
2.3	4 station vacuum chamber venturi assembly up to 25 inches vacuum to run on RO reject water/ tap water or a positive pressure system.

3 Technical Specifications

SI	Description
3.1	Should be able to clean both high flux and low flux dialysers and haemodiafilters
3.2	Should be safe for cellulose based and synthetic membranes.
3.3	Should be compatible with sterilants available in open market.
3.4	Should have LCD Screen and menu guided operations.
3.5	Should have 8-10 standard programs and facility of customized programs.
3.6	Water requirements - flow 3 litres/ minute and pressure 35-50 psi.
3.7	It should have regulators, pressure gauges to monitor pressures.
3.8	It should be able to measure the bundle volume.

4 System Configuration Accessories, spares and consumables

SI	Description
4.1	System as specified

5 Environmental factors

SI	Description
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0-

50deg C and relative humidity of 15-90%

- 5.2 The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%
- 5.3 Vendor should specify the water, electricity and civil work requirements for installation of the equipment.

6 Power Supply

SI	Description
6.1	Power input to be 220-240 VAC, 50Hz fitted with Indian plug
6.2	Voltage corrector/stabilizer of appropriate ratings meeting ISI Specifications.(Input 160-260 V and output 220-240 V and 50 Hz)

7 Standards, Safety and Training

SI	Description
7.1	Should be FDA , CE Certified product
7.2	Manufacturer/Supplier should have ISO certification for quality standards.
7.3	Comprehensive warranty for 2 years and 5 years AMC after warranty
7.4	Comprehensive training for lab staff and support services till familiarity with the system.
7.5	Should have local service facility .The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

8 Documentation

SI	Description
8.1	User/Technical/Maintenance manuals to be supplied in English.
8.2	Certificate of calibration and inspection.
8.3	List of Equipment available for providing calibration and routine Preventive Maintenance Support as per manufacturer documentation in service/technical manual.
8.4	List of important spare parts and accessories with their part number and costing
8.5	Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be

clearly spelt out

8.6 User list to be provided with performance certificate.

03. Equipment Specifications for Haemodialysis Bed.

ECRI Code: 16-436

1 Description of Function

Sl	Description
----	-------------

1.1 Haemodialysis Bed is used for administrating dialysis to the patients comfortably.

2 Operational Requirements

Sl	Description
----	-------------

2.1 Should be ergonomically designed and comfortable to the patient

2.2 Should allow the patient to rest in full sitting position and lying position.

3 Technical Specifications

Sl	Description
----	-------------

3.1 Should have electronically controlled adjustments for back section, leg section and height.

3.2 Should have a patient hand set with controls for all positions.

3.3 Armrest should fold to allow side entry of the patient.

3.4 Head rest should be detachable and should have manual Trendelenburg facility.

3.5 Sheet cushion should be made of proper density foam and should have a smooth surface for easy hygiene and cleaning.

3.6 Frame should be made up of corrosion free galvanized steel with powder coating and should have four 150mm diameter swivelling castor two of which should be lockable

3.7 Should be able to withstand a maximum load of 150 Kg.

3.8 Should have facility for height adjustment.

3.9 Dimensions(approx.+/- 5 cm): Width 63 cm x Length 195 cm(fully stretched)x Adjustable Height(Min 56 cm; Max 78 cm from ground)

3.10 Rubber buffers are to be provided

3.11 Should have an option for manual operation of all controls

3.12 Should have a detachable drip stand and a tray table.

4 System Configuration Accessories, spares and consumables

SI	Description
----	-------------

4.1 System as specified-

5 Environmental factors

SI	Description
----	-------------

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

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

6 Power Supply

SI	Description
----	-------------

6.1 Power input to be 220-240VAC, 50Hz fitted with Indian plug

6.2 Voltage corrector/stabilizer of appropriate ratings meeting ISI Specifications.(Input 160-260 V and output 220-240 V and 50 Hz)

7 Standards, Safety and Training

SI	Description
----	-------------

7.1 Should be FDA , CE, approved/certified product

7.2 Manufactures/Supplier should have ISO certificate to Quality Standard.

7.3 Comprehensive warranty for 2 years and 5 years AMC after warranty

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

7.5 All electrical actuators and mechanisms should be housed inside the structure making the product safer

7.6 Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13450

8 Documentation

SI	Description
----	-------------

- 8.1 User/Technical/Maintenance manuals to be supplied in English.
- 8.2 Certificate of calibration and inspection.
- 8.3 List of important spare parts and accessories with their part number and costing
- 8.4 Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.
- 8.5 User list to be provided with performance certificate.
- 8.6 List of Equipment available for providing calibration and routine Preventive Maintenance Support as per manufacturer documentation in service/technical manual.

04. Specification of Defibrillator with ECG Machine.

UNSPSC Code: 42172101

ECRI Code: 17-116

1 Description of Function

SI	Description
1.1	Defibrillator is required for reviving the heart functions by providing selected quantum of electrical shocks with facility for monitoring vital parameters.

2 Operational Requirements

SI	Description
2.1	Defibrillator should be Bi- Phasic, light weight and latest model
2.2	Should monitor vital parameters and display them
2.3	Should print the ECG on thermal recorders.
2.4	Should work on Manual and Automated external defibrillation (AED) mode. Manual selection up to 200 J.
2.5	Should be capable of doing synchronised & a synchronized cardioversion
2.6	Can be operated from mains as well as battery
2.7	Should have defibrillator testing facility
2.8	Demonstration of the equipment is a must.

3 Technical Specifications

SI	Description
3.1	Should be a Low Energy Biphasic defibrillator monitor with Recorder, having capability to arrest all arrhythmia within a maximum energy of 200 Joules
3.2	Should monitor ECG through paddles, pads and monitoring electrodes and Defibrillate through pads and paddles. Should have Automatic Lead switching to see patient ECG through paddles or leads
3.3	Should measure and compensate for chest impedance for a range of 25 to 1500hms
3.4	Should have a built in 50mm strip printer/ thermal recorder
3.5	Should have charging time of less than 3 seconds for maximum energy. Charging indicator should be included.
3.6	Should have bright electroluminescent display for viewing messages and ECG waveform of 4 seconds
3.7	Should have external paddles with paddles contact indicator – for good paddle contact. Both Adult and paediatric paddles should be available.
3.8	Should have event summary facility for recording and printing at least 250 events and 50 waveforms.
3.9	Should have a battery capable of use for at least 90 minutes or 30 discharges.
3.10	Should be capable of printing Reports on Event summary, configuration, self test, battery capacity etc
3.11	Should have facility for self test/check before use, and set up function.
3.12	Should have SP02 and NIBP integrated facility
3.13	Should be capable of delivering energy in increments of 1-2 joules up to 30J and increments of maximum 50J thereafter.
3.14	Should have user friendly 1, 2, 3 colour coded operation.

4 System Configuration Accessories, spares and consumables

SI	Description
4.1	Defibrillator - qty 1.
4.2	Paddles Adult (pair) - qty 1.

- 4.3 Paddles – Paediatrics (pair) - qty 1.
- 4.4 Patient cable - qty 2.
- 4.5 ECG Rolls - qty 50.
- 4.6 Disposable pads - qty 10 nos.
- 4.7 NIBP Cuff Adult - qty 2.
NIBP Cuff Paediatrics - qty 2
- 4.8 SPO2 Finger Probe - Adult - qty 2.
SPO2 Ear Probe - qty 2.
- 4.9 Complete set of ECG Leads - qty 2.

5 Environmental factors

SI	Description
5.1	The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%
5.2	The unit shall be capable of being stored continuously in ambient temperature of 0 - 50deg C and relative humidity of 15-90%
5.3	Shall meet IEC-60601-1-2:2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

6 Power Supply

SI	Description
6.1	Power input to be 220-240VAC, 50Hz
6.2	Resettable overcurrent breaker shall be fitted for protection

7 Standards, Safety and Training

SI	Description
7.1	Should be FDA and CE approved product
7.2	Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms. (OR EQUIVALENT BIS Standard)
7.3	Drop Test-Withstands 1 meter drop to any edge, corner or surface.

- 7.4 Should conform to international test protocols on exposure to shock forces and to vibration forces. The standard should be documented.
- 7.5 Should meet IEC 529 Level-2 (IP2X) for enclosure protection solid foreign object ingress.
- 7.6 Should meet IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.
- 7.7 Should have local service facility .The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
- 7.8 Comprehensive warranty for 5 years and provision of AMC for next 5 years.

8 Documentation

SI	Description
----	-------------

- 8.1 User Manual in English
- 8.2 Service manual in English
- 8.3 List of important spare parts and accessories with their part number and costing
- 8.4 Certificate of calibration and inspection from factory.
- 8.5 Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly specified.
- 8.6 List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
- 8.7 Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.
- 8.8 Must submit user list and performance report within last 5 years from major hospitals.

05. Specifications Emergency Patient Transfer Trolley

UNSPSC Code: 42171611

ECRI Code: 15-726

1 Description of Function

SI	Description
----	-------------

- 1.1 An Emergency Patient Trolley is used for Patient transfer to and from ICU/OT/Emergency.

2 Operational Requirements

SI	Description
----	-------------

- 2.1 Demonstration of the equipment is a must.

3 Technical Specifications

SI	Description
----	-------------

- 3.1 Should have a three-section mattress base, made of X-Ray translucent high-pressure laminate. Includes facility to insert X-Ray Cassette from either the sides or the ends of the trolley.
- 3.2 Should be able to X Ray the patient from positions along the entire length and width of the trolley.
- 3.3 Should have pneumatic step less adjustment for back section. Trendelenburg (app. 14Degree) and reverse Trendelenburg (app.7 Degree).
- 3.4 Should have hydraulic height adjustment approx. 535-905 mm, by means of a foot paddle on either side of the trolley.
- 3.5 Frame of the trolley should move with mattress base when foot section / back section are adjusted.
- 3.6 Frame should be made up of epoxy powder coated steel
- 3.7 Should have Central braking system with steering facility
- 3.8 Should be equipped with heavy duty castors diameter 150 mm
- 3.9 Should have bumpers at all the four corners of the trolley
- 3.10 Should have facility to fix IV rod at all the four corners and middle of mattress base frame.
- 3.11 Should have place for fixing 'B' Type Oxygen Cylinder
- 3.12 Dimensions:
 Max. Length: app. 2075 mm
 Max. Width : app. 750 mm
 Height :ap. 535 – 905 mm
 Trendelenburg : app. 14 deg step less

Anti Trendelenburg : app. 7 deg step less
X ray viewing area : entire length

- 3.13 Mattress should be made of durable lectrolite material, should be antistatic, should be secured with self adhesive straps

4 System Configuration Accessories, spares and consumables

SI	Description
4.1	Anti static Hygienic Mattress (80mm) with pull straps – qty 1.
4.2	Collapsible Side Rails – qty 1 pair.
4.3	I.V. Rod – qty 2.
4.4	Cylinder Holder for 'B' Type Oxygen Cylinder – qty 1.

5 Environmental factors

SI	Description
	None

6 Power Supply

SI	Description
	None

7 Standards, Safety and Training

SI	Description
7.1	Product should be FDA/CE/ISI approved
7.2	Manufacturer should be ISO certified for quality standards.
7.3	Should have local service facility .The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
7.4	Comprehensive warranty for 5 years and provision of AMC for next 5 years.

8 Documentation

SI	Description
----	-------------

- 8.1 User Manual in English
- 8.2 Maintenance Manual in English
- 8.3 Certificate of Calibration and inspection from the factory
- 8.4 List of important spares and accessories with their part number and costing.
- 8.5 Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.
- 8.6 List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
- 8.7 Must submit user list and performance report within last 5 years from major hospitals.

06. Specification Ambu Bag-

Product Quality Standards:

- Should be CE (Notified body) approved product.
- Manufacturer should be ISO certified for quality standards.

Technical Specification:

Size: Adult and Paediatric -Volume of bag up to 1500ml.(Adult) 500ml. (Child) 240ml. made of silicon-oxygen reservoir system with non- breathing valve with pressure limiting device 2600ml(Adult), 600ml(Child), 250ml(Infant) single patient valve with swivel connector.

07. Specification – Weighing Machines Adult Weighing Scale

Specification

- Sturdy digital platform weighing machine for adult and children.
- Zero adjustment facility should be there.
- Sensitivity: 100 g
- Range of weighing: 0-150kg
- The manufacturer shall have the valid manufacturing license and should have model approval by the legal metrological Deptt. and the weighing scale must be stamped by the by legal metrological Deptt. In case of distributor, the bidder should have valid distributor and repair license from legal metrological Deptt, Govt. of UP.

ISO 9001 certified manufacturer (certificate to be submitted).

08. Specification- Computer with Printer

Computer- Processor-Intel CORE i7 with Windows 8 Operating System, 4 GB RAM and 1 TB HDD with Network card.

Printer- Laser Printer with scanner (three in one) - should print at least 25 pages per minute.
Suitable- UPS must be provided

09. Specification- Water Treatment Plant

Equipment Specifications for Water Treatment System for Hemodialysis

1 Description of Function

SI	Description
----	-------------

1.1 Water Treatment system is required to produce pure water for dialysis

2 Operational Requirements

SI	Description
----	-------------

2.1 The system should be sufficient for online operation of 10 machines with pure water capacity of 1000 litres per hour.

3 Technical Specifications

SI	Description
----	-------------

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 1500-1800 litres/hour.

3.3 R.O. Unit should be compact in sleek cabinet, housing membrane, and 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 10 machines in loop so that the unused water may be fed back to R.O. Unit, thus saving on water rejection.
- 3.7 The system should have programmable disinfection /de-calcification facility using commonly available disinfection / decalcification chemicals.
- 3.8 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.
- 3.9 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 water distribution loop, booster pump and storage water tank should be made up of stainless steel/ Food Grade PVC. Storage water tank should have capacity of at least 5000 litres with water level controller, outlet valves and easy cleaning provisions.

4 System Configuration Accessories, spares and consumables

SI	Description
4.1	System as specified
4.2	The vendor 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 vendor should inspect the site for this purpose.
4.3	The vendor should supply adequate filter cartridges, media or resins to last for at least 5 years. The vendor should visit the site and check the water quality.

5 Environmental factors

SI	Description
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0 -50 deg C and relative humidity of 15-90%
5.2	The hospital will provide vacant space, water outlets and electrical points as specified by the vendor. Other plumbing works and civil works will have to be undertaken by the bidder. Vendor should ensure that there is no environmental damage of any kind takes place.
5.3	The unit shall be capable of operating continuously in ambient temperature of 10 -40

deg C and relative humidity of 15-90%

6 Power Supply

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

7 Standards, Safety and Training

SI	Description
7.1	Should be FDA , CE, BIS approved product
7.2	Output water quality should match AAMI(Association for the Advancement of Medical Instrumentation) standards for Haemodialysis Water(Al < 0.01 mg/L; Ca < 2 mg/L; BACTERIA< 200 CFU/ml)
7.3	The vendor should provide preventive maintenance which includes chemical checks, bacterial and pyrogen checks periodically during the warranty period.
7.4	Comprehensive warranty for 5 years and provision of AMC for next 5 years.
7.5	Should have local service facility .The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

8 Documentation

SI	Description
8.1	User/Technical/Maintenance manuals to be supplied in English.
8.2	Certificate of calibration and inspection.
8.3	List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
8.4	List of important spares and accessories with their part number and costing.
8.5	Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.

10. Specification- Bins

Speciation's as per waste management codes

11. Specification- Minor Surgical Tools with Electrical Instrument Sterilizer.

Complete set should include the following:

- Dressing Scissors 6, sharp/blunt, curved
- Iris Scissors 4.5, straight
- Mayo Scissors 5.5, straight
- Littauer Stitch Scissors 5.5,
- Gillies Dissecting Forceps 1:2 teeth 6,
- Dissecting Forceps 5, block end
- Halstead Mosquito Artery Forceps 5, straight
- Mayo Hegar Needle Holder 6, with TC inserts and gold plated handles
- Gillies Skin Hook
- Kilner Cat Paw Retractor
- McDonald Dissector
- Volkman Scoop, medium
- No.3 scalpel handle suitable for blades #10 - #15
- Probe
- Fine grain leather instrument case

Made up of Medical Instrument Grade Stainless Steel. Manufactures name engraved and CE Certified. The metal should be lightweight surgical alloy, non-standing, corrosion free, non-rusting and should be able to withstand the temperature of autoclaving. It should be not light reflecting (surface should not be shiny) with a buff coating. It should not be brittle.

12. Specification- Digital Multimeter

CE Marked. - Four Digits Display.

13. Specification- UPS- AND Generator

ISI Marked as suitable and approved models on DGS&D Rate Contracts

14. Specification of Dressing Set

Each set should contain Two SS Bowl of Approx.300 ml, Cut Sheet-02, Mosquito Artery Forceps 6"- 02

11 Annexure- II: Essential Monitoring Criteria- for Audits and routine monitoring.

Parameters	Essential Criteria
Reuse of Hollow Fibers	Maximum 10 Times OR till 80% Bundle Volume
Effective Session Time	Minimum 4 Hours
Monitoring by Nurses	Entire Dialysis Session
Standard Norms	Viral Screening, Segregation
Isolation	1 Bed for isolated patients
Display of Schedule	Mandatory at the Central Nursing Station.
Monthly report	Mandatory submission duly signed by Hospital Superintendent and SP-Nephrologist with Invoice.
Patient satisfaction report card	Mandatory submission signed by Patient.
STG	As per MoHFW (GOI) Guidelines
ISO 9001:2008 Accreditation	Provisional to be made within 12 months and final within 18-24 Months
Contract Validity	5 Years subject to ISO accreditation within 24 months and for another 3 years subject to maintaining ISO accreditation.
Equipment	Certified by OEM to be New equipment at the time of installation.
Reuse of Single use Tubing	Not permitted.

12 Annexure-III- Daily Checks-Report will be required during Audit.

Parameter	Remarks- In case of NO please specify the deficiency
1. Dialysis M/C and Dialyzer Reprocessors functional.	YES/NO- S/N of Machines to be recorded
2. Water quality as per AAMI	YES/NO-Record the deficiency
3. Availability of Doctor and Monitoring by Nephrologist as specified.	YES/NO- Record deficiency
4. Availability of Nursing staffs(3:1)	YES/NO- Record deficiency
5. Availability of Technicians.(3:1)	YES/NO-Record deficiency
6. Reuse of Dialyzer.(Max 5 times or till 75% of fibre volume)	YES/NO-Record deficiency
7. Dialysis procedure time> 4 hrs	YES/NO- Record deficiency
8. Availability of BMET-	YES/NO- Record deficiency
9. Availability of Power back up.	YES/NO- Record deficiency
10. Cleanliness in Dry Storage area	YES/NO-Record deficiency
11. Cleanliness in wet storage area.	YES/NO-Record deficiency
12. Accessibility of waiting chairs	YES/NO-Record deficiency

Comments and recommendations of the representative of the Nodal Officer-

Signature of representative of SP

Signature of representative of Hospital

Signature of Medical Superintendent

13 Annexure-IV: Weekly Monitoring Sheet

Parameter	Complied/Not complied	Score Complied=10 Not complied=0	Remarks
1.No dialysis machine and dialyzer down for more than 48 hours	YES/ NO		Record S/N of MACHINES
2. No legs of Bed/Chair broken and all mattresses in working condition.	YES/ NO		Record deviation
3. Power Back up availability	YES/ NO		Record deviation
4. Patient clinical record maintenance of pre and post	YES/ NO		Record deviation
5. Treatment as per STG and monitoring by Nephrologist for each patient personally at least a month.(to maintain records)	YES/ NO		Record deviation
6. Dialysis process timings more than 4 hours.	YES/ NO		Record deviation
7. Display of Schedule at Nursing Station.	YES/ NO		Record deviation
8. Rectification of Daily Checks deficiencies as per daily checks.	YES/ NO		Record deviation
TOTAL SCORE- Out of 80			

Recommendations and comments of representative of Medical Superintendent-

Signature of representative of SP

Signature of representative of Medical Superintendent

14 Annexure – V: Patient Feedback Review Sheet

Name of the Patient		Age		Sex	M/F
Name of the Hospital		Patient ID			

1. During the visit to the centre within how much time you were attended by the staff?				
Within 30 Min.	30 Min. – 1 Hour	1 Hour – 2 Hours	More than 2 Hours	
4	3	2	0	
2. If you have reported for any problem regarding Dialysis services, how many times you reported to rectify your problem or in which instance your problem has been solved?				

First Time	Second Time	Third Time	More than Three Times	
4	3	2	0	
3. How well the Doctor explained the procedure and progress?				
Very Good	Well	Fair	Poor	Can't Say
4	3	2	0	-

4. Do you or your relatives/attendants satisfy with the Dialysis services?				
Completely Satisfied	Moderately Satisfied	Partial Satisfied	Not at all Satisfied	Can't Say
4	3	2	0	
5. How satisfied are you with the cleanliness and behaviour of the staff				
Very Good	Well	Fair	Poor	Can't Say
4	3	2	0	
Date			Signature	
Patient/Patient's Attendant or Relative				

Signature (Designated Hospital Staff)

15 ANNEXURE – VI : WEIGHTED AVERAGE SCORE CALCULATION:

(To be calculated at the end of every month and submitted along with Invoice duly signed by

Payment terms:

HDU-SP will be entitled for 90% payment within 30 days on submission of bills directly to the Authority (Director General, Medical & Health Service, U.P) based on MIS reports on number of procedures accompanied by the Invoice without approval of MS/CMS/Director of the associated Hospital. For Balance 10% payment, the HDU-SP will submit bills to MS/CMS/Director of the associated authority and payment will be provided as per Performance Linked payment after due approval of the Hospital Authority within 45 days of submission of bills. On reconciliation, if it is found that extra payment has been made (during the first payment i.e. 90 %) than the same will be recovered and adjusted in the current months billing cycle.

Formula for Payment disbursement to HDU-SP:

- Basis - 80% Weightage for Weekly Average Scores=WAS and
- 20% weightage for all the patients feedback average Score=FBS in the month.
- Total Average Score= WAS+ FBS

Payment slabs:

Weighted Average Score slabs	% Payment to be disbursed
80-100	100%
60-79	80%
40-59	50%
0-39	No payment

Examples for providing understanding to the defined payment terms:

CASE 1:

- If, Average Score of Weekly Review= 60 [Score (Week1+Week2+Week3+Week4)/ 4]
- If, Average Score of Patient Review = 15 [Score (Patient1+Patient 2+.....+Patient9)/9]
- Therefore, Total weighted average= 60+15= 75 (out of Max. Weighted Average Score of 100)
- **Payment Disbursement:**
 - Initially 90% payment will be released by the Authority based on linkages in MIS to the patient records.
 - Since after reconciliation by the Hospital Authority, it is found that only 80 % payment needs to be released (basis on the payment slabs defined); there would be no further payment to HDU-SP as 90 % has been paid and also there will be a recovery of .10% which has been paid in excess from next month's billing cycle.

CASE 2:

- If, Average Score of Weekly Review= 40 [Score (Week1+Week2+Week3+Week4)/ 4]
- If, Average Score of Patient Review = 10 [Score (Patient1+Patient 2+.....+Patient9)/9]
- Therefore, Total weighted average= 40+10= 50 (out of Max. Weighted Average Score of 100)
- **Payment Disbursement:**
 - Initially 90% payment will be released by the Authority based on linkages in MIS to the patient records.
 - Since after reconciliation by the Hospital Authority, it is found that only 50 % payment needs to be released (basis on the payment slabs defined); there would be no further payment and a recovery of 40 % will be adjusted in the next payment cycles.

16 Annexure-VII- Quarterly Internal Audit Sheet

Parameters	Score: Complied=2, Partially Complied=1 Not Complied=0	Remarks and records
1. Whether all the Essential Equipment has been Calibrated, Maintained and are working.		List the equipment not working
2. Whether the Water Quality is as per AAMI Std.		Record the measured Water Quality.
3. Whether the Patients Schedule is Displayed.		
4. Is the procedure timing recorded for each patient?		Record the deviations if the timing is below 4 hours.
5. Are the Waste Disposals being done as per the Act?		
6. Is the Dialyzer disposed off after maximum 5 uses or with less than 75% fiber volume and is this recorded.		
7. Is the Dialyzer reused on the same patient and is the patient informed about this before the start of procedure.		
8. Has the process of ISO Certification started?		If YES provide the name of agency assisting in the Certification. Has the Quality Manual prepared.
9. Is the Dialysis Help line working.		
10. Whether key Manpower are all available.		Name the manpower with their details and signatures

Comments and recommendations of Auditors and advice to rectify the deficiencies if any.

Member-1

Member-2

Member-3

Representative of SP

Representative of Hospital

17 ANNEXURE-VIII- Third Party Audit Sheet- Six Monthly

Parameters	Score: Complied=2, Partially Complied=1 Not Complied=0	Remarks and records
1. Whether all the Essential Equipment has been Calibrated, Maintained and are working.		List the equipment not working
2. Whether the Water Quality is as per AAMI Std.		Record the measured Water Quality.
3. Whether the Patients Schedule is Displayed.		
4. Is the procedure timing recorded for each patient?		Record the deviations if the timing is below 4 hours.
5. Are the Waste Disposals being done as per the Act?		
6. Is the Dialyzer disposed off after maximum 5 uses and is this recorded.		
7. Is the Dialyzer reused on the same patient and is the patient informed about this before the start of procedure.		
8. Has the process of ISO Certification started?		If YES provide the name of agency assisting in the Certification. Has the Quality Manual prepared.
9. Is the Dialysis Help line working.		
10. Whether key Manpower are all available.		Name the manpower with their details and signatures
11. Whether recommendations of the internal committee have been complied with		

Comments and recommendations of Auditors and advice to rectify the deficiencies if any.

Member-1

Member-2

Member-3

Representative of SP

Representative of Independent Auditors

18 Schedule-G: Financial Bid Schedules

FINANCIAL BID

1. To be submitted under sealed cover and will be opened only for Technically Qualified Bidders. For unqualified bidders this cover will be RETURNED unopened.
2. To be filled CLUSTER WISE separately specifying the CLUSTER No....
3. Discount for a Cluster will remain identical for all procedures.
4. Base Rate will be common for all the CLUSTERS and only the Discount may vary for different clusters. However within the CLUSTER discount will be uniform.

Evaluation will be done CLUSTER WISE.

Bid with highest Discount % for the CLUSTER will be the L-1 Bidder.

Price ACTIVITY SCHEDULE-**For CLUSIER No.....**

Procedure	CGHS- Delhi Rates Non NABH	Discount offered- Percentage
1. Dialysis- Seronegative Cases	INR 1400	
2. Dialysis –Seropositive Cases	INR 1650	
		-----%

Declaration: We agree to deliver above mentioned services in accordance with the General Conditions of Contract and Description of Services given in the Bidding Document for the base prices discounted by% PER PROCEDURE inclusive of all CONSUMABLES required for the procedures mentioned as above up to the period specified in the Bidding Document

Place:**Name:****Date:****Business Address:****Signature of Bidder/Service Provider with SEAL**

19 Schedule- A :Description of the Services

The Hemodialysis Units are required to be set up in 18 District Hospitals in four clusters of hospitals as identified below:

s/n	Cluster	Hospitals where the HDU will be located
	Cluster-1	
01	Meerut Division	GHAZIABAD
02	Saharanpur Division	MUZZAFARNAGAR
03	Moradabad	BIJNAUR
04	Bareilly	BADAUN
05	Agra	MATHURA
	Cluster-2	
06	Kanpur Division	FARRUKHABAD
07	Chitrakoot Division	HAMIRPUR
08	Jhansi Division	JALAUN
09	Aligarh Division	ETAH
	Cluster-3	
10	Lucknow Division.	SITAPUR
11	Devipatan Division.	BAHRAICH
12	Faizabad Division.	SULTANPUR
13	Basti Division	SIDDHARTHANAGAR
14	Gorakhpur Division	KUSHINAGAR
	Cluster-4	
15	Varanasi Division	JAUNPUR
16	Mirzapur Division	SONEBHADRA
17	Allahabad	PRATAPGARH
18	Azamgarh	BALLIA

The Service Provider will undertake the following jobs:

- a.** Supply of the required equipment as per the required specifications as defined in this Schedule- Annexure-1 with certificate from the manufacturer that all equipment provided are brand new and not refurbished.
- b.** Commission the equipment and operationalize the facility after ensuring that the same fulfil the guidelines laid down by the MoHFW/DoMH and securing the approval thereof specified in this Schedule- Annexure-I
- c.** Recruit Certified and trained human resources and upgrade them by continuous training as required to run the dialysis services as specified in the human resource specification in Annexure-1
- d.** Ensure that the equipment is maintained properly and such equipment is insured, adequately and regularly calibrated as per requirements of the manufacturer. Calibration Certificates to be maintained.
- e.** Ensure that the dialysis services are as per the standards and regulations laid down by the MoHFW / Government of Uttar Pradesh. Service Provider shall ensure best quality of tests and protocols and shall submit a half yearly report of clinical audit done by a third party or as nominated by the authority. Service provider to provide the Kt/v and standardised Kt/V report for each patient to the committee.
- f.** Ensure compliance with all the inspection requests by the Steering Committee /Monitoring Committee as constituted by Government of Uttar Pradesh or any agents of the same thereof. Ensure proper monitoring of the services and submit periodic management reports as per the requirement of the Authority by integrating with the MIS provided by the authority.
- g.** Indemnify the Government against any losses, claims or damages arising out of operation of dialysis equipment at the centre(s) operated by the private partner and also any statutory violations committed by the Service Provider at the centre.
- h.** Ensure the process of integration of the dialysis services/ centres with identified hospitals, owned and operated by Government of Uttar Pradesh.
- i.** Overall maintenance of Dialysis centre.
- j.** Install the requisite numbers of machines for dialysis centres as mentioned in the table of IFB and BDS. Allocate one machine per centre for infected cases.
- k.** Must provide -Dialysis Helpline services at the dialysis centres and make necessary set up available for the facility. and should also provide SMS based appointment system for all patients enrolled for services.
- l.** Must use a new Blood Tubing (Marked-Single Use) for every dialysis and discard/dispose the Blood Tubing after every dialysis. However reuse of tubings not marked single use can be reused as per procedures in MoHFW Guidelines and ISN recommendations.
- m.** The service provider shall provide for storage of soft copy and hard copy of all records at the District/Sub-district Hospital at its own cost. In case of change of service

provider for any reason, the stored data must be transferred to the new provider for continuation of storage. The Authority will have exclusive rights on the reports database.

- n.** Maintenance of Hygiene of the patient- It will be the responsibility of the HDU-SP to ensure the Hygiene of the patient like provision of Gown and hand/body scrubbing etc. before the start of Dialysis procedure.

20 Schedule—B :Schedule of Payment

(As described in Clause 1.7 Article-7- Consideration for Payment to HDU-SP in Part-II-Draft Agreement)

Refer the following:

Clause 1.7 Article-7- Consideration for Payment to HDU-SP in Part-II-Draft Agreement)

Annexure-VI-(Weighted Average Scoring and Payment Calculations) of Part-III

Annexure-III (Daily Checks) of Part-III

Annexure-IV-(Weekly Review) of Part-III

Annexure-V-(Patient Review) of Part-III

HDU-SP will be entitled for 90% payment within 30 days on submission of bills directly to the Authority (Director General, Medical & Health Service, U.P) based on MIS reports on number of procedures accompanied by the Invoice without approval of MS/CMS/Director of the associated Hospital. HDU SP will submit the bills on 7th day of every month. MS/CMS/Director has to forward the verified bills along with Daily and Weekly monitoring reports to the Authority within next 7 days. For Balance 10%payment, the HDU-SP will submit bills along with Daily and Weekly monitoring reports to MS/CMS/Director on every 7th day of a month, to the associated authority and payment will be provided as per Performance Linked payment after due approval of the Hospital Authority within 45 days of submission of bills. The performance criteria to be added are "adequacy of dose monitored (as per MoHFW Guidelines), rate of bacterimia monitored and control of Blood Pressure monitored "(as per Mohfw Guidelines.)" and the same will all be reviewed in Quarterly Internal Audit Sheet issued annexure VII of RFP-cum RFQ-part -III

21 Schedule- C : Key Personnel and Subcontractors-HDU-SP-Staff

The following key Personnel will be provided by the Service Provider. Please attach the CV of the Personnel along with Qualification and Relevant Experience matching with the requirements of Manpower Specifications as detailed in Annexure-1, Activity Schedule

SL	Key Personnel	Minimum Qualification	Experience
1	Nephrologist- 01 (per cluster)	MD/DNB in Nephrology MD with special Training in Nephrology.	2 Years
2	Contract Manager- (1 per cluster)	M.B.B.S/PGDHA/MHA	5 Years in Management of Healthcare facility out of which 3 Years designated as Manager.
3	Dialysis Doctors- 01 per shift.	M.B.B.S Degree	1 Year.
4	Dialysis Technicians-03 per shift	12 TH Passed Plus Certificate Course in Dialysis Techniques from any Govt. recognized/HSSC/NCVT	1 Year.
5	Biomedical Engineering Technicians- 01 on call	Diploma/Certification in Electronics/Biomedical Engineering/Medical Device Maintenance	1 Year
6	Dialysis Nurses- 03 per shift.	GNM and Registered with local nursing council.	6 Months in a Dialysis unit.
7	Medical social worker	Degree in sociology	2 years as Medial Social Worker
8	Sweepers	NA	NA

NOTES on Submission of documents against Key Manpower:

- i. Above manpower is provisioned per Haemodialysis Unit.
- ii. Submission of relevant CV for Contract Manager and Nephrologist is mandatory.
- iii. These positions will not be replaced without prior approval of the authorities.
- iv. For the other positions where all the relevant CVs are not available please attach an undertaking indicating the number of staff as specified are going to be employed. For example Dialysis Nurses required to be employed are 03 per shift and if the shifts required are 3 then the committed numbers to be employed will be 09 per centre and an undertaking to provide 09 Nursing Staff per centre should be submitted.
- v. All the manpower will be Trained and Certified by Govt. or Govt. empanelled/ authorised body

22 Schedule- D : Services & Facilities Provided by the Authority

DoMH, Government of Uttar Pradesh

- a) Provide required built-up area of 2000Sq.ft. with sound foundation and all four built up walls for the dialysis center/ facility in the hospital premises of the identified hospitals free of cost.
- b) Provide parking space for stationing transportation vehicles, other vehicles.
- c) Assist in provisions of basic utilities at dialysis centres like
 - i. Uninterrupted continuous supply of water till the facility input point. However the Service Provider will have to install and maintain water treatment plants, water purifiers etc. as per prescribed standards. They will have to make payments to Water Supply Department if required.
 - ii. The Service Provider will be made available the space for setting up the Haemodialysis unit, and water at the input of the Space . The Service Provider will provide all the internal connections for electricity as well as Water –Treated as well as Non Treated. The HDU-SP will have to bear all the cost for Electricity connection as well as consumption.
- d) The Authority will provide MIS incorporating all the requirements of monitoring and evaluations formats which will be web enabled and HDU-SP will have to provide linkages and fill up online the patient records etc. and will conduct regular monitoring and evaluation of the dialysis services based on quantifiable indicators and reports received for the services as per Annexure II to VIII in part-III. Assist in getting Statutory Clearances towards renovation of the space for the development of dialysis centre. The authority will only assist by way of documentations and the Service Provider has to do all the liaisoning towards getting the clearances.
- e) Monitor whether the construction of the centre is violating any statutory provisions.
- f) The Authority will ensure that the decision to refer a patient for dialysis in District/ hospital should originate from a qualified nephrologist in a Government hospital. In all cases, the diagnostic tests (Urea, Creatinine, Sodium, 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. A minimum of 4 Dialysis machines plus one dedicated machine for infective cases (Hepatitis B, Hepatitis C, HIV etc)
- g) Annual review of performance and observance of terms & conditions shall be carried out by a committee which shall include CMO & Head of department of Nephrology of the Govt. Teaching hospital along with other members nominated by the authority. The report of this

annual review shall form the basis for extension of the contract annually within the contract period.-

23 Schedule-E- Dialysis Schedule

The following Schedules will be applicable for Dialysis Procedures:

1. The Dialysis Centre will conduct the procedures 24x7x365 i.e. round the clock throughout the year.
2. The Patient will have to be told in advance about the days of his Dialysis Procedures Schedules.
3. Every Monday the WEEKLY SCHEDULE FOR THE PATIENTS WILL BE DISPLAYED FOR THE WEEK on the website provided by GoUP which will be declared later and in the Central Nursing Station.
4. The Patient will not be made to WAIT for more than THREE HOURS.
5. The Centre will work in three shifts a day.
6. Each Dialysis Machine will work for 6 Days a week and one day will be for compulsory maintenance.
7. No Dialysis Machine will remain dysfunctional for more than 48 HOURS.
8. Minimum Dialysis Procedure (Except for Vascular Access) will be FOUR HOURS.
9. Patient Record will have to be maintained for the procedures.
10. The Single Use Patient Tubing will not be REUSED.
11. The DIALYZERS will not be used more than FIVE Times.
12. The DIALYZERS will be REUSED on the same patient and the Patient will be informed and SHOWN the Patients Name on the DILYZER before being used for the Procedure.
13. The patients from distant areas – (more than 40 Km.) will be accommodated during day times.
14. Minimum three dialysis per machine per day will be done.

24 **Schedule-F- Liquidated Damages.**

The Service Provider shall pay liquidated damages to the Authority at the rate per day as below stated for each day that the Completion Date is later than the Intended **Completion** Date.

The Liquidated Damages rate is 0.05% per day of the contract.

The total amount of liquidated damages shall not exceed the amount as stated below. The Authority may deduct liquidated damages from payments due to the Service Provider. Payment of liquidated damages shall not affect the Service Provider's liabilities.

The maximum amounts of Liquidated Damages will 10% of the contract value. These rates will also be applicable for imposing penalties as specified in Part-II

24. Schedule- H- Addendum

The following addendum will be part of the RFQ Cum RFP:

1. Corrigendum to the documents is attached as Annexure- IX.