Quality & Accreditation Institute
Centre for Accreditation of Health & Social Care

Accreditation Standards for Dialysis Centres

Final Draft
April 2018

I Introduction

Chronic Kidney Disease (CKD) is a worldwide public health problem, both in view of the number of patients and cost of treatment involved. Globally, CKD is the 12th largest cause of death and the 17th cause of disability. This may be an underestimate as patients with CKD are more likely to die of cardiovascular disease than to reach end-stage renal disease. Approximately 30% of patients with diabetes mellitus have diabetic nephropathy and with the growing number of diabetic patients and aging population there is likely a parallel increase in CKD incidence. With increasing prevalence of CKD, the need for renal replacement therapy will also increase. Renal replacement therapy can be achieved through different types of dialysis and kidney transplant. Choice of kidney transplant is limited due to its complexity, cost and availability of donor. Therefore, dialysis remains the choice to consider to support treatment.

Dialysis is a type of renal replacement therapy which is used to provide an artificial replacement for lost kidney functions. There are two main forms of dialysis, hemodialysis and peritoneal dialysis, both of which are life support treatments; but dialysis does not treat kidney diseases. Dialysis may be used for patients who have recently lost kidney functions (acute renal failure) or for patients who have permanently lost kidney functions (chronic or end-stage renal failure).

A dialysis center is a clinical establishment that provides the treatment of patients with renal failure. Sometimes patients with normal renal functions also require hemodialysis like patients with some poisoning. Treatment procedures require professional supervision by experienced staff. The dialysis center may serve both inpatients and outpatients, depending upon the type of medical facility whether it is hospital based or stand alone. It may also provide self-dialysis training and care for peritoneal dialysis in addition to hemodialysis.

In order to ensure quality and safe care, it is important to standardise the structures and processes of dialysis centres. One of the best tool for standardisation is accreditation. It was therefore felt to develop accreditation standards to launch accreditation program for dialysis centres. In line with principles for developing standards, development process began with constituting a Technical Committee comprise of experts in this field representing a wider range of such services. A literature review of such specific accreditation standards available elsewhere was done and a framework was prepared. These standards were developed using the international principles for accreditation standards of International Society for Quality in Health Care (ISQua). These are based on the philosophy of RUMBA (Relevant, Understandable, Measurable, Beneficial and Achievable). Standards are being subjected to a wide consultation process by inviting comments from stakeholders by hosting on our website and also disseminating the information through emails to various dialysis centres. Standards will also be pilot tested.
These Standard are specifically intended for dialysis centres which may be stand-alone or hospital based. The scope of services of these dialysis centres may include:

1. Chronic Haemodialysis
2. Acute Haemodialysis
3. Peritoneal Dialysis
4. Haemofiltration and other similar modalities for adult and paediatric patients

These standards are comprise of 10 chapters, 94 standards and 399 criteria. Criterion is the measurable

element of the standard. We are hopeful that dialysis centres as well as their patients and payers would find these useful and we seek your feedback on continuous basis to improve them as part of our regular review and revision process which will generally takes place every three to four years.

A guidance document to these standard to provide interpretation may be published in time to come.
On behalf of the Board of QAI's Centre for Accreditation of Health & Social Care (CAHSC), I would like to thank all stakeholders involved for their time, commitment and continued support.

Dr. B.K. Rana
Founding CEO, QAI

II Table of Contents

Dialysis Centre Accreditation Standards Framework

Sl. No.	Name of Chapter	No. of Standards	No. of Criteria
1	Governance and Leadership (GAL)	7	21
2	Human Resource Management (HRM)	9	31
3	Facility and Risk Management (FRM)	15	84
4	Information Management System (IMS)	8	33
5	Continual Quality Improvement (CQI)	7	26
6	Patient Assessment and Care (PAC)	14	53
7	Patient Rights and Education (PRE)	8	38
8	Medication Management and Safety (MMS)	10	47
9	Dialysis Care and Safety (DCS)	8	33
10	Hygiene and Infection Control (HIC)	8	33
	Total	**94**	**399**

Chapter 1
Governance and Leadership (GAL)

Introduction

Each centre requires a governance structure that is ultimately responsible for the quality and safety of services provided. This responsibility is derived from its legal identity and operational authority for all activities undertaken by the centre within the ambit of applicable laws and regulations. Each centre, regardless of its complexity, also has a formal structure. Leaders ensure that a system exists that promotes safety and quality, provision of services that meet the needs of patient, availability of adequate resources e.g human, financial & physical and, monitoring and evaluation of improvement activities.

STANDARDS AND CRITERIA		
Standard	**GAL.1:**	**The governing body is committed to, and actively engaged in, quality and safety.**
Criterion	**a.**	The governing body documents its vision, mission and values.
	b.	Expectations of management and senior leaders to create and maintain a culture of safety and quality is documented.
Standard	**GAL.2:**	**The governing body is accountable for the quality and safety of care delivered.**
Criterion	**a.**	Governing body ensures effective internal structures and resources are in place to support quality and safety.
	b.	Governing body makes an appropriate staff responsible to ensure that a culture of quality and safety exists.
	c.	Governing body ensures that there is a quality and safety plan in place.
Standard	**GAL.3:**	**The governing body receives reports on the quality and safety of care delivered.**
Criterion	**a.**	Report on all processes or system failures
	b.	Report on number and type of critical incidents
	c.	Report on quality and safety related performance indicators
	d.	Report on results from peer review activities like internal/external assessment/audits.
Standard	**GAL.4:**	**Accountability and responsibility of key leadership functions are assigned.**
Criterion	**a.**	There is a documented and dated organogram.
	b.	Responsibility for the clinical oversight of services is assigned and supported by the management.
	c.	Management is aware of applicable laws and regulations and committed to abide by these.
Standard	**GAL.5:**	**The centre plans services to meet the needs of the patient population it serves.**
Criterion	**a.**	The centre provides services that are in alignment with its mission and vision.
	b.	The centre regularly reviews the needs of its patients.
	c.	The centre develops an annual operating budget to run its services.
Standard	**GAL.6:**	**The centre delivers services and makes decisions in accordance with its values and ethical principles.**
Criterion	**a.**	The values of the centre are defined.
	b.	The values of the centre are communicated to staff.

	c.	The centre promotes an environment that fosters and requires ethical and legal behaviour.
Standard	**GAL.7:**	**Medical responsibilities are defined and supervised by qualified and experienced personnel.**
Criterion	**a.**	There is a specialized Medical Director/Head that conducts and supervises the services and assumes their responsibility. He is assisted by a deputy possessing same credentials to take responsibilities in absence of the Medical Director/Head.
	b.	The Director /Head and deputy are responsible for the medical care activities. Together, they cover at least eight hours a day of activity.
	c.	There are other doctors specialized in Nephrology, who supervise the patients.

Chapter 2
Human Resource Management (HRM)

Introduction

Human Resources include all the people that work in, for or with the centre and they are integral to ensuring the delivery of quality, patient-centred and safe care. The centre must be able to assure the public or patients that it can meet their needs and deliver quality and safe care through a team of dedicated and qualified staff. The support includes the management team providing a safe physical environment for staff to work in, which is free from harassment or accidents.

STANDARDS AND CRITERA		
Standard	**HRM.1:**	**The centre has a documented process for human resource planning.**
Criterion	**a.**	The centre have suitably qualified and trained adequate manpower to provide the defined scope of services.
	b.	The centre determines the skills, qualifications or knowledge that is required for the centre to achieve its service objectives.
	c.	Expectations of management and senior leaders to create and maintain a culture of safety and quality is documented.
	d.	The centre has a documented job description for all its staff.
	e.	The centre apply due diligence to ensure that potential staff is free from any criminal background
Standard	**HRM.2:**	**The centre has a documented recruitment process.**
Criterion	**a.**	The recruitment process of the centre ensures the recruitment of people with required competencies, skills or knowledge to deliver safe and quality care.
	b.	There is a process for evaluation/ re-evaluation after recruitment/ probation of new employees
	c.	Every staff has a job description and is kept current according to the centre's policy.
	d.	There is a documented procedure for orientation of staff at the time of induction.
	e.	Induction includes providing information about centre, its policies, employee rights and responsibilities and patient's right and responsibilities.
Standard	**HRM.3:**	**The centre has a documented performance evaluation process.**
Criterion	**a.**	The centre has a standardized documented process for evaluating the performance of its staff.
	b.	Performance evaluation is done on the pre-determined criteria and frequency.
Standard	**HRM.4:**	**The centre has a continuous professional development program for its staff.**
Criterion	**a.**	There is a documented professional development policy for staff.
	b.	Staff is provided required training as and when required.
	c.	Staff is trained on safety related to occupation and surrounding environment.
	d.	Staff is trained on respecting patient's preferences and choices, informing about their options for care and treatment, and obtaining informed consent.
	e.	Evaluation of effectiveness of training and feedback mechanism for improvement is done by the centre.

Standard	**HRM.5:**	**A documented disciplinary and grievance handling system exists in the centre.**
Criterion	**a.**	Disciplinary and grievance handling policies and procedures are documented.
	b.	These policies and procedures also address requirements of applicable laws.
	c.	Such policies and procedures are made available to each staff.
Standard	**HRM.6:**	**A documented policy exists to address health needs of staff.**
Criterion	**a.**	The staff is subjected to a pre-employment medical examination.
	b.	The staff engaged in direct patient care is subjected to at-least annual health check-ups and results are recorded.
	c.	Health issues including occupational health hazards of staff are addressed as per documented policy.
Standard	**HRM.7 :**	**The centre has a documented system of credentialing and privileging of medical and nursing staff.**
Criterion	**a.**	The centre identifies the medical and nursing professionals those are permitted by law to provide respective care.
	b.	Such professionals are privileged to provide required care as per their credentials based on education, training and experience.
	c.	Centre verify the core credentials of medical staff appropriately when possible.
Standard	**HRM.8:**	**The centre has a documented system of maintaining personnel files for all staff members.**
Criterion	**a.**	Personnel file is a document that contains at least the qualifications, results of evaluation and appraisals, employment history, trainings attended and job description.
	b.	A personnel file is maintained and updated as necessary for each staff member.
Standard	**HRM.9:**	**The centre has adequate professional and technical staff.**
Criterion	**a.**	The centre shall have a body of professionals whose quality and quantity meet the care needs and which consists of: a. Medical doctors specialized in Nephrology, b. Nutritionists, c. Psychologists or psychiatrists, d. Social workers, e. Vascular surgeons, f. Biochemist/ Microbiologist for reference (medical laboratory)
	b.	The centre shall have at least one dialysis technician for every four patients.
	c.	The centre shall have at least one nurse for every six patients.

Chapter 3
Facility and Risk Management (FRM)

Introduction

The centre will prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Safe, high quality care and support is intrinsically linked to how resources are used including how they are planned, managed and delivered. Centres must assess the risks to people's health and safety during any care or treatment and make sure staff have the skills, experience and competence to keep patients safe. Premises and equipment must be safe and available in sufficient quantities. Good clinical and good laboratory practices are followed in all its operations. Centres must prevent the spread of infection.

STANDARDS AND CRITERIA		
Standard	**FRM.1:**	**Facility management is guided by applicable laws and regulations**
Criterion	**a.**	The centre shall be a legal entity.
	b.	The management of the centre is familiar with and abide by the local and national laws that governs the facility.
	c.	There is a process for planning, designing, development and maintenance of the infrastructure to ensure optimum quality and safety outcomes.
	d.	The updated drawings are available which dealt with site-layout, floor plans and emergency escape routes.
	e.	The management ensures the availability of adequate infrastructure to provide the defined scope of services.
Standard	**FRM.2:**	**There is a documented safety and security plan.**
Criterion	**a.**	The centre has a safety and security plan which is dependent on identified safety and security threats e.g. disasters both natural and manmade.
	b.	The plan provides and maintains safe and secure environment for patients, staff and visitors and process of identifying them in an emergency.
	c.	The centre has security personnel that can handle issues of security and know how and when to report security issues to the management.
	d.	The centre conducts inspection of the facility at least once in a year to identify security and safety threats and findings from inspection are acted upon.
	e.	There are signage both internally and externally available in the centre in a language understood by patient, family and community.
Standard	**FRM.3:**	**There is a documented plan and system for management of hazardous material.**
Criterion	**a.**	The centre has a list of identified hazardous materials and waste in the centre.
	b.	The handling and disposal of hazardous materials and waste are in accordance with the laws and regulations.
	c.	The centre maintains documentation including any permits, licenses, or other regulatory requirements.

	d.	Documented plan include methods of handling, storage and use of hazardous materials.
	e.	Plan include availability of material safety data sheet for all hazardous materials kept by the centre.
	f.	There is a procedure of reporting and investigating hazardous materials spills, exposure etc.
	g.	There is a procedure for disposal of hazardous materials.
	h.	Staff is trained on the proper use of protective equipment and procedures during use, spill or exposure to hazardous materials.
	i.	All hazardous materials are properly labelled.
	j.	Staff are educated on the plan.
Standard	**FRM.4 :**	**The centre has provision of potable water and electricity during working hours.**
Criterion	**a.**	The centre ensures availability of potable water and electricity during working hours.
	b.	The centre has alternative sources of water and electricity.
	c.	There is a potable water and electricity management program that includes inspection, maintenance and testing of the systems on regular basis.
	d.	The quality of water should be checked periodically.
Standard	**FRM.5:**	**There is a documented emergency response plan.**
Criterion	**a.**	The centre has a plan to manage fire and non-fire emergencies and resources are made available during such emergencies.
	b.	The effectiveness of the plan is tested at least once in a year.
	c.	The centre identifies the individual to oversee function of the plan.
	d.	Members of staff are educated on the fire safety plan.
Standard	**FRM.6:**	**There is a documented biomedical equipment management program.**
Criterion	**a.**	The centre ensures availability of required bio-medical equipment as per its services.
	b.	There is defined process of equipment procurement.
	c.	The centre maintained a list of all equipment required and usage logs are maintained.
	d.	There is a documented operational and maintenance (preventive/ breakdown) plan for all equipment.
	e.	Qualified staff operates, inspect and maintain equipment.
	f.	Equipment are periodically inspected and calibrated as applicable to ensure proper functioning.
	g.	There is a maintenance plan for proper heating, ventilation and air-conditioning.
Standard	**FRM.7:**	**The centre has a programme for medical gases, vacuum and compressed air.**
Criterion	**a.**	Documented procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases.
	b.	Medical gases are handled, stored, distributed and used in a safe manner.
	c.	Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.
	d.	The centre regularly tests these alternate sources.
	e.	There is a documented operational, inspection, testing and maintenance plan

		for, piped medical gas, compressed air and vacuum installation.
Standard	**FRM.8:**	**A documented risk management plan is implemented.**
Criterion	**a.**	There is a documented risk management plan.
	b.	There is a process for proactive identification, evaluation and management of immediate and potential risks to patients and staff.
	c.	The centre takes appropriate actions to eliminate or minimize these risks.
	d.	Patient safety incidents are identified, managed and responded to.
	e.	The centre encourages to report patient safety incidents to the management in a timely manner.
	f.	The centre has an induction and ongoing training for the staff on the identification, management and reporting of patient-safety incidents.
	g.	The centre prevents patients and staff from abuse.
Standard	**FRM.9:**	**The centre has adequate treatment rooms and equipment.**
Criterion	**a.**	Dialysis rooms are clean and well-lighted.
	b.	Dialysis rooms are having user friendly toilet.
	c.	The area of the room is suitable for its purposes.
	d.	All containers and bottles are properly labelled.
	e.	There is a provision of isolation room for seropositive patients.
	f.	There are facilities for the personnel's hand hygiene and to clean the patients' fistulae
	g.	The dialysis stations' chairs are suitable for their purpose and they are clean, well-preserved and in good operation conditions.
	h.	All treatment chairs are cushioned and with appropriate reclining.
	i.	There is a recovery room that can be easily accessed from the dialysis room.
	j.	The recovery room has at least the following equipment: - Laryngoscope, - Defibrillator, - Crash cart with resuscitation medication and equipment, - Central oxygen supply or oxygen tank, - Ventilation mask, - Nebulizer, - Necessary medications
	k.	Dialysis room has the necessary equipment to measure and monitor patients' vital signs.
	l.	The equipment preventive and corrective maintenance actions are carried out in timely manner and same is recorded.
Standard	**FRM.10:**	**The centre has adequate facilities for dialyzer reprocessing.**
	a.	The construction and the equipment of the dialyzer reprocessing room ensure safety conditions and are easy to clean.
	b.	Floor, ceiling and walls of the dialyzer reprocessing room are made of a washable material resistant to chemical disinfectants and their fumes. The room has an air extractor to avoid the build-up of toxic fumes. Room conditions are good and there are no signs of deterioration of wall surface.
	c.	Treatment rooms and reprocessing rooms are close to one another. Access restrictions for patients and public to reprocessing rooms are clearly indicated. The

		transfer of the elements that have to be reprocessed is carried out according to a procedure that avoids the passage through public areas.
Criterion	**d.**	Automatic Reprocessing machines go through the following regular controls: − Disinfection and − Concentration of the disinfectant used so as to ensure its antiseptic efficacy, as well as an eventual toxicity due to overdose
	e.	The manual reprocessing follows the right technical conditions. The sinks must be deep enough to avoid splashing and allow for a quick drainage of disposable fluids
Standard	**FRM.11:**	**There is a documented procedure for reprocessing of dialyzers.**
Criterion	**a.**	The procedure includes the concentrations of the disinfectants to be used
	b.	The procedure defines the steps for the preparation of the dilutions
	c.	The procedure defines the quality of water to be used
	d.	The procedure takes into account the biosafety aspects for the personnel
	e.	The procedure includes necessary documentation and records to be maintained
	f.	The procedure includes determination of presence and absence of disinfectant in the dialyzers
	g.	The procedure includes conditions for disposal of the dialyzer
	h.	The procedure includes how to measure and record the initial volume of each dialyzers before using it
Standard	**FRM.12:**	**There is a documented procedure for storage of reprocessed dialyzers.**
Criterion	**a.**	Reprocessed dialyzers are properly stored as per documented procedure.
	b.	The procedure includes identification of reprocessed dialyzers.
	c.	The procedure includes identification and record of the correct capillary.
	d.	The procedure includes materials used for packaging of reprocessed dialyzers.
	e.	The procedure includes storage conditions and their transfer from the reprocessing room.
Standard	**FRM.13:**	**The reprocessing of the dialyzers of seropositive patients is performed under biosafety conditions.**
Criterion	**a.**	The reprocessing inlets used for dialyzers from seropositive patients are located in an area that is physically separated from the rest and they are clearly identified.
	b.	The dialyzers are identified with indelible ink and they are stored in secure individual containers.
	c.	Disposal of such dialyzers is done as per standard precautions.
Standard	**FRM.14:**	**There is a documented process for maintenance of Reverse Osmosis (RO) plant.**
	a.	A documented procedure ensures maintenance of RO plant used for dialysis water.
	b.	The water shall be tested for endotoxin levels every month.
Standard	**FRM.15:**	**Diagnostic laboratory services are available as needed.**
	a.	The centre provides diagnostic laboratory services (in-house or outsourced).
	b.	A documented quality assurance program is implemented.

Chapter 4
Information Management System (IMS)

Introduction

An effective information management system is based on the information needs of the centre. The system should be able to capture, transmit, store, analyse, utilise and retrieve information as and when required for improving clinical outcomes as well as individual and overall performance of the centre. Information can be in any form- paper or electronic or a mix of both.

STANDARDS AND CRITERIA		
Standard	**IMS.1:**	**Documented policy and procedure exist to meet the information needs of the centre.**
Criterion	**a.**	Documented policies and procedures to meet the information needs exist.
	b.	Information management is in accordance with the documented policy and procedure.
	c.	The information needs of the centre are identified and are appropriate to the scope of the services being provided by the centre.
	d.	The centre contributes to external databases in accordance with the law and regulations.
Standard	**IMS.2:**	**The centre implements a robust document control system.**
Criterion	**a.**	The centre has a documented policy and procedure for document control.
	b.	System covers documents generated both from internal and external sources.
Standard	**IMS.3:**	**The centre implements a robust system of controlling and managing data.**
Criterion	**a.**	Formats for data collection are standardized.
	b.	Necessary resources are available for collection and analysis of data.
	c.	Documented procedures are laid down for timely and accurate dissemination of data.
	d.	Documented procedures exist for storing and retrieving data.
Standard	**IMS.4:**	**The centre defines what constitutes a medical record.**
Criterion	**a.**	The medical record contains information regarding reasons for admission, diagnosis and care plan.
	b.	The medical record contains the results of tests carried out and the care provided.
	c.	Procedures performed are incorporated in the medical record.
	d.	When patient is transferred to another centre, the medical record contains the date of transfer, the reason for the transfer and the name of the receiving centre.
	e.	The medical record contains a copy of the discharge note/ summary duly signed by appropriate and qualified personnel.
Standard	**IMS.5:**	**The centre maintains complete and accurate medical record for every patient.**
Criterion	**a.**	Every medical record has a unique identifier.
	b.	Policy identifies those authorized to make entries in medical record.
	c.	Entry in the medical record is named, signed, dated and timed.

	d.	The author of the entry can be identified.
	e.	The contents of medical record are identified and documented.
	f.	The centre has a documented policy for usage of abbreviations and develops a list based on accepted practices.
	g.	The record provides a complete, up-to-date and chronological account of patient care.
	h.	Provision is made for availability of the patient's record to care providers to ensure continuity of care.
Standard	**IMS.6:**	**The centre has documented policy and procedure in place for maintaining confidentiality, integrity and security of records, data and information.**
Criterion	**a.**	Documented policy and procedure exist for maintaining confidentiality, security and integrity of records, data and information.
	b.	The policy and procedure is in accordance with the applicable laws.
	c.	The centre ensures safeguarding of data & record against loss, destruction and tampering.
Standard	**IMS.7:**	**There is a documented policy and procedure exists regarding retention time of records, data and information.**
Criterion	**a.**	Documented policy and procedure are in place on retaining the patient's clinical records, data and information in accordance with the local and national laws and regulations.
	b.	Confidentiality and security of such records and information is ensured.
	c.	The destruction of medical records, data and information is in accordance with the laid-down policy.
Standard	**IMS.8:**	**The centre regularly conducts medical record audit.**
Criterion	**a.**	The medical record audit is periodically conducted.
	b.	The audit is conducted by trained individuals.
	c.	The audit covers timeliness, legibility and completeness of the medical records.
	d.	Appropriate corrective and preventive measures, against any deficiency observed, are undertaken within a defined period of time and are documented.

Chapter 5
Continual Quality Improvement (CQI)

Introduction

Quality Improvement recognises that the safety of the patient is paramount. A centre that is focused on quality improvement continually looks for ways to promote patient safety and quality of care. Quality and safety improvements in healthcare include a patient-safety improvement program that requires healthcare providers to proactively identify risk and to plan, implement and evaluate necessary changes to improve the quality and safety of services.
The centre ensures regular evaluation of these programs through performance indicators and benchmarks to identify both positive outcomes and areas for improvement. Any necessary actions to improve the quality and safety of the services are implemented and learning is disseminated both internally and externally.

STANDARDS AND CRITERIA		
Standard	**CQI.1:**	**The management plans and leads the quality improvement program in the centre.**
Criterion	**a.**	The leaders of the centre are accountable for service performance.
	b.	The leaders lead and plan the quality improvement and patient safety programme.
	c.	The Leaders and management are involved and allocate resources for improvement.
Standard	**CQI.2:**	**The leaders have oversight function of leading quality improvement activities of the centre.**
	a.	The leaders and management determine the areas for improvement.
	b.	Identified areas are measured and improvement activities are instituted.
Standard	**CQI.3:**	**There is a structured quality improvement program.**
Criterion	**a.**	The quality improvement program is developed, implemented and maintained.
	b.	The quality improvement program is documented which is comprehensive and covers all the major elements related to quality assurance.
	c.	There is a designated individual for coordinating and implementing the quality improvement program.
	d.	The designated program is communicated and coordinated amongst all the staff of the centre through appropriate training mechanism.
	e.	Regular audits are conducted to ensure continuous compliance of the program.
	f.	The program includes documented quality control activity.
Standard	**CQI.4:**	**The centre design clinical and managerial processes to promote quality improvement.**
Criterion	**a.**	The centre has a quality improvement team in place.
	b.	The centre identifies and monitors various processes by data collection to determine if there are areas for improvement.

	c.	The centre uses clinical guidelines, protocols or pathways for clinical processes.
Standard	**CQI.5:**	**The centre collects the data, analyse it and use for improvement.**
Criterion	**a.**	The centre collects data on identified indicators like percentage of patients transplanted, mortality after the first 90 days of treatment, seroconversion rates of patients and personnel in hepatitis B and C, patient & staff satisfaction and hand hygiene compliance.
	b.	The data is collected monthly.
	c.	Results are used to evaluate effectiveness of improvement activities.
	d.	The results of data are communicated to all concerned.
Standard	**CQI.6:**	**The centre implements a system for clinical audit.**
Criterion	**a.**	The centre documents a policy and procedure to carry out clinical audit.
	b.	Medical and nursing staff participates in this audit.
	c.	The parameters to be audited are defined by the centre.
	d.	Patient and staff anonymity is maintained.
	e.	Management initiates action on the findings to make improvement.
	f.	All audits are documented.
Standard	**CQI.7:**	**The centre defines and analyse sentinel events.**
Criterion	**a.**	The centre defines sentinel events.
	b.	Sentinel events are appropriately analysed and corrective actions taken.

Chapter 6
Patient Assessment and Care (PAC)

Introduction

Patients are made aware of the services being offered through different modes. Processes are defined for various activities including registration, admission, referral and discharge. Patients once taken into the facility either as an out-patient or as in-patient are assessed and re-assessed as per policy for their clinical needs and treatment.

STANDARDS AND CRITERIA		
Standard	**PAC.1:**	**The centre defines and displays its services.**
Criterion	**a.**	The centre clearly defined the services being provided and is as per the needs of the community.
	b.	Services being provided are displayed for easy access of the user.
	c.	The centre display its operational hours.
Standard	**PAC.2:**	**The centre has a documented registration and admission process.**
Criterion	**a.**	The centre has documented policy and procedure for registration of out- patients and admission of patients.
	b.	The procedure includes out-patient, admission and emergency patients.
	c.	A unique number is generated to identify the patient throughout the centre.
	d.	The procedure includes identifying patients with urgent needs and who require immediate attention and these patients are attended to or treated immediately.
	e.	Patients are accepted only if the centre can provide the services.
	f.	Documented policy and procedure exists to address situation of non-availability of dialysis chair.
Standard	**PAC.3:**	**The centre has adequate mechanism for transfer or referral of patients.**
Criterion	**a.**	The centre has documented procedure that guide the transfer or referral of patients based on their health status and need.
	b.	The procedure of referral to transplant or for other reasons is standardized and is known by the professionals, both care and administrative aspects. The resulting information is recorded in the medical record.
Standard	**PAC.4:**	**Initial assessment is conducted of all patients being cared for in the centre.**
Criterion	**a.**	All patients undergo an initial assessment based on their needs, age and condition.
	b.	The centre defines the contents of the assessment including screening for nutritional needs.
	c.	Emergency patients are urgently assessed based on their needs and condition.
	d.	Only qualified individuals are identified by the centre shall be responsible for assessment of patients.

	e.	The centre defines the time frame for completing the assessment.
	f.	The initial assessment includes nursing assessment done at the time of admission and recorded.
	g.	The initial assessment is documented within one hour or earlier as per policy.
	h.	A care plan is prepared based on the initial assessment and signed by the treating clinician.
Standard	**PAC.5:**	**Patients admitted by the centre undergo a regular reassessment.**
Criterion	**a.**	Patients are reassessed at appropriate interval based on their clinical status.
	b.	Reassessment determines the course of care for continuation, change in care plan or discharge.
	c.	Staff involved in direct patient care document the findings of reassessment.
Standard	**PAC.6:**	**The centre ensures uniform and continuity of patient care.**
Criterion	**a.**	Documented procedure guides the uniform care to patients and care is provided according to appropriate laws and regulations.
	b.	The care plan for every patient is individualized and is dependent on their needs at assessment and reassessment.
	c.	The care plan & delivery of care is modified depending on the changes in the patient's condition.
	d.	The centre has a documented procedure for managing patients with chronic illnesses and end of life issues and staff is trained on the same.
	e.	The centre provides support as required for spiritual, psychological and respite care that is required by patients.
Standard	**PAC.7:**	**Care rendered to patients is evidence based and documented to ensure uniformity.**
Criterion	**a.**	Current clinical guidelines, protocols, pathways and care bundles are available for the care of patients.
	b.	These guidelines are used to guide healthcare providers in making appropriate clinical decisions.
Standard	**PAC.8:**	**There is a process to deal with patients requiring urgent care.**
Criterion	**a.**	Documented policy guides the management of patients brought in for urgent care.
	b.	Documented procedure guides the management of patients brought in for urgent care.
	c.	Staff are trained to handle such patients.
Standard	**PAC.9:**	**The centre has a provision of ambulance service.**
Criterion	**a.**	The centre has appropriate access (owned or outsourced) for ambulance, if required.
	b.	Ambulance is appropriately equipped and meets statutory requirements.
Standard	**PAC.10:**	**The centre has resuscitation services for cardio-pulmonary arrest.**
Criterion	**a.**	Resuscitation services are available to the patient.
	b.	The centre identifies those individuals that are qualified to be responsible for resuscitation activities and are educated on resuscitation techniques.
Standard	**PAC.11:**	**The centre defines policy and procedure for nursing care.**
Criterion	**a.**	The centre has a documented policy which defines minimum documentation by nurse.
	b.	Care provided by nurses is documented in the patient record and must contain vital signs and drug/medication chart.
	c.	All nurse entry must contain the name of the patient, hospital number, nurse that made the entry and date and time.

Standard	**PAC 12: The centre ensures proper treatment planning and monitoring.**	
Criterion	**a.**	The delivery of each session of dialysis is based on a planning initiated at the admission of the patient, kept during all the extension when he is attended and respected by all professionals within the healthcare team.
	b.	Treatment planning involves patients and/or their family.
	c.	The planning provides actions of preparation of the patient and their family in case the death is expected and/or pain management and eases the access to support groups and spiritual counsel.
	d.	Treatment plans are monitored by the medical team.
Standard	**PAC.13: A documented discharge process exists.**	
Criterion	**a.**	The centre plans the discharge process in consultation with the patient and/or family.
	b.	Documented policy and procedure exist for patients leaving against medical advice or on request.
	c.	A discharge summary is provided to all patients.
	d.	The turn-around time for discharge is defined and monitored for improvement.
	e.	The centre plans the discharge process in consultation with the patient and/or family.
Standard	**PAC.14: The centre defines the contents of discharge summary.**	
Criterion	**a.**	Discharge summary contains the patient's name, unique identification number, treating physician name, qualification and registration number, date of admission and date of discharge duly signed by the appropriate qualified medical professional.
	b.	Discharge summary contains the reasons for admission, significant findings and diagnosis and the patient's condition at the time of discharge.
	c.	Discharge summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.
	d.	Discharge summary contains follow-up advice, medication and other instructions in a manner understood to patient/ family.
	e.	Discharge summary incorporates instructions about when and how to obtain urgent care.

Chapter 7
Patient Rights and Education (PRE)

Introduction

Patient is in the centre of the care being provided in a dialysis centre. It is therefore important that patients' rights are documented and known to patients. It is also important to provide education to patients related to their care. Better patient satisfaction or outcome is achieved when patients are adequately informed about their care, their rights are respected and they are involved in the decision making process.

STANDARDS AND CRITERIA		
Standard	**PRE.1:**	**The centre protects rights of patients.**
Criterion	**a.**	Patient rights are documented and displayed.
	b.	Patient rights, beliefs and values are respected in a manner and language they understand.
	c.	Staff is aware of patient's right and protects these.
	d.	Violation of rights is recorded and reviewed for improvement.
Standard	**PRE.2:**	**The centre informs patients about their responsibilities while receiving care.**
Criterion	**a.**	Patient responsibilities are documented and displayed
	b.	Patients are informed about their responsibilities in a manner and language they understand
Standard	**PRE.3:**	**The centre identifies and documents the rights of patient supporting individual beliefs and values.**
Criterion	**a.**	Patient rights include privacy while receiving care.
	b.	Patient rights include dignity and respect while receiving care.
	c.	Patient rights include confidentiality of information.
	d.	Patient rights include personal safety and security.
	e.	Patient rights include informed consent.
	f.	Patient rights include refusal of treatment.
	g.	Patient rights include information on the expected cost of treatment.
	h.	Patient rights include access to his/her medical records.
	i.	Patient rights include right to complaint and how to voice a complaint.
	j.	Patient rights include information on his treatment and healthcare needs.
	k.	Patient rights include respecting any special preferences, spiritual and cultural needs.
	l.	Patient rights include to seek an additional opinion regarding clinical care.
Standard	**PRE.4:**	**The centre educate the patient and family to make informed decisions and their involvement in care planning.**
Criterion	**a.**	Patients and/or family are informed about the planned care and treatment.
	b.	Patients and/or family are explained about their medicines, nutrition, and use of

		medical equipment.
	c.	Patients and/or family are explained about their treatment or procedures.
	d.	Patients and/or family are explained about how to continue their care at home after discharge from the healthcare centre.
	e.	The patient and/or family members are explained about the possible complications.
	f.	The care plan respects and where possible incorporates patient and/or family concerns and requests.
	g.	The patient and/or family members are informed about the results of diagnostic tests and the diagnosis.
	h.	The education is written and communicated in a language that the patient and/or family understands.
Standard	**PRE.5:**	**The centre documents a procedure to obtain informed consent.**
Criterion	**a.**	Documented procedure incorporates the list of situations where informed consent is required and adheres to applicable statutory norms.
	b.	Informed consent includes information regarding the procedure, its risks, benefits, possible complication, alternatives and as to who will perform the procedure in a language that they can understand.
	c.	The procedure describes who can give consent when patient is incapable of independent decision making.
	d.	Informed consent is taken by the person performing the procedure.
Standard	**PRE.6:**	**The centre addresses ethical dilemma in a timely manner.**
Criterion	**a.**	The centre has a documented procedure to receive and address ethical dilemmas in a timely manner.
	b.	The procedure should include decisions not to treat, to withdraw, or discontinue treatment and where treatment is given against the wishes of the patient.
Standard	**PRE.7:**	**The centre has a documented complaint redressal system.**
Criterion	**a.**	A documented complaint redressal procedure exist.
	b.	The procedure includes how to receive, investigate and resolve complaints in a timely manner.
	c.	Patient and/or family is made aware of such procedure for making complaint.
	d.	The centre uses the results of investigation to make improvements.
Standard	**PRE.8:**	**The centre has a system for effective professional communication.**
Criterion	**a.**	The centre develops and implements a procedure of communication for the medical care team for medical instructions, dialysis sessions, treatments and other requirements).
	b.	There is a policy about effective communication during patient handovers.

Chapter 8
Medication Management and Safety (MMS)

Introduction

The purpose of Medication Management is to provide a frame work for safe and effective medication management system. Safe and effective medication management includes the processes for procurement, storage, prescribing, transcribing, preparing, dispensing and administration. All processes of Medication Management of the centre comply with rules and regulations of the law of the land.

STANDARDS AND CRITERIA		
Standard	**MMS.1: Documented policy and procedure exists for the management of medication.**	
Criterion	**a.**	There is a policy on medication management.
	b.	There is a procedure to ensure compliance of the policy.
	c.	A qualified individual has oversight function of medication management in the centre.
	d.	The medication management complies with the applicable laws and regulations.
Standard	**MMS.2: The centre develops a drug formulary based on the needs.**	
Criterion	**a.**	A list of drugs and medicines based on the need as per scope of its services is developed by collaborative process.
	b.	Such list is reviewed and updated, if required at least once in twelve months.
	a.	This formulary is available to users.
Standard	**MMS.3: There is a documented process for procurement of medications.**	
Criterion	**a.**	The centre defines process for procurement of medicines for the formulary.
	b.	The centre has documented procedure to deal with situations when required medicine is not available in the formulary.
	c.	A specific list of high risk medication is available.
Standard	**MMS.4: There is a documented policy and procedure for storage of medication.**	
Criterion	**a.**	There is a documented policy and procedure for storage of medication.
	b.	The centre ensures that medicines are stored according to manufacturer's recommendation.
	c.	A good inventory control system is implemented.
	d.	Look-alike and Sound-alike medications are identified and stored physically apart from each other.
	e.	Emergency medications are identified and available for use immediately in patient care areas.
	f.	The centre has a process for immediate restocking of emergency medications.
	g.	All stored medicines and reagents used in their preparation are labelled with contents, expiration dates and any applicable warning.
	h.	All expired or contaminated medicines are stored separately according to regulatory requirements to prevent inadvertent dispensing.

	i.	There is a policy on storage of concentrated electrolytes to prevent inadvertent administration.
	j.	The centre has a process for disposing of expired or contaminated medicines and same is documented.
Standard	**MMS.5: There is a documented policy and procedure for prescription of medication.**	
Criterion	**a.**	Medications are prescribed as per documented policy and procedure ensuring patient safety.
	b.	Only qualified healthcare providers according to licensure, training or certification can prescribe.
	c.	The centre determines what a complete medication order is but minimally contains patient identification, medication name, dose, route and frequency.
	d.	Medication orders are clear, legible, in capital letters, dated, timed, named and signed.
	e.	Documented policy and procedure to be followed for verbal order.
	f.	A prescription audit is conducted periodically to ensure implementation of prescription policy.
	g.	WHO Patient safety challenge –'Medication Without Harm' is suggested to implement.
Standard	**MMS.6: A documented policy and procedure exists for safe dispensing of medications.**	
Criterion	**a.**	Documented policy and procedure is implemented for dispensing of medications.
	b.	Preparation of injections, either intravenous or intramuscular, is done using aseptic technique.
	c.	The policy include a review process for medicine prescriptions before dispensing and it includes at-least right drug, right patient, right route, right dose and right frequency.
	d.	High risk medications are verified before dispensing.
Standard	**MMS.7: A documented policy and procedure exists for safe administration of medications.**	
Criterion	**a.**	Documented policy and procedure for administration exists and also include patient's self-administration of medications and own medications brought from outside the centre.
	b.	Medications administration is done only by those permitted by law.
	c.	Medication is verified from the order and physically inspected prior to administration.
	d.	Prior to administration, the personal responsible verify the patient, medication, dosage, route and timing.
	e.	Medication administration is recorded in the patient records.
Standard	**MMS.8: The centre has a system of reporting and analysing near misses, medication errors and adverse drug events.**	
Criterion	**a.**	Near miss, medication error and adverse drug event are defined.
	b.	Documented procedure exists to capture near miss, medication error and adverse drug event.
	c.	Data is collected and analysed for such incidents to make improvement.
Standard	**MMS.9: There is a documented policy and procedure for the use of narcotic drugs and psychotropic substances.**	
Criterion	**a.**	There is a documented policy for use of such substances in consonance with applicable regulations.
	b.	A documented procedure is implemented for the use of narcotic drugs and psychotropic substances.
	c.	Such drugs are stored in a secure manner.

	d.	A proper record is kept of the usage, administration and disposal of these drugs.
Standard	**MMS.10: A documented process is used for the management of medical supplies and consumables.**	
Criterion	**a.**	There is a defined process for acquisition of medical supplies and consumables.
	b.	Medical supplies and consumables are used in a safe manner.
	c.	Medical supplies and consumables are stored in a clean, safe and secure environment following the manufacturer's recommendation(s).
	d.	Sound inventory control practices guide storage of medical supplies and consumables.

Chapter 9
Dialysis Care and Safety (DCS)

Introduction

It is important that the dialysis centre has adequate facility and knowledge to carry out various procedures which are current and based on evidence as far as possible. Different policies and procedures are required to be in place to ensure that procedures being performed provide desired outcomes and care is safe. Dialysis procedures adhere to best practices.

STANDARDS AND CRITERIA		
Standard	**DCS.1: The centre ensures proper pre-dialysis care.**	
Criterion	**a.**	The vascular access is performed by a qualified and trained professional.
	b.	Vascular access procedure is documented and performed in an identified place.
	c.	The centre evaluates the possibility of an eventual renal transplantation for all the patients who go into replacement therapy, according to the current legal provisions and provide guidance and referral accordingly.
Standard	**DCS.2: The centre ensures proper dialysis care.**	
Criterion	**a.**	The centre has evidence-based dialysis care policies and procedures describing the sequence of activities and decisions including pre-connection, connection and disconnection, as well as the people responsible for each step.
	b.	Dialysis include, among others, the following activities: - Patient's identification - Procedures for the isolation of seropositive patients (HBV+/HCV+/HIV+) - Pre-connection - Connection - Monitoring - Disconnection - Hand hygiene and gloves changing by the personnel between treatments - Use of aseptic techniques when appropriate - Single use of injection devices and other consumables - Cleaning of chairs and equipment between treatments - Records - Recovery monitoring - Daily disinfection of dialysis equipment

	c.	Dialysis procedure also include: - Sequence of pre-connection checks - Installation and use of dialyzers - Connection - Monitoring of dialytic sessions - Disconnection - Medication preparation and administration - Records
Standard	**DCS.3:**	**The centre ensures proper post-dialysis care.**
Criterion	**a.**	The centre has documented procedure for post-dialysis care describing the activities carried out since the moment patient is disconnected from the dialysis equipment until he leave the centre.
	b.	Post-dialysis includes, among others, activities related to the control of patients' weight and vital signs.
	c.	The post-dialysis care activities are recorded in each patient's medical record.
Standard	**DCS.4:**	**The centre has documented policies and procedures for peritoneal dialysis.**
Criterion	**a.**	The centre has documented policy to provide peritoneal dialysis.
	b.	The centre follows a documented procedure to carry out peritoneal dialysis.
	c.	The centre is equipped with adequate resources.
	d.	There are documented policies and procedures to cover the following: - Patients' training activities - Preparation of medical records - Biosafety procedures (cleaning of equipment, waste and peritoneal fluid bags disposal, etc.) - Use of personal protective equipment - Material for patients' training
	e.	There are complete and updated medical records of each patient in peritoneal dialysis which should include following details: - Medical, psychological and social evaluation prior to the admission - Progress regularly updated - Results of routine tests - Evaluation of the type of peritoneal membrane - Record of adverse events, especially peritonitis and catheter-related infections - Vaccination and serology follow-up - Eventual hospitalizations records - Evidence of patient and relatives' training - Evidence of training on how to use a cycler machine (if applicable)
Standard	**DCS.5:**	**Documented policy and procedure exists for care of vulnerable patients.**
Criterion	**a.**	Policy and procedure are documented and are in compliance with prevailing laws, national and international guidelines.
	b.	The centre ensure safe and secure environment for such patients.
	c.	Informed consent is obtained from the patient's representative as per documented procedure.
	d.	Staff is appropriately trained to provide care to such patients.
Standard	**DCS.6:**	**Documented policy and procedure exists for any research activity.**
Criterion	**a.**	Documented policy and procedure address any research activity carried out in the

		centre in compliance with applicable regulatory, national and international guidelines.
	b.	Appropriate Ethics Committee oversee all research activity.
	c.	Patient's informed consent is taken before enrolling into research/ clinical trial.
Standard	**DCS.7:**	**The centre ensures patient safety.**
Criterion	**a.**	There is a process of patient's identification.
	b.	The needles, dialyzers and other perfusion elements are appropriate.
	c.	Documented procedure for avoiding catheter and tubing misconnections.
	d.	Records of the vital signs of the patient
	e.	Control of the patient´s weight before and after the session
Standard	**DCS.8:**	**There is a structured patient-safety program in the centre.**
Criterion	**a.**	A documented patient-safety program is implemented.
	b.	The patient-safety programme is comprehensive and covers all the major elements related to patient safety.
	c.	The scope of the program is defined to include adverse events ranging from "no harm" to "sentinel events".
	d.	There is a designated individual for coordinating and implementing the patient-safety program.
	e.	The patient-safety program is reviewed and updated at least once in a year.
	f.	The patient-safety program includes and implements national/ international patient safety goals/ solutions as far as practicable.

Chapter 10
Hygiene and Infection Control (HIC)

Introduction

Changing technology and disease profile continue to present new challenges for infection prevention and control within healthcare centres. Patients are at risk of developing healthcare associated infections because of decreased immunity among patients; the increasing variety of medical procedures and invasive techniques creating potential routes of infection; and the transmission of drug-resistant bacteria among crowded hospital populations, with poor infection control practices. Healthcare associated infections are among the most common complications affecting patients.

STANDARDS AND CRITERIA		
Standard	**HIC.1:**	**The centre has a comprehensive hygiene and infection control program.**
Criterion	**a.**	There is a hygiene and infection control program that covers clinical and non-clinical areas and is managed by a trained individual.
	b.	The infection control program includes infection control policies and procedures for clinical and non-clinical areas.
	c.	The infection control program include proper waste disposal including medical and non-medical waste.
	d.	The infection control program includes cleaning, disinfection and sterilization activities.
	e.	The infection control program includes prevention and control of healthcare associated infections (HAI).
	f.	The program includes hand hygiene program.
Standard	**HIC.2:**	**There is a documented process to ensure infection control in medication management.**
Criterion	**a.**	The pharmacy and other areas where medicines are kept are clean.
	b.	There is a procedure for cleaning of refrigerators where drugs are kept and a cleaning log is maintained.
	c.	The hospital's hand hygiene practices are followed when dispensing medications.
	d.	There is a procedure for cleaning of medication shelves, floors and other areas.
Standard	**HIC.3:**	**There is a documented process to ensure infection control in linen management.**
Criterion	**a.**	The centre has a procedure for handling dirty, soiled and clean linen.
	b.	Dirty or soiled linens are separated from clean linen.

	c.	Linen soiled with blood or body fluids are handled with appropriate personal protective equipment eg. gloves, face masks and aprons.
Standard	**HIC.4:**	**There is a documented process to ensure infection control in sterilization unit.**
Criterion	**a.**	The centre has identified an area for cleaning of instruments with traffic control in place to avoid cross-contamination.
	b.	There is a process for decontamination of dirty instruments immediately after use or before they are cleaned using appropriate disinfectants.
	c.	The area for wrapping and packaging of instruments is adequate, clean and safe.
	d.	The process of packaging of instruments and other items to be sterilized is performed properly and in accordance with the policy.
Standard	**HIC.5:**	**The centre has a documented policy on biomedical waste segregation and disposal in accordance with laws.**
Criterion	**a.**	A documented policy on handling biomedical waste exists.
	b.	Waste segregation is performed at the site of generation.
	c.	Appropriate personal protective equipment are available and used when handling waste.
	d.	The centre identifies a centralized area for collection of medical and non- medical wastes in accordance with laws.
	e.	The centralized area for waste collection is covered and free from rodents and flies.
	f.	There are puncture proof sharps boxes for disposing of needles, syringes and surgical blades.
	g.	There is a process of safe disposal of biomedical waste within the centre and to final waste disposal point.
Standard	**HIC.6:**	**The centre has system of use of Personal Protective Equipment (PPEs).**
Criterion	**a.**	The centre must make PPEs (e.g. gloves, protective eye wear, mask, apron, gown, boots/ shoe covers, cap/ hair cover) available at all times.
	b.	Staff must be regularly trained and educated on the appropriate use and disposal of PPEs
	c.	Support staff including medical aides, cleaners, and laundry staff must wear PPEs in situations where they may have contact with blood, body fluids, secretions and excretions.
	d.	PPEs should be worn by laboratory staff, who handle patient specimens.
Standard	**HIC.7:**	**The centre has a policy on hand hygiene.**
Criterion	**a.**	The centre implements a system of hand hygiene practices
	b.	Healthcare workers wash or decontaminate hands using a plain soap, antimicrobial agent, such as an alcoholic hand rub after dealing with blood/ body fluids/ secretions/ excretions/ contaminated items, and in between contacts with patients
Standard	**HIC.8:**	**The centre has a policy and procedure for general cleaning and disinfection.**
Criterion	**a.**	Clinical and non-clinical areas are kept clean.
	b.	There is a cleaning procedure for clinical areas e.g. operating theatre, laboratories.
	c.	There is a process to ensure proper preparation and use of disinfectant.