SURVEY ITEM & SELF-ASSESSMENT						
CHRONIC DIALYSIS TREATMENT STANDARDS						
	PREAMBLE *The Chronic Dialysis Treatment Standards are applicable to all haemodialysis facilities and services in public and private sectors as well as facilities and services run by not-for-profit organisations. These facilities and services are either hospital-based or 'free standing' and provide only chronic haemodialysis treatment.* *The purpose of these standards is to ensure safe medical practice, patient safety and quality service at the haemodialysis facilities and services.*					
TOPIC 13C.1: STANDARD 13C.1.1	ORGANISATION AND MANAGEMENT *The Haemodialysis Centre shall be organised to provide a high standard of ambulatory care to the community in a safe and caring manner with due regard for the needs and privacy of patients and confidentiality of their personal information. The Haemodialysis Centre shall be easily accessible and continuity of care assured.*					
CRITERION NO	CRITERIA FOR COMPLIANCE:		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS	
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING / RISK
13C.1.1.1 CORE	Vision, Mission and values statements of the Haemodialysis Centre are accessible. Goals and objectives that suit the scope of the Haemodialysis Centre are clearly documented and measurable that indicates safety, quality and patient centred care. These reflect the roles and aspirations of the service and the needs of the community. These statements are monitored, reviewed and revised as required accordingly and communicated to all staff.					
	EVIDENCE OF COMPLIANCE					
		1. Vision, Mission and values statements of the Haemodialysis Centre are available, endorsed and dated by the Governing Body/Person In Charge (PIC) of the Haemodialysis Centre.				
		2. Goals and objectives of the Haemodialysis Centre are available, endorsed and dated.				
		3. These statements are communicated to all staff (orientation programme, minutes of meeting, etc).				
		4. Achievement of goals and objectives are monitored, reviewed and revised accordingly.				
13C.1.1.2 CORE	There is an organisation chart which provides a clear representation of the structure, functions and reporting relationships between the Person In Charge (PIC) and staff of the Haemodialysis Centre. The organisation chart is accessible to all staff and clients.					

	EVIDENCE OF COMPLIANCE						
		1. Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC) and staff of the Haemodialysis Centre.					
		2. Organisation chart of the centre is endorsed, dated and accessible.					
SURVEY ITEM & SELF-ASSESSMENT							
STANDARD 13C.1.2	*The Haemodialysis Centre shall have a person responsible for all aspects of the Centre's operations. The Person In Charge can be the owner or appointed by the owner of the Haemodialysis Centre.* *The Person In Charge (PIC) shall adopt a governing framework that constitutes the internal legislation that is suitable for the particular needs and circumstances of the Centre.*						
CRITERION NO	CRITERIA FOR COMPLIANCE:			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS	
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING / RISK
13C.1.2.1 CORE	Governance of the Haemodialysis Centre The governance of a Haemodialysis Centre shall be the responsibility of the Person In Charge (PIC), who shall be: a) A Nephrologist or b) A Paediatric Nephrologist or c) An internal medicine specialist who had completed not less than 200 hours of recognised training in haemodialysis treatment and maintains an affiliation with a nephrologist or d) A registered medical practitioner other than those listed above who had completed not less than 200 hours of recognised training in haemodialysis treatment and maintains an affiliation with a nephrologist.						
	EVIDENCE OF COMPLIANCE						
		1. Letter of appointment of PIC if the PIC is not the owner.					
		2. Valid Annual Practising Certificate (APC) of the PIC.					
		3. Certificate of completion for 200 hours of recognised training in haemodialysis treatment. (If the PIC is not a nephrologist).					
		4. Letter of affiliation with nephrologist.(If the PIC is not a nephrologist)					
		5. Certificate of National Specialist Register (NSR). (only applicable for physician and nephrologist)					

13C.1.2.2 CORE	The Person In Charge shall adopt a governing framework in accordance with statutory and other legal requirements. 1. Ensuring proper functioning and maintenance of the facility and equipment 2. Ensuring that the centre complies to the norms and standards required 3. Ensuring that each patient has a nephrologist to assume all or part of the medical care of the patient 4. Visits the centre at least once a month 5. Ensuring that there are standing arrangement with other medical practitioners to provide immediate medical care, essential life-saving measures and implementing emergency procedures on any person requiring such treatment or services in the event that the PIC is not available 6. Ensuring the safety of patients and staff of the haemodialysis unit 7. Periodically review of policy and procedures 8. Performance assessment and improvement programme 9. Staff education and performance 10. Ensure patient education programme 11. If the PIC is not a nephrologist, the PIC should consult with the affiliated nephrologist on management of haemodialysis patients (To refer to roles and responsibilities of PIC)					
	EVIDENCE OF COMPLIANCE					
		1. Valid licence from Private Medical Practice Control Section (*Cawangan Kawalan Amalan Perubatan Swasta,* CKAPS).				
		2. List of roles and responsibilities of the PIC which include but not limited to the following: a) ensure haemodialysis patients are accessible to appropriate medical care, as and when needed;				
		b) ensure that the Centre has a nephrologist to assume all or part of the medical care of the patients. The centre shall have an affiliated nephrologist if the owner or PIC is not a nephrologist				
		i) Letter of appointment of affiliated nephrologist if the owner/PIC is not a nephrologist				
		ii). Valid Annual Practising Certificate (APC) of the affiliated nephrologist.				
		iii) Certificate of National Specialist Register (NSR).				

		iv) List of roles and responsibilities of the affiliated nephrologist which include but not limited to the following: • Advise on the facilities, equipment and staffing requirements of the centre • Advise on policies and standards for haemodialysis treatment in conformity with the requirements of the regulations and/or any nationally accepted guidelines • Plan clinical management of the dialysis patients • Prescribing haemodialysis treatments. All haemodialysis treatment shall be prescribed by a nephrologist. • Review each individual patient at least once in every three months. Such review shall be comprehensive and shall include but not limited to clinical examination, review of blood and other test results and medications • Recommend changes or modifications to treatment as deemed necessary from time to time in order to maintain the quality of care • Visits the centre at least once every 3 months.						
		c) involvement in development and periodic review of policies and procedures;						
		d) performance assessment and improvement programme;						
		e) staff education and performance;						
		f) ensure patient education programme is available;						
		g) ensure proper functioning and maintenance of all facilities and equipment.						
SURVEY ITEM &SELF-ASSESSMENT								
STANDARD 13C.1.3	ACCESS TO CARE *Patients with end-stage kidney disease shall have access to safe, efficient and effective haemodialysis treatment.*							
	CRITERIA FOR COMPLIANCE:					SURVEYOR FINDINGS		

CRITERION NO			SELF RATING	FACILITY COMMENTS	AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK
13C.1.3.1 CORE	<u>Acceptance of Patients into Haemodialysis Centre</u> Patients with end-stage kidney renal disease requiring chronic haemodialysis treatment are accepted for treatment based on the Centre's Mission and resources. The Centre has a process for accepting patients, informing them of the services available and costs of treatment. It has procedures in place to assist patients for any financial subsidies that they are entitled to.						
	EVIDENCE OF COMPLIANCE						
		1. The Centre has written policies and procedures on assessment and acceptance of patients.					
		2. The numbers of patients accepted do not exceed the capabilities of the Centre both from the facilities and staffing aspects.					
		3. Documented evidence of assisting relevant patients to obtain appropriate financial assistance. (This is not applicable for centres that do not provide financial assistance.)					
13C.1.3.2 CORE	<u>Access to regular dialysis treatments.</u> Centre has the responsibility to ensure that patients received the dialysis treatment as per nephrologist's prescription						
	EVIDENCE OF COMPLIANCE						
		1. Evidence that the centre has a mechanism to accommodate for patients' request to change their dialysis schedule for valid reasons, e.g., attending family emergencies, attending other medical appointments.					
13C.1.3.3	<u>Access to Other Medical Care</u> The Centre has access to a hospital or other consultants' services should the patients require other medical treatment: a) The Centre has arrangements with other healthcare providers, including ambulance services to provide urgent care for patients. b) Arrangement for other medical care including but not limited to dietetic and vascular access services.						
	EVIDENCE OF COMPLIANCE						

		1. Evidence that patients have been attended by registered medical practitioner timely in the case of emergency						
		2. Access to ambulance services, e.g. at least contact numbers of two (2) ambulance service providers.						
		3. Evidence of patient counselling on: a) haemodialysis treatment.						
		b) dietetic advice. (Documentation in the patient's clinical notes/referral letter) Additional : Missed Treatment, Fluid Restriction						
		c) medication adherence						
		d) infection control measure. This includes but not limited to: - • hand hygiene • CVC care • fistula care • respiratory care & cough etiquette						
		e) immunisation recommended for dialysis patients. This includes but not limited to: • Hepatitis B • Influenza • Pneumococcal • COVID-19						

SURVEY ITEM & SELF-ASSESSMENT	
TOPIC 13C.2: STANDARD 13C.2.1	HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT *The Centre shall have adequate number of qualified and trained staff as well as other supporting staff commensurate with the workload.*

CRITERION NO	CRITERIA FOR COMPLIANCE:	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK

13C.2.1.1	<u>Haemodialysis Centre Manager/Staff in-charge</u> There shall be a Haemodialysis Centre Manager/Staff in-charge with post basic qualification in renal nursing whose responsibility is to ensure the proper management of the Centre, compliance with regulatory requirements and patient safety and welfare. a) There is a qualified Haemodialysis Centre Manager/Staff in-charge with post basic qualification in renal nursing with at least two (2) years' experience in haemodialysis services. b) Roles and responsibilities of Haemodialysis Centre Manager/Staff in-charge are identified. EVIDENCE OF COMPLIANCE 1. Letter of appointment of the Haemodialysis Centre Manager/Staff in-charge. 2. Evidence of post basic qualification in renal nursing with at least two (2) years' experience in haemodialysis services. 3. Valid Annual Practicing Certificate (APC). 4. List of job description of Centre Manager/Staff in-charge is available.					
13C.2.1.2	<u>Staffing</u> The Centre shall ensure that it has sufficient staff with formal training to meet patient- care needs. a) Nursing staff assigned to a centre shall have at least six (6) months training in renal nursing and/or post basic qualification in renal nursing. b) The Centre shall maintain a personal information file for each employee documenting their qualifications, training, experience and continuing education activities. EVIDENCE OF COMPLIANCE 1. Evidence of six (6) months training in renal nursing and/or post basic qualification in renal nursing. 2. Evidence of privileging for nursing staffs who do not have post basic qualification in renal nursing. 3. Documentation of the responsibilities, duties and working hours of staff. 4. Evidence of staff to patient ratio as per regulatory requirements.					

		5. Evidence of staff trained in cardiopulmonary resuscitation (CPR). Roaster list for every shift with one (1) CPR trained staff					
		6. Personal file of staff is kept and made available. The file should include qualification, training, experience, and continuing medical education (CME) activities					
		7. Possession of valid Annual Practicing Certificates for Staff Nurses and Assistant Medical Officers.					
13C.2.1.3	Other support staff The Centre may employ other non-clinical staff whose roles and responsibilities are clearly defined. Other support staff are appointed and clearly assigned to support the service needs.						
	EVIDENCE OF COMPLIANCE						
		1. Letters of appointment are available.					
		2. List of job description is well defined and available.					
		3. Staff orientation and training records.					
		4. Staff personal file are kept.					
SURVEY ITEM & SELF-ASSESSMENT							
TOPIC 13C.3: STANDARD 13C.3.1	POLICIES AND PROCEDURES CARE OF HAEMODIALYSIS PATIENT *All patients in the Centre shall receive haemodialysis treatment according to current national and/or international evidence based guidelines.*						
CRITERION NO	CRITERIA FOR COMPLIANCE:		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK
13C.3.1.1	Clinical Care of Haemodialysis Patients All dialysis patients shall be regularly reviewed by a nephrologist at least three (3) monthly. The nephrologist review shall be comprehensive and includes assessment of dialysis related as well as non-dialysis related/other medical problems of the patients.						
	EVIDENCE OF COMPLIANCE						
		1. Policy on haemodialysis treatment					

		2. Evidence of nephrologist's review in the dialysis patient's medical notes. This review shall include: a) history and physical examination of any complaints relating to the general health of the patient;						
		b) any intradialytic complications;						
		c) dialysis clinical charts;						
		d) results of the recent investigations done;						
		e) status of vascular access;						
		f) fluid adherence, volume and blood pressure						
		g) complications of long term haemodialysis treatment including nutritional status;						
		h) review of current kidney transplant status.						
		3. Medications prescribed to the patient.						
		4. For non-dialysis patient, any other appropriate treatment based on the patient's general health/co-morbidity.						
13C.3.1.2	<u>Haemodialysis Prescription</u> All patients shall have a prescription for haemodialysis treatment which shall be reviewed at least three (3) monthly.							
	EVIDENCE OF COMPLIANCE							
		1. There is a prescription for haemodialysis treatment documented by a nephrologist.						
		2. Clinical charts of patients documenting each treatment shall be made available.						
		3. Dialysis prescription for each patient shall be made available. This prescription shall include dialysis treatment parameters such as: a) dry weight;						
		b) blood flow;						
		c) dialysate flow;						
		d) type and amount of anticoagulation;						
		e) dialysis duration						
		f) dialysis frequency						
		g) type of dialysers;						
		h) dialysate calcium						

		j) medications to be given on during dialysis (e.g. Erythropoietin, Intravenous Iron).						
		4. Patient's haemodialysis prescription reviews every three (3) monthly by the nephrologist or more frequently as appropriate.						
13C.3.1.3	<u>Haemodialysis Outcome</u> All patients shall have haemodialysis outcome indices monitored at least three (3) monthly.							
	EVIDENCE OF COMPLIANCE							
		1. Policy on monitoring of haemodialysis outcome						
		2. Investigations done at least every three (3) months shall include but not limited to the following: a) studies on anaemia;						
		b) nutritional status;						
		c) adequacy of dialysis;						
		d) mineral metabolism;						
		e) Virology studies. Virology studies shall be done at least six (6) monthly. The results of the investigations shall be documented and monitored. (Refer Appendix 1)						
		3. There is documented evidence on action taken based on the indices monitored.						
SURVEY ITEM & SELF-ASSESSMENT								
<u>STANDARD 13C.3.2</u>	<u>ETHICAL PRACTICE AND PATIENT & FAMILY RIGHTS</u> *The Centre shall establish ethical guidelines that promote appropriate, safe and efficacious haemodialysis treatment. It shall have policies supporting patients' rights as well informing them of their responsibilities.* *The Centre shall ensure that at all times the best interests of patients shall prevail when there is a conflict between the business interests of the Centre and the patients' welfare.*							
CRITERION NO	CRITERIA FOR COMPLIANCE:			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK

13C.3.2.1	<u>Confidentiality of Patient's Personal and Medical History</u> Information on the patient's personal and medical history shall be always kept confidential. The Centre shall abide by the Malaysian Medical Council's guidelines on confidentiality of patient's record. EVIDENCE OF COMPLIANCE 1. Written policy and procedures to protect the confidentiality of the patient's personal and medical information. 2. Evidence of patients' personal and medical information is kept in a secure manner and accessible only to designated staff.					
13C.3.2.2	<u>Informed Consent</u> There shall be an informed consent before patient is started on haemodialysis treatment. The informed consent document shall include the nature of treatment, short and long term potential complications, cost of care and access to other non-dialysis care. EVIDENCE OF COMPLIANCE 1. There are policies and procedures that clearly define the process for informed consent. 2. Documented informed consent form specific for haemodialysis is in place. 3. Information on haemodialysis treatment and other related matters are available.					
13C.3.2.3	<u>Patient Rights and Responsibilities</u> The Centre shall have a guide on the rights and responsibilities of the patient undergoing dialysis to ensure his/her well-being and a best possible outcome. This shall be communicated to the patient when he/she starts treatment at the Centre. EVIDENCE OF COMPLIANCE 1. Charter of patients' rights is made available to all patients. 2. Responsibilities of patients are clearly communicated to them. 3. The Centre shall provide services six (6) days a week including on public holidays.					

		4. Patients' rights and responsibilities are displayed prominently in the Haemodialysis Centre: a) There shall be adequate written information to the patient on the nature of treatment, level of care expected and the fees charged.					
		b) Patients have a right to change haemodialysis centre and PIC must facilitate the transfer to the best interest of the patients.					
		c) There shall be established a grievance mechanism and such mechanism be prominently displayed in the Centre.					
		d) Evidence that patients have been informed and agreed to their responsibilities as a patient in the Centre. This can be in the form of a patient information sheet which is formally acknowledged by the patient.					
13C.3.2.4	The Person In Charge (PIC) of a Centre shall ensure adequate monitoring of patients during dialysis and subsequent patient care.						
	EVIDENCE OF COMPLIANCE						
		1. Evidence of patient's review every three (3) months by nephrologist.					
		2. Evidence of patient's review as and when clinical needs arise.					
13C.3.2.5	In the case of closure of the Centre, the PIC shall ensure there is continuity of care of all patients including transfer of patients to another Haemodialysis Centre.						
	EVIDENCE OF COMPLIANCE						
		1. Standard operating policy and procedure on continuity of care of all patients including transfer of patients to another Haemodialysis Centre.					
SURVEY ITEM & SELF-ASSESSMENT							
STANDARD 13C.3.3	PREVENTION AND CONTROL OF INFECTION *The Centre shall have a policy as well as guidelines on prevention, monitoring and management of dialysis-related infection. Dialysis-related infection shall include but not limited to Blood Borne Viral Infections, Catheter Related Blood Stream Infections (CRBSI), fistula infection and other healthcare related infections.*						
	CRITERIA FOR COMPLIANCE:				SURVEYOR FINDINGS		

CRITERION NO			SELF RATING	FACILITY COMMENTS	AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK
13C.3.3.1	<u>Infection Control System and Processes</u> The Centre has a Standard Operating Procedures for infection control programme that includes but not limited to the following: a) infection control policies and procedures; b) infection control systems; c) handling of needle stick injury. d) multi-resistant organism e) tuberculosis						
	EVIDENCE OF COMPLIANCE						
	1.	Standard operating procedures on infection control					
	2.	Training of staff on infection control					
	3.	Regular meetings with staff on infection control					
	4.	Patient education on infection control					
	5.	Evidence of staff and patient immunisation					
	6.	Risk assessment audits Include but not limited to: • Hand hygiene • Catheter Exit site • Catheter hub • Catheter connection • Catheter disconnection • Fistula care • Medication preparation • Dialyzer reprocessing • Environmental cleaning & disinfection • PPE					
13C.3.3.2	<u>Pre-admission Screening</u> Screening of Blood Borne Viral Infections (Hepatitis B, C & HIV) shall be carried out before patient is admitted for treatment at Haemodialysis Centre.						
	EVIDENCE OF COMPLIANCE						
	1.	There shall be policies on screening of blood borne viral infections prior to admission.					

		2. Evidence of screening being performed for new and prevalent patients in patient's medical records.					
13C.3.3.3	<u>Monitoring of Infections</u> All patients in Haemodialysis Centre shall undergo regular scheduled monitoring for Blood Borne Viral Infections.						
	EVIDENCE OF COMPLIANCE						
		1. There shall be a policy on monitoring for Blood Borne Viral Infections for all patients in a Haemodialysis Centre.					
		2. Evidence of a plan of schedule monitoring. (Refer Appendix 1)					
13C.3.3.4A	There shall be procedures for handling patients with positive blood-borne viral infections.						
	EVIDENCE OF COMPLIANCE						
		1. Policy on management of infected patients					
		2. Where applicable, there is evidence of designated treatment areas or procedures for those who are positive for Hepatitis B virus (HBV), Hepatitis C virus (HCV) and HIV with corresponding segregation of reprocessing facilities and storage of reprocessed dialysers.					
13C.3.3.4B	There shall be procedures for handling patients with respiratory droplets or air-borne infections, e.g., COVID-19, MERS-CoV, Influenza, tuberculosis						
	EVIDENCE OF COMPLIANCE						
		1 Policy on management of infected patients					
		2 Evidence of staff training					
		3. Evidence of patient education					
		4. Evidence and tracker for vaccination					
		5. Audit on adherence to mask and physical distancing					
13C.3.3.5	<u>Screening for Visiting Patients and Centre's patients who have temporary dialysis elsewhere</u> Patients from other centres who request to dialyse at the Centre shall undergo screening for Blood Borne Viral Infections. The Centre's own patients who return from dialysis treatment at other centres shall undergo similar screening.						

	EVIDENCE OF COMPLIANCE					
	1. Policies and procedures are in place to ensure screening of patients who dialyse temporarily in the Centre.					
	2. Policies and procedures for screening of the Centre's patients who temporary dialyse outside the Centre. (Reference: National Haemodialysis Quality & Standards, 2018)					
	3. Evidence of result on screening tests of visiting patients.					
	4. Evidence of tests being performed for the Centre's patients who have returned to dialyse in the Centre after treatment elsewhere.					
	5. There shall be policy and procedures for patients with CVC care					
	a) Policy and procedures on CVC Care					
	b) CRBSI surveillance					
	c) Audit process on CVC care					
	6. The shall be policy and procedures on Fistula management					
	a) Policy and procedures on fistula care					
	b) Audit process on fistula care					
	c) Fistula surveillance Program					
13C.3.3.6	Designated Staff in Infection Control A designated staff who has training in prevention and control of infection shall oversee all prevention and control of infection measures in the Centre. The role & responsibilities include but not limited to: a) Conduct infection control surveillance b) Organise infection control training for staffs c) Organise patient education on infection control d) Conduct regular infection control meeting with PIC e) Propose & execute quality improvement measure f) Submit incident reporting to MOH for HBV, HCV & HIV seroconversion, and clusters of pyogenic infection					
	EVIDENCE OF COMPLIANCE					

		1. Designated nurse with post basic renal nursing oversee the prevention and control infection measures in the Centre.					
13C.3.3.7	<u>Documentation of Infections</u> There shall be complete documentation of infection complications within the Centre, which include Catheter Related Blood Stream Infections (CRBSI), fistula infection, and Blood Borne Viral and bacteria infections and COVID-19 infection. EVIDENCE OF COMPLIANCE						
		1. The Centre shall have documentation and reporting mechanism when infections occur.					
		2. Clinical and laboratory evidence of such infections.					
		3. There is evidence of actions being taken following such infection.					
13C.3.3.8	<u>Management of Infected Patients</u> There shall be policies and procedures on management of infected patients including drug treatment (where appropriate), isolation/segregation of treatment areas and use of designated equipment. EVIDENCE OF COMPLIANCE						
		1. Written guidelines/policies on handling of infected patients and referral of patients to other centres. (Refer Appendix 2)					
13C.3.3.9	<u>Management of Clinical waste</u> In Accordance to Guidelines on the handling & Management of Clinical waste in Malaysia by Department of Environment, Ministry of Natural Resources and Environment 3rd Edition 2009 Refrigerated storage areas/units for clinical wastes should be considered where wastes have to be stored in bulk up in a secured room (Applicable if Clinical waste not collected daily for disposal) EVIDENCE OF COMPLIANCE						
		1. A secured and Refrigerated storage areas/units for clinical wastes must be available where the temperature of the refrigerated storage areas/unit should be kept at 4°C to 6 °C.					

		2. Documented evidence of daily logging of room temperature where clinical waste is stored.						
		3. Documented evidence of clinical waste collections date and time must be available						
SURVEY ITEM & SELF-ASSESSMENT								
TOPIC 13C.4: STANDARD 13C.4.1	FACILITIES AND EQUIPMENT *The Centre complies with the requirements of the local authority, Private Healthcare Facilities and Services (PHFS) Act, Medical Devices Act, and any other relevant regulatory requirements.*							
CRITERION NO	CRITERIA FOR COMPLIANCE:			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK
13C.4.1.1	Structural Design of Haemodialysis Centre The Centre shall have adequate space for the different functions of haemodialysis treatment as provided for under the Regulations of the Private Healthcare Facilities and Services Act for haemodialysis treatment: There is adequate space and storage areas to allow staff to carry out their duties safely and efficiently according to standards set by the relevant authorities and regulatory requirements.							
	EVIDENCE OF COMPLIANCE							
		1. The approved floor plan should be available and displayed in the Centre.						
13C.4.1.2	Equipment Standards Major equipment used in haemodialysis treatment shall have certification from relevant regulatory authorities.							
	EVIDENCE OF COMPLIANCE							
		1. There is documented evidence that major equipment used in haemodialysis treatment complies with relevant standards set by national and international bodies, e.g. SIRIM Berhad (Standards and Industrial Research Institute of Malaysia), Medical Device Authority, etc.						
		2. The schematic diagram of water treatment system shall be available and displayed in the centre						

		3. A list of items in the resuscitation cart made available					
		4. Documented evidence that the items in the resuscitation cart re checked at regular intervals					
13C.4.1.3	<u>Water treatment system</u> Centre shall have a water treatment system that delivers water quality that meets the AAMI 2015/ISO 23500:2014 Standards						
	EVIDENCE OF COMPLIANCE						
		1. The schematic diagram of water treatment system shall be available and displayed in the centre					
13C.4.1.4	<u>Resuscitation equipment</u> Centre shall have a complete set of resuscitation equipment						
	EVIDENCE OF COMPLIANCE						
		1. A list of items in the resuscitation cart made available					
		2. Documented evidence that the items in the resuscitation cart re checked at regular intervals					
13C.4.1.5	<u>Maintenance of Equipment</u> The equipment in the Centre are maintained in good working order and subject to regular planned preventive maintenance (PPM) and calibration.						
	EVIDENCE OF COMPLIANCE						
		1. Policy on equipment maintenance					
		2. Contract for equipment maintenance.					
		3. There should be a log book on the maintenance and repairs of all major equipment.					
13C.4.1.6	Centre shall have policy and procedure on monitoring of water quality. a) Monitoring of equipment b) Water treatment system						
	EVIDENCE OF COMPLIANCE						
		Documented evidence of chemical disinfection performed. There is documented evidence of:					

		a) Daily logging (Refer Appendix 5)						
		b) Chlorine testing						
		c) Water hardness testing						
		d) Monthly endotoxin testing						
		e) 6-monthly chemical testing						
13C.4.1.7	Centre shall have policy and procedure on management of cold-chain medications a) Monitoring of equipment b) Pharmaceutical refrigerator							
	EVIDENCE OF COMPLIANCE							
		1 Documented evidence on temperature logging						
		2 Documented evidence of action taken should there be temperature excursion						
SURVEY ITEM & SELF-ASSESSMENT								
TOPIC 13C.5: STANDARD 13C.5.1	SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES *The Centre has a framework of quality objectives and the processes to achieve these objectives.* *The PIC of Centre shall ensure staff involvement in the continuous safety and performance improvement activities.*							
CRITERION NO	CRITERIA FOR COMPLIANCE:			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS & RISK ASSESSMENT	SURVEYOR RATING	RISK
13C.5.1.1	Plan for Performance Improvement Activities The PIC shall ensure that there is a clear plan to improve quality of care in the Centre.							
	EVIDENCE OF COMPLIANCE							
		1. Written plan on performance improvement activities.						
		2. The plan shall be reviewed and updated regularly.						

13C.5.1.2	<u>Training in Performance Improvement Activities</u> Staff are trained in performance improvement activities and undergo continuous education. The PIC assigns the responsibility for performance improvement activities to a designated staff.					
	EVIDENCE OF COMPLIANCE					
		1. Records of staff attending continuing education activities on performance improvement.				
		2. Letter of assignment of responsibilities for performance improvement activities.				
13C.5.1.3	<u>Documentation of Performance Improvement Activities</u> Appropriate documentations of safety and performance improvement activities are kept. There are data collection formats to monitor performance improvement activities.					
	EVIDENCE OF COMPLIANCE					
		1. Documentation of quality parameters to include:				
		a) Clinical outcome measures (Refer Appendix 3)				
		b) Water quality (Refer Appendix 4 & 5)				
		c) Risk Assessment Audit				
		d) Infection Control Audit				
		2. Records of incident reporting and mandatory incident reporting to Ministry of Health (MOH): a) Mandatory i. Viral Hepatitis and HIV seroconversion				
		ii. Intradialytic death in chronic stable dialysis patient.				
		b) Other incidents that require root cause analysis and corrective and preventive actions include but not limited to: i. Patient fall ii. Medication errors iii. Pyogenic reactions iv Catheter dislodgement v. Venous needle dislodgement vi. Need prick injuries				
		3. Certificate of compliance from National Renal Registry (NRR)				

13C.5.1.4	Disaster preparedness Centre shall have policy and procedure on disaster preparedness.					
	EVIDENCE OF COMPLIANCE					
	1. Documented on procedures during disaster.					
	2. Documented evidence of plan for patient transfer in the event of disaster.					
	3. Staff training on disaster preparedness.					
	4. Patient education disaster preparedness.					
	5. Patient's data should be regularly updated inclusive of latest blood parameter, medication lists and contact numbers.					
SERVICE SUMMARY						
SURVEYOR SUMMARY:						

OVERALL RATING:
OVERALL RISK:

Appendix 1

Minimum scheduled laboratory investigations for chronic haemodialysis patients:

Tests	Frequency
Full blood count	Every 3 monthly
Iron Study: Serum Iron Serum ferritin Total Iron Binding Capacity (TIBC) Iron saturation (Tsats)	Every 3 monthly
Blood Urea (pre & post dialysis)	Every 3 monthly
Renal Function Test	Every 3 monthly
Liver Function Test Alanine Transaminases Alkaline phosphatase Serum albumin	Every 3 monthly *Consider monthly transaminases for 3 months in patients who have been dialyzing* *elsewhere or patients who received blood transfusion.*
Calcium & phosphate	Every 3 monthly
Fasting iPTH	Every 3-6 monthly
Fasting Serum Lipid	Every 6 monthly
Blood sugar	Every 3 monthly (diabetics) Every 6 monthly (non-diabetics)
HbA1C (if diabetics)	Every 3-6 monthly
Virology Hep B s Ag Anti Hep B s antibody titer Anti HCV Anti HIV	 Every 3 monthly (annually if Hep B s Ag is positive) Every 6 monthly Every 3 monthly (if anti HCV negative) Every 3 monthly

Appendix 2

Infection Control Precautions for All Patients *(Adapted from CDC guidelines)*

- Proper hand washing technique.
- Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Ensure a supply of clean non-sterile gloves and a glove discard container near each dialysis station.
- Wash hands after gloves are removed and between patient contacts, as well as after touching blood, body fluids, secretions, excretions, and contaminated items.
- A sufficient number of sinks with warm water and soap shall be available to facilitate hand washing.
- If hands are not visibly soiled, use of a waterless antiseptic hand rub can be substituted for hand washing.
- Items taken to a patient's dialysis station, including those placed on top of dialysis machines, shall be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being returned to a common clean area or used for other patients.
- Unused medications or supplies (e.g., syringes, alcohol swabs) taken to the patient's station shall not be returned to a common clean area or used on other patients.
- Prepare medications in a room or area separated from the patient treatment area and designated only for medications.
- Do not handle or store contaminated (used supplies, used equipment, blood samples, or biohazard containers) in areas where medications and clean (unused) equipment and supplies are handled.
- Deliver medications separately to each patient. Common carts shall not be used within the patient treatment area to prepare or distribute medications.
- If trays are used to distribute medications, clean them before using for a different patient.
- Intravenous medication vials labelled for single use, including erythropoietin, shall not be punctured more than once. Once a needle has entered a vial labelled for single use, the sterility of the product can no longer be guaranteed.
- Residual medication from two or more vials shall not be pooled into a single vial.

- If a common supply cart is used to store clean supplies in the patient treatment area, this cart shall remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts shall not be moved between stations to distribute supplies.
- Staff members shall wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood).
- Staff members shall not eat, drink, or smoke in the dialysis treatment area or in the laboratory.
- Patients can be served meals or eat food brought from home at their dialysis station. The glasses, dishes, and other utensils shall be cleaned in the usual manner; no special care of these items is needed.
- Establish written protocols for cleaning and disinfecting surfaces and equipment in the dialysis unit, including careful mechanical cleaning before any disinfection process. If the manufacturer has provided instructions on sterilization or disinfection of the item, these instructions shall be followed. For each chemical sterilant and disinfectant, follow the manufacturer's instructions regarding use, including appropriate dilution and contact time.
- After each patient treatment, clean environmental surfaces at the dialysis station, including the dialysis bed or chair, countertops, and external surfaces of the dialysis machine, including containers associated with the prime waste. Use any soap, detergent, or detergent germicide.
- Between uses of medical equipment (e.g., scissors, hemostats, clamps, stethoscopes, blood pressure cuffs), clean and apply a hospital disinfectant (i.e., low-level disinfection); if the item is visibly contaminated with blood, use a tuberculocidal disinfectant (i.e., intermediate-level disinfection).
- For a blood spill, immediately clean the area with a cloth soaked with a tuberculocidal disinfectant or a 1:100 dilution of household bleach (300-600 mg/L free chlorine) (i.e., intermediate-level disinfection). The staff member doing the cleaning shall wear gloves, and the cloth shall be placed in a bucket or other leak proof container.
- Published methods shall be used to clean and disinfect the water treatment and distribution system and the internal circuits of the dialysis machine, as well as to reprocess dialyzers for reuse.
- These methods are designed to control bacterial contamination, but will also eliminate blood-borne viruses. For single-pass machines, perform rinsing and disinfection procedures at the beginning or end of the day.
- For batch re-circulation machines, drain, rinse, and disinfect after each use. Follow the same methods for cleaning and disinfection if a blood leak has occurred, regardless of the type of dialysis machine used.
- Routine bacteriologic assays of water and dialysis fluids shall be performed according to the recommendations. (Refer Appendix 4 & 5)

- Venous pressure transducer protectors shall be used to cover pressure monitors and shall be changed between patients, not reused. If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300--600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.

- Housekeeping staff members in the dialysis facility shall promptly remove soil and potentially infectious waste and maintain an environment that enhances patient care.

- All disposable items shall be placed in bags thick enough to prevent leakage. Wastes generated by the haemodialysis facility might be contaminated with blood and shall be considered infectious and handled accordingly.

Appendix 3

Clinical Outcome Measures and Quality Initiatives in Dialysis

1. Dialysis Adequacy (Kt/V)

- 95% of patients have prescribed Kt/V more than 1.3
- 85% of patients have delivered Kt/V more than 1.2

2. Urea Reduction Ratio (URR)

- ≥ 85% have URR more than 65%

3. Haemoglobin (Hb)

- For those patients in erythropoietin (EPO), ≥ 70% of patients should achieved Hb level 10-12 g/dl.

4. Transferrin Saturation (Tsats)

- ≥ 80% achieved Tsat＞20%

5. Annual mortality rate

- Annual mortality rate for dialysis patient taking of all factors should not be more than 15%.

6. Catheter related blood stream infection (CRBSI)

- Catheter related blood stream infection (CRBSI) should not be more frequent than 3:1000.

Appendix 4

Water Quality

1. Dialysis water shall be produced by the process of Reverse Osmosis (RO).

2. The minimum standards indicated below is based on the ISO 23500:2011.

3. Chemical Contaminants

3.1 Permissible levels of chemical contaminants shall be observed and adhered to. (*See Appendix 5)*

3.2 Method of Testing

· Chlorine and Chloramines and water hardness testing shall be performed on site using commercially available test kits.

· Full analysis for chemical contaminants shall be performed by an accredited laboratory.

3.3 Minimum Frequency of Testing

· Daily using commercially available test kits for chlorine and chloramines.
· Six (6) monthly testing in an accredited laboratory for chemical analysis.

3.4 Site of Testing

· Daily testing for Chlorine and Chloramines shall be done after each carbon column.
· Daily testing for hardness after softener column.
· Six (6)-monthly full laboratories testing for chemicals shall be done at raw water point, pre and post RO.

3.5 Action if limits exceeded

Evaluate water treatment system and rectify as necessary.

· All the results shall be properly documented and made available for inspection.

4. Microbial Contaminant

4.1 Method of Testing

- Total viable counts (Colony Forming Units) using spread plate or membrane filtration technique using Trypton Glucose Extract Agar (TGEA) or equivalent.

- Calibrated loop technique shall not be used.
- The presence of pyrogen/endotoxin shall be determined using Limulus Amoebocyte Lysate (LAL) method.

4.2 Frequency of Testing

- Monthly for bacterial count and endotoxin test.

4.3 Sites of Sampling

- Minimum sites of sampling for testing

i. Post RO membrane
ii. First point of the distribution loop
iii. End point of distribution loop (Last machine port)
iv. Reprocessing bay (for indirect feed)

4.4 Handling of water sample

- Assay within 30 minutes of collection
- If immediate assay is not possible, refrigerate immediately at 5°C and assay within24 hours of collection.

4.5 Limits and Action Level

Maximum Allowed

- CFU level <100 CFU/ml
- Endotoxin level <0.25EU/ml

Action Level

- CFU level >50 CFU/ml
- Endotoxin Level >0.125EU/ml

(Ref: AAMI/ISO 23500:2011)

If Action Levels are observed, disinfection and retesting shall be done immediately to restore the quality into acceptable level.

4.6 Laboratory

All samples shall be sent to an accredited laboratory recognized by the Director General of Health.

4.7 Record

All the results shall be properly documented and made available for inspection.

Appendix 5

Maximum allowable levels of toxic chemicals and dialysis fluid electrolytes in dialysis water

Contaminants with documented toxicity in haemodialysis	
Contaminant	Maximum Concentration (mg/l)
Aluminium	0.01
Total Chlorine	0.1
Copper	0.1
Fluoride	0.2
Lead	0.005
Nitrate (as N)	2
Sulfate	100
Zinc	0.1

Electrolytes normally included in dialysis fluid		
Electrolytes	Maximum Concentration	
	(mg/dl)	(mmol/l)
Calcium	2	0.05
Magnesium	4	0.15
Potassium	8	0.2
Sodium	70	3

Maximum allowable levels of trace elements in dialysis water	
Contaminants	Maximum Concentration (mg/l)
Antimony	0.006
Arsenic	0.005
Barium	0.1
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Mercury	0.0002
Selenium	0.09
Silver	0.005
Thallium	0.002

From ISO 23500:2011