

Points of Inspection: Haemodialysis Draft guideline 1 (Non Clinical) GHD(NK) 1			Renal unit check list (R300) and regulation (R187)
	Yes	No	Comment
<p style="text-align: center;"><u><b>Introduction</b></u></p> <p>The purpose of this document is neither prescriptive nor regulatory. It merely provides a working document for commentary by Healthcare professions and administrators in the domain. It takes into consideration minimum quality of care, Patient and health care worker safety, and municipal bylaws amongst others. It also seeks to provide renal care facilities to develop their quality management systems in assessing their own competencies and self-correct if necessary. Renal dialysis services can be provided either in an independent facility or as part of a healthcare facility such as hospitals, day surgical centres or rehabilitation centres. In so far as the "Independent Facility" is concerned, additional requirements needs to be met to maintain minimum standards.</p>			
<b>Dialysis Unit Identification.</b>			
Renal Unit name:			
Renal Unit address:			
Owner's:			
Owner's HPCSA NR:			
Owner's PR. NR:			
Partners HPCSA nr.			
Partners PR NR.			
Business license nr.			
Fire Dept. approval.			
DOH licence:			
Name and PR nr. Nephrologist			
Name and PR nr. Physician in absence of nephrologist.			
Name and or nr. Of GP in absence of physician.			
<b>Layout of the unit and other aspects</b>			
Layout of unit must be developed in compliance with the manufacturers recommendation			
<b>In Patient rooms must comply to R158 as set out in section 28 ann.B</b>			
5m <sup>2</sup> Floor area per patient			
<b>Doors</b> :1.2 m wide minimum			
Floor			
Concrete washable			
No carpets			
No wooden skirting			
Impervious material			

<b>Ceiling</b>			
Dustproof			
<b>Walls</b>			
Smooth finish			
Painted washable			
Impervious material			
washable, impervious, covering 450mm above			
<i>distance of 150mm on each side of fitting</i>			
<b>Natural light</b>			
Treatment room, patient area, waiting room and holding area must have natural light.			
<b>Noise levels -</b>			
acoustic ceiling and floors materials and partitions			
<b>Beds/chairs IN Patient area.</b>			
Space between beds 900mm			
Space between foot of bed/chair and opposite bed is 1500mm			
Nurse call bell per bed/chair. Can only switch off at patients bed.			
1 electrical socket per bed			
1 suction pt. per bed or portable suction unit. (daily checklist) suction tubing ready with Yankuer catheter			
1 oxygen outlet per bed or oxygen cylinders: minimum 1.84kg with bullnose regulators per 5 stations			
Screening facilities between beds/chairs.			
Chairs should recline to Trendelenburg position. Must have adequate arm rest space for cannulation			
Drain for dialysis: Must be adequately sealed to prevent smells. Effluent must drain into sewer and not into storm water drain			
<b>Equipment</b>			
Emergency trolley with Drugs, Intubation tray, AED and Cardiac board			
Emergency trolley checked daily and signed and dated			
AED checked daily			
Ambubag, Guedal airways ET Tubes of various sizes, Laryngoscope			
<b>Isolation cubicle for dialysis of patient with Antigen HepB Ag positive.</b>			
Separate Isolation cubicle glass partitions			
Wall partition at head of bed must not be less than 2 meters.			
clinical hand wash basin in isolation cubicle			
<b>Clinical hand wash basin patient area</b>			
One clinical hand wash basin per 4 beds.			
<b>Reception area.</b>			

Reception area adjacent to waiting area to receive and register patients, provide admin.			
<b>Waiting area</b>			
Waiting area must be large enough to accommodate all the patients waiting.			
<b>Holding area</b>			
Adjacent to the treatment room for patients on trolleys and wheelchairs			
Adequately privacy			
Separated from the waiting area for outpatients			
<b>Nurses station</b>			
Unobstructed view of all the beds			
All activities are co-ordinated from the nursing station			
Drug cupboard and drug registers should be located here and sister should carry the key			
<b>Toilets</b>			
Separate male and female toilets. Must have a working Nurse Call button.			
1 female toilet and 1 male toilet per 8 beds (R158)			
Hand wash basin for each toilet or when sharing basin 1 for every two toilets.			
One toilet must be disabled friendly			
<b>Engineering services</b>			
Ventilation: 10 air changes per hour minimum.			
Lighting minimum 300 lux.			
Electrical installation. Consumer code for rewiring of premises SABS specification 0147			
NBR apply			
<b>Guideline and ward policies</b>			
Clinical guidelines			
Ward policies updated?			
<b>Outpatient rooms</b>			
List of outpatient rooms.			
Minimum floor area of 5m <sup>2</sup> per patient.			
<b>Recordkeeping</b>			
Are all patient records up to date?			
Are their care plans reflecting needs of the patient?			
Whistle blowing policy. Have staff all signed for it.			
Confidentiality policy: Have the staff signed the policy? Compliance to POPI Act			
Confidential records in lockable cupboard?			
<b>Storerooms</b>			

Storerooms for records, equipment, products, medicines?			
Toxic Dangerous liquids in low cupboards marked with Poison sign			
Stock control systems in place?			
Linen cupboard must be ventilated.			
Are medicine supply cupboards locked?			
<b>Notices</b>			
Are all notices on notice boards up to date and signed and dated?			
<b>Dress code</b>			
ID badge and dress code correct?			
Outside clothes to be changed to scrubs in change room			
Staff to change aprons and gloves between patients			
Is there space for personal clothes			
Is there a bin for soiled scrubs?			
<b>Fridge</b>			
Fridge temperature at 2-8 degrees Celsius and in middle of fridge, External temp sensor with alarm for cold chain items			
Fridge cleaned once a week. Log book signed.			
<b>Suitable access to the unit</b>			
Clearly marked access			
Good lighting			
Wide door wheelchair/stretchers/beds			
Entrance covered			
Dropping off zone for ambulances wide and covered			
located on fringe of acute hospital			
Disabled renal patient parking			
Car parking adjacent to entrance			
Ground floor for disposal of waste			
Located near public transport.			
Signage on road indicating drop off, ambulances, deliveries			
In case of an independent RDU or if it is part of another healthcare facility, a contract with a hospital within 10-15 minutes driving time (close proximity) for emergency transfer of patients must be provided.			
Adequate access to Emergency Medical services.			
<b>Privacy</b>			
Adequate screening for privacy			
<b>Patient monitoring area</b>			

Chair weighing scales and wheelchair weighing scales			
Patient monitoring area-Blood pressure, temp and weight and general health.			
<b>Procedure room</b>			
12m <sup>2</sup> sized room			
Medicine fridge			
Preparation working surface.			
Electrical socket			
Oxygen and suction points			
Examination bed			
Desk and chairs.			
Clinical hand wash basin			
<b>Storage equipment room</b>			
All equipment to be stored in equipment room on shelves and brackets or standing on floor (dialysis machines)			
<b>Home training</b>			
Private area for home training, counter, basin			
and separate drain for fluid disposal			
<b>Staff rest and toilet facilities and staff change facilities</b>			
Easy access to staff rest facilities			
Easy access to staff toilets			
Wash hand basin			
Storage equipment room			
Staff changes facilities for males and females.			
Provisions for soiled clothing.			
Storage for personal clothes and effects.			
<b>Access to a kitchen</b>			
Fridge and work area and microwave and kettle.			
Kitchen must have a hand basin			
<b>Wheel chair storage area</b>			
All wheelchairs to be stored here.			
<b>A sterile supply room /clean utility room</b>			
Room for storage of clean linen			
Sterilized packs and dressings			
Pharmaceutical supplies			
May be used as set up area for procedures.			

Sterile packs on shelves.			
A dirty collecting room for temporary storage of waste and dirty linen with a back door for collection			
<b>Sluice room(dirty utility room)</b>			
A sluice room with separate back door. May combine with dirty collection room 7m <sup>2</sup>			
Sluice room must have a facility for pans, bottles			
Wash basin			
A sluice sink plus slop hopper or combination sluice sink with drain to sewer			
<b>A cleaners room</b>			
Shelves for cleaning material			
With slop hopper low sink and high up taps for bucket collection			
Hooks for mops			
Hand wash basin.			
If cleaner room plus sluice room plus dirty collection room is combined			
<b>Infection control</b>			
Cleanliness and Infection Control Policy			
Make sure that the most recent Infection Control report carried out independently is available			
Ensure that the Practice has nominated an Infection Control Leader and that person is available to see Inspectors			
Isolation room is required in all new units with negative pressure (6 air changes per hour)			
The Practice should have an Infection Control Policy document and provide evidence of its review.			
Are premises clean and tidy?			
Re-useable medical equipment cleaned between each patient? Use of stickers, cleaning book.			
Has all staff been trained in infection prevention and control?			
Clean area to prepare for parenteral medications			
Staff bare arms below elbows			
Notice and logs when areas last cleaned?			
The Practice should have in place a policy for disposing of business waste and clinical waste including 'sharps'.			
Contaminated waste disposal			
Used lines are stored where? Should be stored in sluice room.			
No waste carried through patient area or treatment area.			
Red bags for infected waste and linen			
Biohazardous sharps containers for. Not to be filled > 2/3rd s capacity.			
Skin antisepsis?			
Catheter hub disinfection every time catheter is accessed?			
Antimicrobial ointment to catheter exit sites			
Proper decontamination devices, equipment, supplies, surfaces.			

Perform observations of vascular access+ hand hygiene( share)			
Change gloves and aprons between patients?			
Training on infection control topics? E.G hand washing ,vascular access			
Prevention of Hepatitis B? dedicated room,machine,equipment.staff Don't reuse			
Patients to clean hands when arriving and leaving?			
Staff to wear protective clothing?			
Single use dialyzer discarded?			
TB screening?			
Disposable gloves when touching patient or contaminated areas			
Are products for hand hygiene available at point of care? E.g. liquid soap, roller towel,Handbasin and pedal bin?			
Hand wash before and after contact with patient or equipment			
Legionella Testing Inspectors have recently asked for evidence of legionella testing.			
HBV vaccination of staff an patients and booster doses			
Hospital infection control dept. is involved in decisions?			
Competency evaluation on infection control 6 monthly?			
Clinical washbasin and plastic lined pedal controlled bin			
Medicine Refrigerator The Practice should have regular records kept of temperatures found in the vaccine fridge.			
Isolation room terminal clean check lists/?			
Are cleaning schedules on display?			
Decontamination Policy in unit?			
<b>Staffing</b>			
Staffing Trained and untrained ratio on a shift (minimum 1:4 with at least 60% permanent)			
All staff registered or enrolled at respective councils			
Clinical tech in Renal should be trained in dialysis speciality. Adhere to Scope of practice restrictions			
E Register only acceptable when staff member has recently paid the annual fee			
<b>Water treatment systems</b>			
<b>Water treatment system and equipment must conform to the prescribed National, Provincial and Municipal requirements.</b>			
Max level of bacteria in water not to exceed 100 CFU for haemodialysis or 10 CFU for HDF after a 7 day culture .Action if 50 CFU (HDF Ultrapure Water Quality Specs)			
Max level of endotoxin not to exceed 2 EU/ml.Action 1 EU/ml. <0.25EU/ml action if 0.125EU/ml			
Log book must be signed daily and monthly for monthly tests.			
<i>Routine water testing</i>			
Contaminants:TDS daily.Must be < than 10 micro Siemens/cm			
Bacterial sample-monthly in the 3rd week .Pre and Post RO sterilization			
Water chemistry -2 x a year.			

Clinical governance of water plant			
Has RO system plus tank been sterilized with manufacturers recommended sterilant (depending on length of loop), RO membrane and tank			
What is the method of sterilization?			
Duration of sterilant recirculation			
Duration of rinsing			
Testing for residual sterilant with starch paper post sterilization			
Has the RO system a CE mark as per government gazette?			
Plumbers certificate -effluent in sewer and NOT storm water Plumbers log book and certificate			
Is RO file up to date?			
Monthly sterilization date and signature.			
All issues recorded such as leaks, filter colour changes, dropping pressure, fluctuations in conductivity.			
All results must be filed			
Job card for each visit by RO technician			
In service training on water system. Attendance registers.			
<b>Quality improvement processes?</b>			
Any program that has improved quality processes in unit?			
<b>Nephrologist prescription</b>			
Nephrologist weekly consultations			
Nephrologist remote consultations?			
<b>Adequacy of haemodialysis</b>			
Measurement of dialysis efficiency? KT/V SARS Guidelines			
Measurement of dialysis efficiency? URR SARS Guidelines			
Renal Anaemia Management SARS Guidelines			
<b>Fire safety</b>			
Fire equipment in right place with appropriate dates. Only CO2 extinguishers as Dry Chemical Powder may cause breathing problems			
Inspectors may 'walk around' both inside and outside the unit and check for fire extinguishers, alarm points and exit signs. Ensure that fire exits are not blocked and surfaces are clear.			
Equipment maintenance			
Ensure that records of equipment maintenance and PAT testing of electrical equipment are available.			
Equipment might include scales, ECG machine, and spirometry machines.			
There should be evidence of support system for all computer hardware and software used in the Practice.			
<b>Policies</b>			
This policy for issuing prescriptions such as the period of supply and any agreed restrictions or limitation of drugs			



prescribed.			
The procedure for ensuring the allergies are recorded in patient's computer records			
The policy document for dealing with a medical emergency such as an epidemic. (e.g., Ebola, Asian Flu etc.)			
The Practice should have in place a business continuity, disaster and recovery plan.			
The Practice should be able to provide information about the ownership of the premises. Provided under such a lease.			
If leased a copy of the lease should be available along any evidence of building maintenance			
Access to the premises for disabled people with suitable toilet facilities and accessible treatment and consulting rooms.			
The Practice should have a clear and visible policy on charging private medical aide patients. Billing Practitioner responsible for patient			
The procedure for managing the practice accounts should be set out in a policy documents.			
A copy of the most recent annual accounts should be available			
The Practice should have a policy setting out how the finances of the practice are managed.			
Is there a policy for ensuring the quality of medical records? Records should be timely and accurate.			
The Practice should be able to explain the daily on-call arrangements within the rooms. There may be a notice board			
Is there evidence of regular clinical audit in the practice and in particular case review of patient notes?			
Confidential patient records locked in office			
Policies should include Social Media policy, Infection Control, Resuscitation Drill and SOP, generator maintenance etc.			
<b>Training</b>			
Evidence of Training records			
Adverse events and management records			
Training manuals			
<b>Drug control</b>			
Is the drug cupboards locked .Control of key?			
Is there evidence of weekly check on drugs?			
<b>Health and safety protocols</b>			
Emergency Disaster plan			
Renal unit plan at entrance			
Fire drill and alarm			
Vaccination of staff			
Safety hazards identified? Outcomes of safety programmes?			
Hazardous substances should be marked or labelled?			
<b>Patient safety</b>			
Any medication errors recorded e.g. IV heparin?			
Vascular access issues: Training and monitoring of cannulators, records of infiltration and mitigation			
Other			

<b>Consulting room doctor</b>			
Clean drawsheets between patients			
Bed, chairs and desk.			
Medical equipment such as glucometer, flow meter, BP apparatus, ENT set and emergency trolley.			
<b>Dialysis Equipment</b>			
<p>All equipment used in the delivery and monitoring of therapy should comply with the relevant standards for medical electrical equipment (BS-EN 60601-2-16:1998, BS 5724-2-16:1998, IEC 60601-2-16:1998. Medical electrical equipment. Particular Requirements for safety. Particular requirements for the safety of haemodialysis, Haemodiafiltration and hemofiltration equipment).</p> <p>Y Disposables such as dialysers and associated devices are classified as medical devices and Should display the CE mark. The presence of such a mark signifies compliance with the national and international standards: haemodialysers, haemodiafilters, haemofilters, Haemoconcentrators and their extra corporeal circuits (BS-EN 1283:1996). Plasma filters (BS/150 13960).</p> <p>Machines should be considered for replacement after seven years' service or after Completing 50,000 hours operation, whichever is first?</p>			
<b>Reuse of Dialysers</b>			
Those reusing dialysers marked 'for single use only' should have read the MDA Device Bulletin DB 2000(04) Single-use medical devices: implications and consequences of reuse.			

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