

## End Stage Renal Disease Facilities V-Tags & Identifiers

TAG	IDENTIFIER	TAG	IDENTIFIER	TAG	IDENTIFIER
<b>V100</b>	<b>CfC: 494.20 Compliance with Fed/State/Local Laws</b>	V196	Carbon adsorp-monitor, test frequency	No tag	Info tagfo monitor H2O & dialysate sys
V101	Compliance with Fed/State/Local laws	V197	Carbon adsorp-action if first test +	V252	Microb monitor-mo H2O samples/method
		V198	Chemical injection systems	V253	Microb monitor-mo dialysate sample/collect/freq
<b>V110</b>	<b>CfC: 494.30 Infection Control</b>	V199	RO-Meets AAMI/monitored, recorded on log	V254	Microb monitor-sample before disinfect
V111	IC-Sanitary environment	V200	RO-Monitor/alarm/prevent use of unsafe H2O use	V255	Microb monitor-repeat cultures
V112	IC-CDC MMWR 2001	V201	RO-Chemical analysis-frequency	V256	Cultures-dip samplers require QC
V113	IC-Wear gloves/hand hygiene	V202	DI-Contain monitor/logged 2x/day	V257	Cultures-refrig over 2 hrs/no calib loop
V114	IC-Sinks available	V203	DI-Alarms/divert to drain	V258	Endotoxin testing in house-how to
V115	IC-Gowns, shields/masks-no staff eat/drink	V204	DI-Require carbon pre/UF post	V259	Personnel-P&P
V116	IC-If to station=disp/dedicate or disinfect	V205	DI-Polish or back up	V260	Personnel-training program/periodic audits
V117	IC-Clean/dirty;med prep area;no common med carts	V206	DI-Chemical analysis-frequency	No tag	Duplicative of requirements at V192, V197
V118	IC-Single use vials	V207	UF-Effective/opaque housing/monitor	V270	Ch/chl breakthrough-corrective action
V119	IC-Supply cart distant/no supplies in pockets	V208	H2O storage & distribution-design	V271	Ch/chl breakthrough-holding tank use
V120	IC-Transducer protectors-not wetted/changed	V209	H2O tank-shape/vent/disinfected/filter p	V272	Ch/chl breakthrough-notify med dir
V121	IC-Handling infectious waste	V210	H2O storage-monitoring	V273	Ch/chl breakthrough: action=correction
V122	IC-Disinfect surfaces/equip/written protocols	V211	Dist sys-constant flow/no dead ends	V274	H2O test-deviations require response
No tag	IC-Pt isolation procedures	V212	H2O dist systems-no added burden	V275	Adverse events-actions expected
V124	IC-HBV-Test all/rev results/status b4 admit	V213	Dist sys-culture/LAL/sites/freq(new)/log	V276	IC use of preconfig HD-follow FDA label
V125	IC-HBV- Seroconversion=investigation	V214	Bact control devices-UV light	V277	In-center preconfig HD-meets AAMI RD52
V126	IC-HBV-Vaccinate pts & staff	V215	UV lights-filters post	V278	In-center preconfig HD cultures/LALs 4x/yr
V127	IC-HBV- Test pts/staff post last dose	V216	Ozone-sys requirements/monitoring	<b>V300</b>	<b>CfC: 494.50 Reuse of Hemodialyzers &amp; Bloodlines</b>
V128	IC-HBV-Isolation (existing facility)	V217	Hot H2O disinf sys-temp/time/follow DFU/pipe	V301	General requirements-no reuse for HBV+ pts
V129	IC-HBV-Isolation (new facility)	V218	Hot H2O disinfection sys-monitoring	No tag	Duplicative of requirement at V327
V130	IC-HBV0- Isolation machines/equip/supplies	V219	Bact control-disinfect 1X/mo/ dwell	V303	Dialyzer labeled for multiple reuse
V131	IC-HBV-Isolation-staffing	V220	Bact control-supply line disinfected	V304	Reprocessing-meets AAMI RD47 2001/2002
V132	IC-Training & education	No tag	Info tag on bicarb & acid conc delivery	V305	Records-meet req for med records
V142	IC-O'sight: monitor activities & implement P&P	V222	Acid bulk storage tanks-safety controls	V306	Dialyzer reprocessing manual
V143	IC-Aseptic techniques for IV meds	V223	Conc prep-materials compatibility	V307	Personnel qualifications
V144	IC-Staff report IC issues	V224	Mixing systems-H2O/drain/electric	V308	Training-curriculum
V145	IC-Report communicable diseases	V225	Mixing systems-safe environment/PPE	V309	Training docu includes med dir cert
V146	IC-Catheters;general	V226	Mix sys-DFU/monitor/PM/log/sanitize	V310	Personnel health monitoring records
V147	IC-Staff education-catheters/catheter care	V227	Mixing systems-self designed	V311	Pt considerations-medical issues
V148	IC-Monitor cath-related BSI rates/surv	V228	Mixing systems-labeling	V312	Pts inform re dialyzer reuse process
		V229	Mixing systems-perm record/verif test	V313	Equipment-design/construction/function
<b>V175</b>	<b>CfC: 494.40 Water &amp; Dialysate Quality</b>	V230	Mixing systems-cleaning	V314	H2O systems meet AAMI bacti/chem quality
V176	Water purity: ANSI/AAMI RD52:2004	V231	Acid conc mix sys-empty all/prev corrosion	V315	Reprocessing systems-utility requirements
V177	Max level chem contam in H2O/chem analysis	V232	Bicarb mix sys-empty/disinfect/prev corrosion	V316	Maintenance per DFU or 2x/yr/record
V178	Bact H2O-maximum & action levels	V233	Bicarb mix sys-stor/use time/min combine	V317	Repairs=qual personnel;test b4 ret to use
V179	Bact H2O-medical director responsible	V234	Bicarb mix sys-not overmixed	V318	Reprocessing area & ventilation
V180	Bact convent dialysate-max & act levels	V235	Additives-mixing spikes	V319	Environmental safety regarding chemicals
V181	Bact of ultrapure dialysate	V236	Additives-label spiked jugs/label specific pt	V320	Personnel protective gear
V182	Equipment-general/back up plan	V237	Conc distribute-materials compatible	V321	Storage area/segregate dialyzers
No tag	Info tag on H2O components-general	V238	System configurations-elevated tanks	V322	Reprocess supplies-specs & testing
V184	Environment-secure & restricted	V239	Bicarb conc distrib-wkly disinfect/dwell/conc	V323	Inventory control
V185	Environment-access to ports/meters	V240	Bicarb distribution sys-use of UV	V324	Process control test-methods established
V186	Environment-alarms in treatment area	V241	Bicarb distribution sys-ozone disinfect	V325	Process control test-conc of germicide
V187	Environment-schematic diagrams/labels	V242	Conc distribute-bicarb monitor initially	V326	Reprocess record complete/available to pt
V188	Sediment filters-config & monitoring	V243	Bicarb jugs rinsed daily/stored dry	V327	Hemodialyzer labeling-unique to pt
V189	Cartridge filters-config & monitoring	V244	Bicarb jug maintenance/disinfection	V328	Time labeled b4 or 1st use, updated each use
V190	Softeners-auto regenerate/timers/salt lvl	V245	Acid conc dist-conc labeled & color-coded red	V329	Label composition & placement
V191	Softeners-test hardness/log	V246	Bicarb conc dist-color coded blue & sealed	V330	Information rec on label/similar name warn
V192	Carbon adsorption-two tanks/sample ports		Conc outlets-separate/labeled/connect safety	V331	Reprocessing-transportation & handling
V193	Carbon adsorption-banks of tanks	V248	Dialys proport-match ratio-all conc/machine		Rinse/clean-preclean equip/pressures
V194	Carbon adsorption-Iodine #900/replacement		Dialys proport-match mach config w/ratio used		Rinsing/cleaning-use AAMI quality H2O
V195	Carbon adsorption-10 minutes EBCT	V250	Dialys proport-monitor pH/conductivity		

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V334	Dialyzer header cleaning & disinfection	V412	PE-ER prep-pts oriented/trained	<b>V540</b>	<b>CfC: 494.90 Patient Plan of Care</b>
V335	Rinse/clean-chem used/rinse after each	V413	PE- ER equip-on premises-O2, AED, suction	V541	POC-Goals= community-based standards
V336	TCV measured q use/orig vol known	V414	PE-Emergency plans: EMS contact	V542	POC-IDT develops plan of care
V337	Blood path integrity test after q use	V415	PE-Annual eval-emergency/disaster plans	V543	POC-Manage volume status
V338	Germicide: sufficient for point of use	V416	PE-Contact local EOC annually	V544	POC-Achieve adequate clearance
V339	Germ process-high-level disinfect	V417	PE-Fire safety-Life Safety Code 2000	V545	POC-Effective nutritional status
V340	Dialyzer germicide=90% conc/caps disinfect	V418	PE-LSC-sprinklers	V546	POC-Manage mineral metabolism
V341	Chemical germ conc-verification testing	V419	PE-LSC-Waiver if State req meet Fed req	V547	POC-Manage anemia/H/H measured q mo
V342	Dialyzer exterior-low-level disinfection		PE-LSC-waiver	V548	POC-Home pt-eval safe ESA admin
V343	Dialyzer inspect p reprocess/all aspects			V549	POC-Monitor ESA response
V344	Disposition of rejected dialyzers	<b>V450</b>	<b>CfC: 494.70 Patients' Rights</b>	V550	POC-Vascular access-monitor/referrals
V345	Reprocessed dialyzer storage	V451	PR-Pts informed of rights when begin tx	V551	POC-VA monitor/ prevent failure/stenosis
V346	Prep 4 dialysis-written P&Ps for germ test	V452	PR-Respect & dignity	V552	POC-P/S counseling/referrals/HRQOL tool
V347	Prep 4 dialysis-visual inspect-all aspects	V453	PR-Receive understandable information	V553	POC-Home dialysis plan or why not
V348	Verify pt ID-2 people	V454	PR-Privacy & confidentiality-treatment	V554	POC-Transplantation status plan or why not
V349	Verify of germicidal contact	V455	PR-Privacy & confidentiality-records	V555	POC-Rehab status addressed
V350	Germicide presence test of each dialyzer	V456	PR-Participate in care;disc/refuse tx	V556	POC-Completed/signed by IDT & pt
V351	Germicide presence-process control/sampling	V457	PR-Can have advance dir; told fac AD P&P	V557	POC-Initial implemented-30 days/13 tx
V352	Dialyzer priming/rinsing the germicide	V458	PR-Informed-all modalities&settings	V558	POC-Implement updates-15 days p pt assess
V353	Test for resid germ/max time rinse to use	V459	PR-Informed of pt care policies	V559	POC-Outcome not achieved-adjust POC
V354	Monitor-dialysis/pt's clinical course	V460	PR-Informed of reuse & options	V560	POC-Pts seen by med staff 1x/mo
V355	Monitoring-fever/chills/other symptoms	V461	PR-Informed of own medical status	V561	POC-Track TP ref/status;contact TP ctr yrly
V356	Recording adv events/dialyzer c/o log	V462	PR-Informed of services & charges	V562	POC-Pt/family education & training
V357	Dialyzer failures/blood leaks recorded	V463	PR-Receive services outlined in POC		
V358	Monitoring-pt clinical results/Kt/V		PR-Informed of rules/expects-conduct	<b>V 580</b>	<b>CfC: 494.100 Care at Home</b>
V359	Ultrafiltration-monitoring pt's weight	V465	PR-Informed of internal grievance process	V581	H-IDT resp for services=in-center pts
V360	QA-General/records/trend analysis	V466	PR-Informed of external grievance processes	V582	H-IDT oversees home training
V361	Sch of QA acts-med dir responsible		PR-Informed-may file grievance anon	V583	H-Training by certified home train facility
V362	QA audits-pt considerations annually		PR-Informed-d/c/trans P&P inc IVD	V584	H-Training conducted by qualified RN
V363	QA audits-manuals/P&P annual & prn	V469	PR-Receive written notice 30 days pre IVD	V585	H-Training content includes ER prep home pts
V364	QA audits-phys plant/enviro safety 1x/yr	V470	PR-Rights posted;state/NW contact info	V586	H-Pt/caregiver demo comprehend training
V365	QA audits-reprocessing supplies 2x/yr			V587	H-Fac get/review pt records q 2 mo
V366	QA audits-hemodialyzer labeling quarterly	<b>V500</b>	<b>CfC: 494.80 Patient Assessment</b>	V588	H-Support services must be provided
V367	QA audits-reprocess proced monthly;2x/yr	V501	PA-IDT members/responsibilities	V589	H-Monitor home adapt/home visits=POC
V368	QA audits-preparation for dialysis:4x/yr	V502	PA-Assess current health status/comorbid	V590	H-Coordination of care by member of IDT
V378	Reprocess dialyzers & bloodlines by DFU	V503	PA-Appropriateness of dialysis Rx	V591	H-Home pt plan of care dev/updated
V379	Dialyzers exposed to only one germicide	V504	PA-Assess B/P & fluid management needs	V592	H-Pt consultation with IDT members prn
No tag	Duplicative of requirements at V354, V355, V464, V465, V466	V505	PA-Assess lab profile	V593	H-Monitor H2O/dialysate inc on site eval
V381	Blood/dialysate cultures for adv pt react	V506	PA-Immunization/medication history	V594	H-Preconfig HD sys -test H2O/dialy per DFU/FDA
V382	Cluster of adv pt reactions=suspend reuse	V507	PA-Assess anemia	V595	H-Meet RD 52:2004
V383	FDA reporting of adverse outcomes	V508	PA-Assess renal bone disease	V596	H-Fix H2O/dialysate prob/arrange back-up tx
<b>V400</b>	<b>CfC: 494.60 Physical Environment</b>	V509	PA-RD-nutritional status	V597	H-Provide ordered supplies/equipment
V401	PE-Safe/functional/comfortable environment	V510	PA-MSW-psychosocial needs	V598	H-Plan for ER back-up dialysis
V402	PE-Building-construct/maintain for safety	V511	PA-Dialysis access type & maintenance	V599	H-Recordkeeping system
V403	PE-Equipment maintenance-manufacturer's DFU	V512	PA-Eval for self care/modality/setting		
V404	PE-Pt care environment-sufficient space	V513	PA-Transplantation referral		
V405	PE-Comfortable temperature	V514	PA-Eval family/support systems		
V406	Accommodate pt privacy	V515	PA-Eval current phys act lvl/voc/phys rehab		
V407	PE-HD pts in view during treatments	V516	PA-Frequency-initial-30 days/13 tx		
V408	PE-Emergency preparedness-procedures	V517	PA-F/U reassessment-within 3 mo of initial		
V409	PE-ER prep staff-initial/annual/inform pts		PA-Assess HD adeq q mo;PD adeq q 4 mo		
V410	PE-Pt care staff-current CPR cert	V519	PA-Frequency reassessment-stable 1x/yr		
V411	PE-Nurs staff trained in ER equip & meds	V520	PA-Frequency reassess-unstable q mo		



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**§ 494.20 Condition: Compliance with Federal, State, and Local Laws and Regulations (V100-101):** Emphasizes the Centers for Medicare & Medicaid Services' (CMS) role as a partner with State and local governments and with other Federal agencies. The purpose of this Condition is to affirm the principle that Medicare reimbursement should be distributed to ESRD facilities that comply with local, State and Federal laws and rules. This Condition is not intended to adjudicate laws and rules from other governmental agencies. Therefore, this Condition should only be cited when a specific "deficient" practice has been adjudicated with the appropriate entity, and a final decision of non-compliance with the other entity's requirement has been reached. Facilities are expected to comply fully with investigations conducted by public health, regulatory, or law enforcement authorities.

**§ 494.30 Condition: Infection Control (V110-148):** Incorporates as regulation two documents from the Centers for Disease Control and Prevention (CDC), along with CMS developed regulations. These infection control requirements apply to both the chronic dialysis facility's in-center dialysis and any home dialysis program(s).

**§ 494.40 Condition: Water and Dialysate Quality (V175-278):** Incorporates by reference the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standard for Dialysate for Hemodialysis," ANSI/AAMI RD52:2004 and has the authority of regulation. This AAMI document references portions of their "American National Standard for Water Treatment Equipment for Hemodialysis Applications, ANSI/AAMI RD62:2001 as the specifications for various water treatment components. The referenced portions of ANSI/AAMI RD62:2001 are also incorporated by reference, and have the authority of regulation.

**§ 494.50 Condition: Reuse of Hemodialyzers and Bloodlines (V300-383):** Applies only if the facility reuses hemodialyzers or bloodlines. The AAMI "Reuse of Hemodialyzers" Third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference as regulation as part of this Condition (V304-V368).

**§ 494.60 Condition: Physical Environment (V400-420):** Addresses the requirements related to the building and equipment of the facility and incorporates by reference the ambulatory health care occupancy provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. This Condition also includes requirements for emergency preparedness for medical and non-medical issues.

**§ 494.70 Condition: Patients' Rights (V450-470):** Requires the facility to provide respect, privacy, information, and appropriate services for their patients, as well as an internal grievance mechanism and information about external grievance mechanisms.

**§ 494.80 Condition: Patient Assessment (V500-520):** Addresses the requirements for an interdisciplinary assessment of patient needs; the requirements related to meeting those needs are contained in the Condition of Patient plan of care at 494.90.

**§ 494.90 Condition: Patient Plan of Care (V540-562):** Directly related to the Condition of Patient assessment, as the plan of care is built upon the patient assessment. The individual plan of care is revised after each patient assessment, and portions of the plan of care must be updated if the target goals for each area are not achieved or not sustained.

**§ 494.100 Condition: Care at Home (V580-599):** Applies to those facilities that provide training and support services for any type of home dialysis. This Condition focuses on items that are unique to the home dialysis modality. All of the ESRD Conditions must be met regardless of whether the setting is in-center or at home.

**§ 494.110 Condition: Quality Assessment and Performance Improvement (V625-640):** Looks at facility aggregate data and requires facility-based assessment and improvement of care, while the Plan of care Condition expects patient-based improvement of care.

**§ 494.120 Condition: Special Purpose Renal Dialysis Facilities (V660-667):** Outlines the requirements for dialysis facilities that provide care to patients who need dialysis on a short-term basis because of emergency conditions or because they are staying at remote vacation camps. These "special purpose renal dialysis facilities" (SPDF) require a special certification. This certification may not exceed 8 months in any 12-month period of time.

**§ 494.130 Condition: Laboratory Services (V675-676):** Describes the requirements for clinical laboratory services required to meet the needs of ESRD patients.

**§ 494.140 Condition: Personnel Qualifications (V680-696):** Defines the qualifications of dialysis facility staff and lists the minimum required content for patient care technician training programs.

**§ 494.150 Condition: Responsibilities of the Medical Director (V710-716):** Defines the role the facility medical director is expected to assume to ensure the delivery of quality patient care and clinical outcomes. Most deficient practices identified in the delivery of quality patient care and patient clinical outcomes are most appropriately cited under the Conditions pertinent to the practice (e.g., infection control practices, lack of patient assessment or plan of care implementation). Citation of these standards or this Condition should be considered when deficient practices are pervasive, the results of the deficient practices are egregious, or the deficient practice identified is not covered under other Conditions.

### § 494.160 [Reserved]

**§ 494.170 Condition: Medical Records (V725-733):** Requires the facility to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records.

**§ 494.180 Condition: Governance (V750-773):** Addresses the overall management of the facility. It requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. This Condition also holds the governing body accountable for establishing an internal grievance process and decreasing the potential for involuntary discharge of patients; for emergency coverage and backup; for electronic data submission; and the relationship of the facility to the ESRD Network.