

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

TAG	IDENTIFIER	TAG	IDENTIFIER	TAG	IDENTIFIER
V100	<b>CfC: 494.20 Compliance with Fed/State/Local Laws</b>	V196	Carbon adsorption: monitoring, testing frequency	No tag	Informational tag; re monitoring water & dialysate systems
V101	Compliance with Fed/State/Local laws	V197	Carbon adsorption: action if first test positive	V252	Microbial monitoring: mo water samples/method
		V198	Chemical injection systems	V253	Microbial monitoring: mo dialysate sample/collection/freq
<b>V110</b>	<b>CfC: 494.30 Infection Control</b>	V199	RO: meets AAMI/monitored, recorded on log	V254	Microbial monitoring: sample before disinfect
V111	IC: Sanitary environment	V200	RO: monitor/alarm/prevent use of unsafe water	V255	Microbial monitoring: repeat cultures
V112	IC: CDC MMWR 2001	V201	RO: chemical analysis: frequency	V256	Heterotrophic plate count: dip samplers require QC
V113	IC: Wear gloves/hand hygiene	V202	DI: continuous monitoring resistivity/logged 2 x day	V257	Heterotrophic plate count: refrig if delay >2 hrs/no calib loop
V114	IC: Sinks available	V203	DI: alarms/divert to drain	V258	Bacterial endotoxin test: LAL testing in house: how to
V115	IC: Wear gowns, shields/masks; staff not eat/drink in tx area	V204	DI: require carbon pre/UF post	V259	Personnel : P&P
V116	IC: Items taken to station disposed/dedicated or disinfected	V205	DI: polish or back up	V260	Personnel: training program/periodic audits
V117	IC: Clean/dirty areas; 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	Ultrafiltration: effective/opaque housing/monitoring	V270	Ch/chl breakthrough: corrective action
V119	IC: Supply cart distant/No supplies in pockets	V208	Water storage and distribution: design	V271	Ch/chl breakthrough: holding tank use
V120	IC: Transducer protectors: not wetted/changed	V209	Water storage tank: shape/vent/disinfected/filter post	V272	Ch/chl breakthrough: notify Medical Director
V121	IC: Handling infectious waste	V210	Water storage: monitoring	V273	Ch/chl breakthrough: action = correction
V122	IC: Clean, disinfect surfaces & equipment/written protocols	V211	Water distribution sys: continuous flow rates/no dead ends	V274	Water test results: deviations require corrective action plan
No tag	IC: Patient isolation procedures	V212	Water distribution systems: no added burden	V275	Adverse events: actions expected
V124	IC: HBV: test all pts, review results/pt status known preadmit	V213	Dist sys: culture/LAL/sample sites/frequency(new)/log	V276	I-C use of preconfigured HD systems: follow FDA labeling
V125	IC: HBV: seroconversion=investigation	V214	Bacterial control devices: ultraviolet irradiators	V277	In-center preconfigured HD: meets AAMI RD52
V126	IC: HBV: vaccinate patients & staff	V215	Ultraviolet irradiators: filters post	V278	In-center preconfigured HD: quarterly cultures/LALs
V127	IC: HBV: test pts/staff post last dose	V216	Ozone generators: system requirements/monitoring	<b>V300</b>	<b>CfC: 494.50 Reuse of Hemodialyzers and Bloodlines</b>
V128	IC: HBV: isolation (existing facility)	V217	Hot water disinf sys: temp/time/follow DFU/piping	V301	General requirements: no reuse for HBV+ pts
V129	IC: HBV: isolation (new facility)	V218	Hot water disinfection systems: monitoring	No tag	Duplicative of requirement at V327
V130	IC: HBV: isolation of machines/equipment/supplies	V219	Bacterial control: disinfect monthly/disinfection dwell	V303	Dialyzer must be labeled for multiple reuse per FDA
V131	IC: HBV: isolation – staffing	V220	Bacterial control: machine supply line disinfected	V304	Reprocessing requirements: meets AAMI RD47 2001/2002
V132	IC: Training and education	No tag	Informational tag re: bicarb & acid concentrate delivery	V305	Records: meet req for med records
V142	IC: Oversight: Monitor activities & implement policies	V222	Acid bulk storage tanks: safety controls	V306	Dialyzer reprocessing manual
V143	IC: Aseptic techniques for IV meds	V223	Concentrate preparation: materials compatibility	V307	Personnel qualifications
V144	IC: Staff report IC issues	V224	Mixing systems: water/drain/electric	V308	Training: curriculum
V145	IC: Report communicable diseases	V225	Mixing systems: safe environment/PPE	V309	Training documentation includes med dir certification
V146	IC: Catheters; general	V226	Mixing sys: follow DFU/monitor/PM/log/sanitization	V310	Personnel health monitoring records
V147	IC: Staff education re catheters/catheter care	V227	Mixing systems: self designed	V311	Patient considerations: medical issues
V148	IC: Monitor cath related BSI rates/surveillance	V228	Mixing systems: labeling	V312	Patients informed regarding dialyzer reuse process
		V229	Mixing systems: permanent record/verification testing	V313	Equipment: design/construction/function
<b>V175</b>	<b>CfC: 494.40 Water and Dialysate Quality</b>	V230	Mixing systems: cleaning	V314	Water systems meet AAMI bacti/chem quality/monitoring
V176	Water purity: ANSI/AAMI RD52:2004	V231	Acid conc mixing sys: empty completely//prevent corrosion	V315	Reprocessing systems: utility requirements
V177	Max level of chemical contaminants in water/chem analysis	V232	Bicarb mixing sys: empty/disinfect/prevent corrosion	V316	Maintenance per DFU or semiannual/maintenance record
V178	Bacteriology of water-maximum and action levels	V233	Bicarb mixing sys: storage/use time limits/min combine	V317	Repairs by qualified personnel: fxn test before return to use
V179	Bacteriology of water-Medical Director responsible	V234	Bicarb mixing sys: not overmixed	V318	Reprocessing area and ventilation
V180	Bacteriology of conventional dialysate-max and action levels	V235	Additives: mixing spikes	V319	Environmental safety regarding chemicals
V181	Bacteriology of ultrapure dialysate	V236	Additives: labeling spiked jugs/labeling if for specific pt	V320	Personnel protective gear
V182	Equipment-general/back up plan	V237	Concentrate distribution: materials compatibility	V321	Storage area/segregation of dialyzers in process
No tag	Informational tag re water treatment components-general	V238	System configurations: elevated tanks	V322	Reprocessing supplies: specifications and testing
V184	Environment: secure and restricted	V239	Bicarb conc distribution: weekly disinfect/dwell times/conc	V323	Inventory control
V185	Environment: access to ports/meters	V240	Bicarb distribution systems: use of UV	V324	Process control testing: methods established
V186	Environment: alarms in treatment area	V241	Bicarb distribution systems: ozone disinfection	V325	Process control testing: concentration of germicide
V187	Environment: schematic diagrams/labels	V242	Concentrate distribution: Bicarb monitoring initially	V326	Reprocessing record complete/available to patient
V188	Sediment filters: config and monitoring	V243	Bicarb jugs rinsed daily/stored dry	V327	Hemodialyzer labeling: unique to patient
V189	Cartridge filters: config and monitoring	V244	Bicarb jug maintenance/disinfection	V328	Time of labeling: before or at first use, updated p each use
V190	Softeners: automatically regenerated/timers/salt/salt level	V245	Acid conc distribution: conc labeled & color-coded red	V329	Label composition and placement
V191	Softeners: testing hardness/log	V246	Bicarb conc distribution: color coded blue & sealed	V330	Information recorded on label/similar name warning
V192	Carbon adsorption: two tanks/sample ports	V247	Conc outlets: separate/labeled/connection safety	V331	Reprocessing: transportation and handling
V193	Carbon adsorption: banks of tanks	V248	Dialysate proportioning: match ratio: all conc/machine	V332	Rinsing/cleaning: precleaning equipment/pressures
V194	Carbon adsorption: Iodine #900/replacement	V249	Dialysate proport: match machine config w/ratio in use	V333	Rinsing/cleaning: use AAMI quality water
V195	Carbon adsorption: 10 minutes EBCT	V250	Dialysate proportioning: monitor pH/conductivity		

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V334	Dialyzer header cleaning and disinfection	V412	Emergency preparedness: patients oriented/trained	<b>V540</b>	<b>CfC: 494.90 Patient Plan of Care</b>
V335	Rinsing/cleaning: chemicals used/rinse after each	V413	Emergency equipment: on premises: O2, AED, suction	V541	Patient Plan of Care: Goals= community-based standards
V336	TCV measured after q use/original volume known	V414	Emergency plans: EMS contact	V542	IDT develops plan of care
V337	Blood path integrity test after q use	V415	Annual evaluation of emergency/disaster plans	V543	Manage volume status
V338	Germicide: sufficient for point of use	V416	Contact local disaster management agency annually	V544	Achieve adequate clearance
V339	Germicidal process high-level disinfection achieved	V417	Fire safety: Life Safety Code 2000	V545	Effective nutritional status
V340	Dialyzer germicide = 90% conc/port caps disinfected	V418	LSC: sprinklers	V546	Manage mineral metabolism
V341	Chemical germicidal concentration: verification testing	V419	LSC: Waiver if state requirements meet Fed req	V547	Manage anemia/H/H measured monthly
V342	Dialyzer exterior: low-level disinfection	V420	LSC: waiver	V548	Home patient: eval safe ESA administration
V343	Dialyzer inspection after reprocessing: all aspects/aesthetics			V549	Monitor ESA response
V344	Disposition of rejected dialyzers	<b>V450</b>	<b>CfC: 494.70 Patients' Rights</b>	V550	Vascular access: monitor/referrals
V345	Reprocessed dialyzer storage	V451	Patients informed of rights when begin treatment	V551	VA monitor to prevent failure/stenosis
V346	Prep for dialysis: written P&Ps for germicide testing	V452	Respect & dignity	V552	Psychosocial counseling/referrals/assessment tool
V347	Prep for dialysis: visual inspection: all aspects	V453	Receive information in an understandable way	V553	Home dialysis plan or why not
V348	Verification of patient identification: 2 people	V454	Privacy & confidentiality in treatment	V554	Transplantation status plan or why not
V349	Verification of germicidal contact	V455	Privacy & confidentiality in records	V555	Rehab status addressed
V350	Germicide presence test of each dialyzer	V456	Participate in care; discontinue/refuse treatment	V556	POC completed/signed by IDT & patient
V351	Germicide presence: process control/sampling	V457	Execute advance directives; facility policy re AD	V557	Initial POC implemented: 30 days/13 tx
V352	Dialyzer priming/rinsing the germicide	V458	Informed: all modalities & settings	V558	Implement updates of POC: 15 days p pt assessment
V353	Testing for residual germicide/max time rinsed to use	V459	Informed: patient care policies	V559	Outcome not achieved: adjust POC
V354	Monitoring: dialysis/patient's clinical course	V460	Informed: whether facility practices reuse; if so, options	V560	Patients seen by med staff member monthly
V355	Monitoring: fever/chills/other symptoms	V461	Informed: own medical status	V561	Track TP referrals/communicate with TP ctr annually & if Δ
V356	Recording adverse events/dialyzer complaint log	V462	Informed: services & charges	V562	Patient/family education & training
V357	Dialyzer failures/blood leaks recorded	V463	Receive services outlined in POC		
V358	Monitoring: patient clinical results/Kt/V	V464	Informed: rules/expectations re patient conduct	<b>V 580</b>	<b>CfC: 494.100 Care at Home</b>
V359	Ultrafiltration: monitoring patient's weight	V465	Informed: internal grievance process	V581	IDT resp = services equivalent to in-center patients
V360	Quality assurance: general/Records/trend analysis	V466	Informed: external grievance processes	V582	IDT oversees home training
V361	Schedule of QA activities: medical director responsible	V467	Informed: right to file int/ext grievance w/o risk/anon	V583	Training provided by certified home training facility
V362	QA audits: patient considerations annually	V468	Informed: d/c & transfer policies inc involuntary dc	V584	Training conducted by qualified RN
V363	QA audits: manuals and procedures annually & pm	V469	Receive written notice 30 days before involuntary dc	V585	Training content including emergency prep for home pts
V364	QA audits: physical plant/environmental safety annually	V470	Rights posted with state/NW contact #s and addresses	V586	Pt/caregiver demonstrated comprehension of training
V365	QA audits: reprocessing supplies semiannually			V587	Fac receive/review self monitoring data every 2 months
V366	QA audits: hemodialyzer labeling quarterly	<b>V500</b>	<b>CfC: 494.80 Patient Assessment</b>	V588	Support services must be provided
V367	QA audits: reprocessing procedures monthly; semiannually	V501	Patient assessment: Interdisciplinary Team mbrs/resp.	V589	Monitor home adaptation; home visits = POC
V368	QA audits: preparation for dialysis quarterly	V502	Assess current health status inc comorbid	V590	Coordination of care by member of IDT
V378	Reprocess dialyzers and bloodlines by DFU	V503	Appropriateness of dialysis Rx	V591	Home patient plan of care dev/updated
V379	Dialyzers not exposed to more than one germicide	V504	Assess B/P & fluid management needs	V592	Pt consultation with members of IDT as needed
No tag	Duplicative of requirements at V354 and V355	V505	Assess lab profile	V593	Monitor water/dialysate inc on site evaluation
V381	Blood/dialysate cultures for adverse patient reactions	V506	Immunization/medication history	V594	Preconfig HD sys: testing water/dialysate follow DFU/FDA
V382	Cluster of adverse patient reactions=suspend reuse	V507	Assess anemia	V595	Meet RD 52:2004
V383	FDA reporting of adverse outcomes	V508	Assess renal bone disease	V596	Correct water/dialysate problem or arrange back-up dialysis
		V509	RD: nutritional status	V597	Provide ordered supplies/equipment
<b>V400</b>	<b>CfC: 494.60 Physical Environment</b>	V510	MSW: psychosocial needs	V598	Plan for ER back-up dialysis
V401	PE: Safe, functional, comfortable environment	V511	Dialysis access type & maintenance	V599	Recordkeeping system
V402	PE: Building: constructed/maintained to ensure safety	V512	Eval for self care, modality & setting		
V403	PE: Equipment maintenance: manufacturer's DFU	V513	Transplantation referral		
V404	PE: Patient care environment: sufficient space	V514	Eval family/support systems		
V405	PE: Comfortable temperature	V515	Eval current physical activity level & voc/physical rehab		
V406	PE: Accommodations for patient privacy	V516	Frequency: initial: 30 days/13 tx		
V407	PE: Hemodialysis patients in view during treatments	V517	F/U reassessment: within 3 months of initial		
V408	Emergency preparedness: procedures	V518	Assess HD adequacy monthly/PD adequacy q 4 months		
V409	ER preparedness of staff: initial/annual/re informing patients	V519	Frequency reassessment: stable = annual		
V410	Patient care staff: current CPR certification	V520	Frequency reassessment: unstable = monthly		
V411	Nursing staff trained in emergency equip and meds				

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TAG	IDENTIFIER	TAG	IDENTIFIER
<b>V625</b>	<b><i>CfC: 494.110 Quality Assessment &amp; Performance Improvement</i></b>	<b>V710</b>	<b><i>CfC: 494.150 Responsibilities of the Medical Director</i></b>
V626	Covers scope of services/effective/IDT involved	V711	Medical director qualified/accountable to Governing Body
V627	Ongoing ; uses indicators = improved health outcomes	V712	MD resp: QAPI Program
V628	Measure, analyze and track quality indicators	V713	MD resp: Staff ed, training & performance
V629	QAPI Indicator: Adequacy of dialysis	V714	MD resp: Develop, review& approve P&P
V630	QAPI Indicator: Nutritional status	V715	MD resp: Ensure all adhere to P&P
V631	QAPI Indicator: Mineral metabolism/bone disease	V716	MD resp: Ensure involuntary discharge P&P followed
V632	QAPI Indicator: Anemia management		
V633	QAPI Indicator: Vascular access		<b><i>CfC: 494.160 [Reserved]</i></b>
V634	QAPI Indicator: Medical injuries/errors		
V635	QAPI Indicator: HD reuse program	<b>V725</b>	<b><i>CfC:494.170 Medical Records</i></b>
V636	QAPI Indicator: Pt. satisfaction & grievances	V726	Medical Records: complete, accurate, accessible
V637	QAPI Indicator: Infection control: trend/plan/act	V727	MR: Protect patient records from loss/keep confidential
V638	Continuously monitor/take action/track/sustain improve	V728	MR: Obtain written permission for release
V639	Prioritizing improvement activities	V729	MR: Complete records promptly
V640	Immediately correct any IJ issues	V730	MR: Centralize all info; each member of IDT has access
		V731	MR: Maintain home patient records
<b>V660</b>	<b><i>CfC: 494.120 Special Purpose Renal Dialysis Facilities</i></b>	V732	MR: Retain all records 6 years from discharge/death
V661	Special Purpose: two categories	V733	MR: Transfer requested records within 1 working day
V662	Approval period: 8 months		
V663	Service limitations	<b>V750</b>	<b><i>CfC: 494.180 Governance</i></b>
No tag	Defines applicable V tags for camp SPDF	V751	Identifiable Governing Body w/full authority/responsibility
No tag	Defines applicable V tags for emergency SPDF	V752	Appoint CEO/Administrator
V666	Physician contact	V753	Adm resp for staff appointments
V667	Records transferred within 30 days	V754	Adm resp for fiscal operations
		V755	Adm resp for relationship with ESRD NW
<b>V675</b>	<b><i>CfC: 494.130 Laboratory Services</i></b>	V756	Adm resp for resources for QAPI
V676	CLIA labs/meet needs of patients	V757	Staff # & ratio meet patient needs
		V758	RN, MSW, & RD available to meet patient needs
<b>V680</b>	<b><i>CfC: 494.140 Personnel Qualifications</i></b>	V759	RN present at all times
V681	Staff licensed as req/qualified/demonstrate competencies	V760	GB: responsible for staff oriented to facility & resp
V682	Medical Director: BC + 12 mo dialysis exp	V761	Staff have access to continuing education
V683	Medical Director exception (CMS approval)	V762	GB: responsible for medical staff credentialing
V684	Nurse manager: 12 mo RN + 6 mo dialysis	V763	GB: Informs medical staff of P&P and QAPI program
V685	Self care/home training nurse: 12 mo RN + 3 mo modality	V764	Services furnished on the main premises
V686	Charge nurse: 12 mo nursing + 3 mo dialysis	V765	Internal grievance process components & implemented
V687	RN/LPN Charge supervision	V766	GB & med dir ensure all staff follow disch/transfer P&P
V688	Staff nurse: meet state requirements	V767	Involuntary discharge process requirements
V689	Dietitian: RD	V768	GB: provide pts/staff direction re emergency med care
V690	Dietitian: 1 year experience	V769	Physician roster available
V691	Social worker: MSW; grandfather only if hired before 1976	V770	Transfer agreement with hospital for inpatient care
V692	PCT: state requirements & HS diploma	V771	Electronic data submission required for program adm
V693	PCT: complete training program	V772	Responds to NW requests/works toward goals
V694	PCT training program content	V773	Disclosure of ownership
V695	PCT certified		
V696	Water treatment system techs training		

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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.