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<b>Note to the Reader:</b> This document has been prepared to allow comment and suggestions on the guidance to surveyors. In order to have time to allow this input prior to the effective date of the regulations, CMS chose to build this surrogate draft document, using in the Proposed Regulation column language from the proposed ESRD Conditions for Coverage as published for comment in the Federal Register on February 4, 2005 and from the AAMI and CDC documents which were proposed to be incorporated by reference. <b>This is not an opportunity for further comment on the regulation language.</b> It <u>is</u> an opportunity for input for the “Draft Interpretive Guidelines” section. CMS intends to consider suggestions offered as this document is adapted to the Final Rule once it is published.		
<b>Subpart A – General Provisions</b>		
	<b>494.1 Basis and Scope</b>  (a) Statutory basis. This part is based on the following provisions: (1) Section 2991 of the Social Security Amendments of 1972 (Pub. L. 92-603), which extended the Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. (2) Section 1138(a)(1)(B) of the Act, which requires hospitals to be members and abide by the rules and requirements of the Organ Procurement and Transplantation Network. (3) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution. (4) Section 1861(s)(2)(F) of the Act, which describes “medical and other health services” covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis and support services, and	

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	<p>institutional dialysis services and supplies.</p> <p>(5) Section 1861(a) of the Act, which specifies exclusions from coverage.</p> <p>(6) Section 1881 of the Act, which authorizes Medicare coverage and payment for treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of recombinant epoetin alpha (EPO)</p> <p>(7) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113, which requires Federal agencies to achieve greater reliance on voluntary standards and emphasize, where possible, the use of standards developed by private consensus organizations.</p>	
	<p>(b) Scope. The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.</p>	
	<p><b>§494.10 Definitions</b></p> <p>As used in this part –</p> <p>Dialysis facility means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services, or (3) both. A dialysis facility may be an independent or hospital-based unit (as</p>	

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	<p>described in 413.174(b) and (c) of this chapter), or a self-care dialysis unit that furnishes only self-dialysis services.</p> <p>Discharge means the termination of patient care services by a dialysis facility.</p> <p>Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.</p> <p>Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in 494.100(a) of this part.</p> <p>Interdisciplinary team means the group of persons, specified at 494.80 of this part, responsible for providing patient care to each dialysis patient.</p> <p>Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in 494.100(a) of this part.</p> <p>Transfer means a temporary or permanent move of a patient from one dialysis facility to</p>	

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	another that requires a transmission of the patient's medical record to the facility receiving the patient.	
<b>100</b>	<p><b>§494.20 Condition: Compliance with Federal, State, and local laws and regulations.</b></p> <p>The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations</p>	To determine compliance with this condition, review the findings of the survey related to potential non-compliance with these laws and regulations. Relevant laws include those listed in this Condition, and staff licensure requirements listed at 494.140 (Personnel qualifications). Before you may cite this Condition due to a violation of state law, any state adverse action must be final.
<b>101</b>	pertaining to licensure,	This tag relates to states which have licensing requirements for ESRD facilities. Request to see a copy of the current license. Cite this tag only after any state ESRD licensure adverse action is final.
<b>102</b>	staff licensure and other personnel staff qualifications	This tag relates to licensure or certification of staff as required by state or Federal law. Cite this tag if one or more staff members do not have the required license/certification.
<b>103</b>	fire safety, equipment, building codes,	Recognize that a new facility would need to have a building occupancy permit prior to opening for business; for an initial survey, request to see this. Cite violations of fire safety at this tag. Refer to the LSC requirements at 494.60(e) (Physical environment: Fire safety).
<b>104</b>	drugs, medical device usage,	If you suspect non-compliance with FDA requirements, notify the CMS RO. The RO will notify the FDA of your observations. If a device may have caused or contributed to a serious injury or illness, the facility must notify the manufacturer and the FDA (1-800-638-6725) using User Facility reporting requirements. Cite this tag if the facility failed to report as required.
<b>105</b>	and any other relevant health and safety requirements.	Other relevant Federal agencies would include Occupational Safety and Health Administration and the Office of Civil Rights.
<b>Subpart B – Patient Safety</b> <b>Resource:</b> Philip Aspden, Janet M. Corrigan, Julie Wolcott, Shari M. Erickson, Editors, Committee on Data Standards for Patient Safety, <i>Patient Safety: Achieving a New Standard of Care</i> (executive summary) - <a href="http://books.nap.edu/execsumm_pdf/10863.pdf">http://books.nap.edu/execsumm_pdf/10863.pdf</a>		
<b>110</b>	<b>§494.30 Condition: Infection Control</b>	This condition discusses the infection control strategies which must be

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	<p>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p>	<p>implemented in the dialysis environment, due to the increased risk of exposure to blood-borne pathogens and the immunocompromised condition of ESRD patients.</p> <p>These requirements are based on the published Centers for Disease Control and Prevention recommendations for the prevention of the transmission of infections in dialysis facilities, which are adopted by reference:</p> <p><b>“Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients’ Morbidity and Mortality Weekly Report, volume 50 number RR05, April 27, 2001</b>  <a href="http://www.cdc.gov/mmwr/PDF/rr/rr5005.pdf">www.cdc.gov/mmwr/PDF/rr/rr5005.pdf</a></p> <p><b>CDC RECOMMENDED PRACTICES</b>  <b>Infection Control Precautions for Outpatient Hemodialysis Settings Compared with Inpatient Hospital Settings</b></p> <p>Contact transmission is the most important route by which pathogens are transmitted in health-care settings, including hemodialysis units. Contact transmission occurs most commonly when microorganisms from a patient are transferred to the hands of a health-care worker who does not comply with infection control precautions, then touches another patient. Less commonly, environmental surfaces (e.g., bed rails, countertops) become contaminated and serve as an intermediate reservoir for pathogens; transmission can occur when a worker touches the surface then touches a patient or when a patient touches the surface.</p> <p>In the hemodialysis setting, contact transmission plays a major role in transmission of bloodborne pathogens. If a health-care worker’s hands become contaminated with virus-infected blood from one patient, the worker can transfer the virus to a second patient’s skin or blood line access port, and the virus can be inoculated into that patient when the skin or access port is punctured with a needle.</p>

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		<p>Contact transmission can be prevented by hand hygiene (i.e., hand washing or use of a waterless hand rub), glove use, and disinfection of environmental surfaces. Of these, hand hygiene is the most important. In addition, nonsterile disposable gloves provide a protective barrier for workers' hands, preventing them from becoming soiled or contaminated, and reduce the likelihood that microorganisms present on the hands of personnel will be transmitted to patients. However, even with glove use, hand washing is needed because pathogens deposited on the outer surface of gloves can be detected on hands after glove removal, possibly because of holes or defects in the gloves, leakage at the wrist, or contamination of hands during glove removal.</p> <p>Standard Precautions are the system of infection control precautions recommended for the inpatient hospital setting. Standard Precautions are used on all patients and include use of gloves, gown, or mask whenever needed to prevent contact of the health-care worker with blood, secretions, excretions, or contaminated items.</p> <p>In addition to Standard Precautions, more stringent precautions are recommended for hemodialysis units because of the increased potential for contamination with blood and pathogenic microorganisms (see Infection Control Practices Recommended for Hemodialysis Units). For example, infection control practices for hemodialysis units restrict the use of common supplies, instruments, medications, and medication trays and prohibit the use of a common medication cart. These extra precautions are needed due to the increased risk for exposure to blood-borne pathogens for both patients and staff.</p> <p><b>Survey Procedures:</b> Throughout the survey process, the surveyor must personally observe infection control precautions to ensure compliance with the CDC recommendations and CMS rules. This includes the use of Personal Protective Equipment, such as a cover gown, mask or face shield during activities which present potential blood exposure.</p>

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		<p>Infection control requirements apply to both the chronic dialysis facility in-center dialysis and the home dialysis program.</p> <p>If deficiencies in infection control practices are multiple, pervasive or of an extent to present a risk to patient health and safety, consider citing at the Condition level.</p>
111	<p><b>(a) Standard: Procedures for infection control.</b></p> <p>The facility must demonstrate that it follows standard infection control precautions by implementing—</p> <p>(1) The “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” with the exception of screening for Hepatitis C. found in “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients’ Morbidity and Mortality Weekly Report, volume 50 number RR05, April 27, 2001, pages 20 and 21, developed by the Centers for Disease Control and Prevention, which are incorporated by reference, to prevent and control cross-contamination and the spread of infectious agents, . Incorporation by reference of the CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” was approved by the Director of the Federal Register in accordance with a 5 U.S.C. 552(a) and 1 CFR part 51.</p>	<p>To determine the facility's compliance with the CDC guidelines for infection control, the surveyor must utilize all components of the survey process- observations of care delivery, interviews with staff and patients, and review of medical records, facility logs, policies and procedures and QAPI documentation.</p> <p>The excerpts from the CDC guidelines (identified as <b>CDC RECOMMENDED PRACTICES</b>) that follow in this condition include a comprehensive look at the infection control program strategies that would be expected to be implemented in hemodialysis units.</p> <p><b>CDC RECOMMENDED PRACTICES:</b></p> <p>Preventing transmission among chronic hemodialysis patients of bloodborne viruses and pathogenic bacteria from both recognized and unrecognized sources of infection requires implementation of a comprehensive infection control program. The components of such a program include infection control practices specifically designed for the hemodialysis setting, including routine serologic testing and immunization, surveillance, and training and education (Box).</p>



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		<p data-bbox="932 250 1917 305"><b>BOX. Components of a comprehensive infection control program to prevent transmission of infections among chronic hemodialysis patients</b></p> <div data-bbox="932 315 1917 673"> <ul style="list-style-type: none"> <li data-bbox="932 326 1556 354">• <b>Infection control practices for hemodialysis units.</b> <ul style="list-style-type: none"> <li data-bbox="974 370 1902 425">– Infection control precautions specifically designed to prevent transmission of bloodborne viruses and pathogenic bacteria among patients.</li> <li data-bbox="974 444 1892 472">– Routine serologic testing for hepatitis B virus and hepatitis C virus infections.</li> <li data-bbox="974 492 1629 519">– Vaccination of susceptible patients against hepatitis B.</li> <li data-bbox="974 539 1797 566">– Isolation of patients who test positive for hepatitis B surface antigen.</li> </ul> </li> <li data-bbox="932 586 1591 613">• <b>Surveillance for infections and other adverse events.</b></li> <li data-bbox="932 633 1446 660">• <b>Infection control training and education.</b></li> </ul> </div> <p data-bbox="909 745 1934 1328">The infection control practices recommended for hemodialysis units will reduce opportunities for patient-to-patient transmission of infectious agents, directly or indirectly via contaminated devices, equipment and supplies, environmental surfaces, or hands of personnel. These practices should be carried out routinely for all patients in the chronic hemodialysis setting because of the increased potential for blood contamination during hemodialysis and because many patients are colonized or infected with pathogenic bacteria. Such practices include additional measures to prevent HBV transmission because of the high titer of HBV and its ability to survive on environmental surfaces. For patients at increased risk for transmission of pathogenic bacteria, including antimicrobial-resistant strains, additional precautions also might be necessary in some circumstances. Furthermore, surveillance for infections and other adverse events is required to monitor the effectiveness of infection control practices, as well as training and education of both staff members and patients to ensure that appropriate infection control behaviors and techniques are carried out.</p> <p data-bbox="909 1369 1600 1396"><b>Infection Control Practices for Hemodialysis Units</b></p>



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		<p>In each chronic hemodialysis unit, policies and practices should be reviewed and updated to ensure that infection control practices recommended for hemodialysis units are implemented and rigorously followed (see Recommended Infection Control Practices for Hemodialysis Units at a Glance). Intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.</p> <p><b>Survey Procedures:</b> Cite this Standard if you identify significant problems in infection control during your survey of the facility.</p>
112	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Wear disposable gloves when caring for the patient or touching the patient’s equipment at the dialysis station;</p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>During the process of hemodialysis, exposure to blood and potentially contaminated items can be routinely anticipated; thus, gloves are required whenever caring for a patient or touching the patient’s equipment. To facilitate glove use, a supply of clean nonsterile gloves and a glove discard container should be placed near each dialysis station.</p> <p>Staff members should 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). Such protective clothing or gear should be changed if it becomes soiled with blood, body fluids, secretions, or excretions.</p> <p>Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. However, patients can be served meals or eat food brought from home at their dialysis station. The glasses, dishes, and other utensils should be cleaned in the usual manner; no special care of these items is needed.</p> <p><b>Survey Procedures:</b> Observe staff while performing procedures which have the potential for exposure to blood and other potentially infectious substances. This may include caring for patients' vascular accesses, removing blood lines and dialyzers from</p>

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		dialysis machines, preparing the machines for dialysis and administering intravenous medications. Staff should don PPE appropriate to the anticipated potential exposure.
113	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b> Remove gloves and wash hands between each patient or station.</p>	<p><b>CDC RECOMMENDED PRACTICES</b> Hands always should be washed 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 should 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.</p> <p><b>Survey Procedures:</b> Observe staff delivering care to the patients, with focus on glove changing and hand washing/sanitizing. To maintain adequate infection control and prevent cross-contamination between patients, staff should demonstrate awareness that each patient and their dialysis station are one unit. Staff must always change gloves and wash/sanitize their hands when moving from one patient/station to another. An example of this would be staff touching the face of one patient's machine to obtain information, and then proceeding to do the same at the next patient's machine. Vigilant glove/hand hygiene practices are especially important during the patient shift changeover, when a patient, whose dialysis has just ended, is sitting in the chair during vascular access care while the staff members are preparing the dialysis machine for the next patient.</p>
114	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b> Items taken into the dialysis station should</p>	<p><b>CDC RECOMMENDED PRACTICES</b> Any item taken to a patient’s dialysis station could become contaminated with blood and other body fluids and serve as a vehicle of transmission to other patients either directly or by contamination of the hands of personnel. Therefore, items taken to a patient’s dialysis station, including those placed on top of dialysis machines, should either 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</p>

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	<p>either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <ul style="list-style-type: none"> <li>– Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use only on a single patient.</li> <li>– Unused medications (including multiple dose vials containing diluents) or supplies (e.g., syringes, alcohol swabs) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</li> </ul>	<p>should not be returned to a common clean area or used on other patients.</p> <p><b>Survey Procedures:</b> Observe where staff members obtain supplies for patients, and whether they return unused supplies to a common area. Staff should not keep supplies (e.g. rolls of tape, gauze, syringes) in their pockets or on the dialysis machines. After use, all equipment, supplies, and linens, must be considered as potentially blood contaminated, and should be separated, handled with caution, and either disinfected or discarded. Non-disposable items that cannot be cleaned and disinfected should be dedicated for use only on a single patient. There are no exceptions to this rule. If blood pressure cuffs are used for multiple patients, they must be of a material which can be adequately disinfected. If an item is visibly contaminated with blood, staff should use a tuberculocidal disinfectant (i.e. an intermediate –level disinfectant).</p>
115	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>Additional measures to prevent contamination of clean or sterile items include a) preparing medications in a room or area separated from the patient treatment area and designated only for medications; b) not handling or storing contaminated (i.e., used) supplies, equipment, blood samples, or biohazard containers in areas where medications and clean (i.e., unused) equipment and supplies are handled; and c) delivering medications separately to each patient.</p> <p>Residual medication from two or more vials should not be pooled into a single vial</p> <p><b>Survey Procedures:</b> Observe where medications are prepared and stored. The dialysis technicians may prepare patients' heparin and xylocaine in different areas than where the licensed nurses prepare the patients' ESAs, Vitamin D, iron, etc.</p>
116	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR</b></p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>Common carts should not be used within the patient treatment area to prepare or distribute medications.</p>

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	<p><b>494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Do not use common medication carts to deliver medications to patients.</p>	<p>If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.</p> <p><b>Survey Procedures:</b> Observe Licensed Nurses preparing and administering medications to patients. The medications should be drawn in a centralized location and taken to the individual patient stations for administration.</p>
<b>117</b>	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Do not carry medication vials, syringes, alcohol swabs, or supplies in pockets.</p>	<p><b>Survey Procedures:</b> Observe staff during patient care, especially during the patient shift changeover. Due to the significant risk of cross-contamination, there should not be any dialysis supplies kept in staff's pockets.</p>
<b>118</b>	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>If trays are used to distribute medications, clean them before using for a different patient.</p> <p><b>Survey Procedures:</b> Observe for the use of medication trays. If they are placed on the patient's dialysis machine, chair or side table, they must be disinfected before being used for another patient.</p>
<b>119</b>	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a</b></p>	<p><b>Survey Procedures:</b> The facility patient treatment area should have designated areas for "clean" and</p>

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	<p><b>Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Clean areas should be clearly designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to where used equipment or blood samples are handled.</p>	<p>"dirty" supplies and procedures. Staff must remain aware of the separation of clean and dirty tasks, to prevent cross-contamination.</p> <p>Observe if there are areas labeled "clean" and "dirty", such as countertops, sinks, containers of disinfectant, etc. Observe staff practices: are dirty tasks conducted, or dirty items placed in the "clean" areas?</p>
120	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines’ pressure monitors. Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.</p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>Venous pressure transducer protectors should be used to cover pressure monitors and should be changed between patients, and 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. Frequent blood line pressure alarms or frequent adjusting of blood drip chamber levels can be an indicator of this problem</p> <p><b>Survey Procedures:</b></p> <p>Observe venous transducer protectors while patients are on dialysis. If they are</p>

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		<p>wet with blood, do the staff members change them immediately?</p> <p>During dialysis machine maintenance review, ask if the internal transducer filters are changed when contaminated with blood.</p>
121	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Clean and disinfect the dialysis station (e.g., chairs, beds, tables, machines) between patients.</p> <ul style="list-style-type: none"> <li>– Give special attention to cleaning control panels on the dialysis machines and other surfaces that are frequently touched and potentially contaminated with patients’ blood.</li> <li>– Discard all fluid and clean and disinfect all surfaces and containers associated with the prime waste (including buckets attached to the machines).</li> </ul>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>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).</p>
122	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>For dialyzers and blood tubing that will be</p>	<p><b>Survey Procedures:</b></p> <p>For facilities that reuse dialyzers, observe the practices for containing the blood-contaminated fluid in the extracorporeal circuit at the end of dialysis.</p>



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	reprocessed, cap dialyzer ports and clamp tubing.	
123	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p>Place all used dialyzers and tubing in leakproof containers for transport from station to reprocessing or disposal area.</p>	<p>The requirements for dialyzer reprocessing at §494.50 identify that used dialyzers shall be handled and transported "in a clean and sanitary manner".</p> <p><b>Survey Procedures:</b> Observe how used dialyzers are transported or disposed of. For non-reuse dialyzers, the leakproof containers could be biohazardous waste receptacles. For reuse dialyzers, this could be a leakproof basket or bucket used for transporting capped dialyzers for reprocessing.</p>
124	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients</b></p> <p><b>Schedule for routine testing as follows:</b></p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p><b>Routine Serologic Testing</b> Chronic Hemodialysis Patients. Routinely test all chronic hemodialysis patients for HBV and HCV infection (see Recommended Practices at a Glance), promptly review results, and ensure that patients are managed appropriately based on their testing results (see later recommendations for each virus). Communicate test results (positive and negative) to other units or hospitals when patients are transferred for care. Routine testing for HDV or HIV infection for purposes of infection control is not recommended.</p> <p>The HBV serologic status (i.e., HBsAg, total anti-HBc, and anti-HBs) of all patients should be known before admission to the hemodialysis unit. For patients transferred from another unit, test results should be obtained before the patients’ transfer. If a patient’s HBV serologic status is not known at the time of admission, testing should be completed within 7 days. The hemodialysis unit should ensure that the laboratory performing the testing for anti-HBs can define a 10 mIU/mL concentration to determine protective levels of antibody.</p>



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	<div><p><b>Schedule for Routine Testing for Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Infections</b></p><table><tr><th>Patient Status</th><th>On Admission</th><th>Monthly</th><th>Semiannual</th><th>Annual</th></tr><tr><td>All patients</td><td>HBsAg,* Anti-HBc* (total), Anti-HBs,* Anti-HCV, ALT†</td><td></td><td></td><td></td></tr><tr><td>HBV-susceptible, including nonresponders to vaccine</td><td></td><td>HBsAg</td><td></td><td></td></tr><tr><td>Anti-HBs positive (≥10 mIU/mL), anti-HBc negative</td><td></td><td></td><td></td><td>Anti-HBs</td></tr><tr><td>Anti-HBs and anti-HBc positive</td><td></td><td colspan="3">No additional HBV testing needed</td></tr><tr><td>Anti-HCV negative</td><td></td><td>ALT</td><td>Anti-HCV</td><td></td></tr></table><p>* Results of HBV testing should be known before the patient begins dialysis. † HBsAg=hepatitis B surface antigen; Anti-HBc=antibody to hepatitis B core antigen; Anti-HBs=antibody to hepatitis B surface antigen; Anti-HCV=antibody to hepatitis C virus; ALT=alanine aminotransferase.</p></div>	Patient Status	On Admission	Monthly	Semiannual	Annual	All patients	HBsAg,* Anti-HBc* (total), Anti-HBs,* Anti-HCV, ALT†				HBV-susceptible, including nonresponders to vaccine		HBsAg			Anti-HBs positive (≥10 mIU/mL), anti-HBc negative				Anti-HBs	Anti-HBs and anti-HBc positive		No additional HBV testing needed			Anti-HCV negative		ALT	Anti-HCV		<p>Routine HCV testing should include use of both an EIA to test for anti-HCV and supplemental or confirmatory testing with an additional, more specific assay (Figure). Use of RT-PCR for HCV RNA as the primary test for routine screening is not recommended because few HCV infections will be identified in anti-HCV negative patients. However, if ALT levels are persistently abnormal in patients who are anti-HCV negative in the absence of another etiology, testing for HCV RNA should be considered.</p> <p><b>Prevention and Management of HCV Infection</b></p> <p>HCV transmission within the dialysis environment can be prevented by strict adherence to infection control precautions recommended for all hemodialysis patients (see Recommended Practices at a Glance). Although isolation of HCV-infected patients is not recommended, routine testing for ALT and anti-HCV is important for monitoring transmission within centers and ensuring that appropriate precautions are being properly and consistently used.</p> <p><b>HCV-Positive Patients.</b> Patients who are anti-HCV positive (or HCV RNA positive) do not have to be isolated from other patients or dialyzed separately on dedicated machines. Furthermore, they can participate in dialyzer reuse programs. Unlike HBV, HCV is not transmitted efficiently through occupational exposures. Thus, reprocessing dialyzers from HCV-positive patients should not place staff members at increased risk for infection.</p> <p>HCV-positive persons should be evaluated (by consultation or referral, if appropriate) for the presence or development of chronic liver disease according to current medical practice guidelines. They also should receive information concerning how they can prevent further harm to their liver and prevent transmitting HCV to others. Persons with chronic liver disease should be vaccinated against hepatitis A, if susceptible.</p>
Patient Status	On Admission	Monthly	Semiannual	Annual																												
All patients	HBsAg,* Anti-HBc* (total), Anti-HBs,* Anti-HCV, ALT†																															
HBV-susceptible, including nonresponders to vaccine		HBsAg																														
Anti-HBs positive (≥10 mIU/mL), anti-HBc negative				Anti-HBs																												
Anti-HBs and anti-HBc positive		No additional HBV testing needed																														
Anti-HCV negative		ALT	Anti-HCV																													

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		<p><b>Prevention and Management of HIV Infection</b></p> <p>Routine testing of hemodialysis patients for HIV infection for infection control purposes is not necessary or recommended. However, patients with risk factors for HIV infection should be tested so that, if infected, they can receive proper medical care and counseling regarding preventing transmission of the virus.</p> <p>Infection control precautions recommended for all hemodialysis patients (see Recommended Practices at a Glance) are sufficient to prevent HIV transmission between patients. HIV-infected patients do not have to be isolated from other patients or dialyzed separately on dedicated machines. In addition, they can participate in dialyzer reuse programs. Because HIV is not transmitted efficiently through occupational exposures, reprocessing dialyzers from HIV-positive patients should not place staff members at increased risk for infection.</p> <p><b>Survey Procedures:</b> The surveyor should be familiar with the CDC Table for hepatitis B screening, and refer to it during review of patients' medical records. If patients have not been tested accordingly, ask how the facility keeps track of hepatitis B surveillance.</p> <p>Because Medicare coverage does not include routine screening for Hepatitis C, these regulations do not pertain to such routine screening. However, if any patient displays symptoms of ,or is suspected of being infected with Hepatitis C, then it would be expected that testing for Hepatitis C be performed.</p>
125	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All Patients (cont.)</b></p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p><b>Hepatitis B Vaccination</b></p> <p><b>Vaccine Schedule and Dose.</b> Hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients and for all staff members. Vaccination is recommended for pre–end-stage renal disease patients before they become dialysis dependent and for peritoneal and home dialysis patients</p>

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	<p><b>Hepatitis B Vaccination</b></p> <p>Vaccinate all susceptible patients against hepatitis B.</p>	<p>because they might require in-center hemodialysis. Hepatitis B vaccine should be administered by the intramuscular route and only in the deltoid muscle for adults and children. Intradermal or subcutaneous administration of hepatitis B vaccine is not recommended.</p> <p>If an adult patient begins the vaccine series with a standard dose before beginning hemodialysis treatment, then moves to hemodialysis treatment before completing the series, complete the series using the higher dose recommended for hemodialysis patients. No specific recommendations have been made for higher doses for pediatric hemodialysis patients. If a lower than recommended vaccine dose is administered to either adults or children, the dose should be repeated.</p> <p>If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. For the three-dose primary vaccine series, the second and third doses should be separated by an interval of at least 2 months; if only the third dose is delayed, that dose should be administered when convenient. When hepatitis B vaccine has been administered at the same time as other vaccines, no interference with the antibody response of the other vaccines has been demonstrated.</p> <p><b>Survey Procedures:</b> Review patients' medical records for evidence that HBV-susceptible patients were offered hepatitis B vaccination. There should be documentation that patients were informed of the vaccination and either opted to receive it or refused it.</p>
126	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Infection Control Precautions for All</b></p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p><b>Postvaccination Testing and Revaccination of Nonresponders.</b> Test all vaccinees for anti-HBs 1–2 months after the last primary vaccine dose, to determine their response to the vaccine (adequate response is defined as &gt;10 mIU/mL). Patients and staff members who do not respond to the primary vaccine series should be revaccinated with three additional doses and retested</p>

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	<p><b>Patients (cont.)</b></p> <p><b>Hepatitis B Vaccination (cont.)</b></p> <p>Test for anti-HBs 1-2 months after last dose.</p> <ul style="list-style-type: none"> <li>– If anti-HBs is &lt;10 mIU/mL, consider patient susceptible, revaccinate with an additional three doses, and retest for anti-HBs</li> <li>– If anti-HBs is &gt;10 mIU/mL, consider patient immune, and retest annually.</li> <li>- Give booster dose of vaccine if anti-HBs declines to &lt;10 mIU/mL and continue to retest annually.</li> </ul>	<p>for response. No additional doses of vaccine are warranted for those who do not respond to the second series.</p> <p>Evaluate staff members who do not respond to revaccination to determine if they are HBsAg positive. Persons who are HBsAg positive should be counseled accordingly (e.g., need for medical evaluation, vaccination of sexual and household contacts). Primary nonresponders to vaccination who are HBsAg negative should be considered susceptible to HBV infection and counseled regarding precautions to prevent HBV infection and the need to obtain postexposure prophylaxis with hepatitis B immune globulin for any known or probable percutaneous or mucosal exposure to HBsAg-positive blood.</p> <p><b>Follow-Up of Vaccine Responders.</b> Retest patients who respond to the vaccine annually for anti-HBs. If anti-HBs declines to &lt;10 mIU/mL, administer a booster dose of hepatitis B vaccine and continue to retest annually. Retesting immediately after the booster dose is not necessary. For staff members who respond to the vaccine, booster doses of vaccine are not necessary, and periodic serologic testing to monitor antibody concentrations is not recommended.</p> <p><b>Patients with a History of Vaccination.</b> Routine childhood vaccination against hepatitis B has been recommended since 1991 and routine adolescent vaccination since 1995. Thus, many persons who develop end-stage renal failure will have a history of vaccination against hepatitis B. These persons should have responded to the vaccine when their immune status was normal, but if their anti-HBs levels are &lt;10 mIU/mL when they begin dialysis, they should be revaccinated with a complete primary series.</p> <p><b>Survey Procedures:</b> Review patients' medical records for determination of compliance with post-HBV vaccination follow up testing.</p>
127	CDC “Recommended Infection Control Practices for Hemodialysis Units at a	<b>CDC RECOMMENDED PRACTICES Prevention and Management of HBV Infection</b>

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	<p><b>Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Management of HBsAg-Positive Patients</b></p> <p>Follow infection control practices for hemodialysis units for all patients.</p>	<p>Preventing HBV transmission among chronic hemodialysis patients requires a) infection control precautions recommended for all hemodialysis patients; b) routine serologic testing for markers of HBV infection and prompt review of results; c) isolation of HBsAg-positive patients with dedicated room, machine, other equipment, supplies, and staff members; and d) vaccination. Additional infection control practices are needed because of the potential for environmentally mediated transmission of HBV, rather than internal contamination of dialysis machines. The need for routine follow-up testing, vaccination, or isolation is based on patients’ serologic status.</p> <p><b>HBV-Susceptible Patients.</b> Vaccinate all susceptible patients (see Hepatitis B Vaccination). Test susceptible patients monthly for HBsAg, including those who a) have not yet received hepatitis B vaccine, b) are in the process of being vaccinated, or c) have not adequately responded to vaccination. Although the incidence of HBV infection is low among chronic hemodialysis patients, preventing transmission depends on timely detection of patients converting from HBsAg negative to HBsAg positive and rapid implementation of isolation procedures before cross-contamination can occur.</p>
128	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Management of HBsAg-Positive Patients (cont.)</b></p> <p>Dialyze HBsAg-positive patients in a separate room using separate machines, equipment, instruments, and supplies.</p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p><b>HBV-Infected Patients.</b> To isolate HBsAg-positive patients, designate a separate room for their treatment and dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV-susceptible patients. Chronically infected patients (i.e., those who are HBsAg positive, total anti-HBc positive, and IgM anti-HBc negative) are infectious to others and are at risk for chronic liver disease. They should be counseled regarding preventing transmission to others, their household and sexual partners should receive hepatitis B vaccine, and they should be evaluated (by consultation or referral, if appropriate) for the presence or development of chronic liver disease according to current medical practice guidelines. Persons with chronic liver disease should be vaccinated against hepatitis A, if susceptible.</p>

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		<p>Chronically infected patients do not require any routine follow-up testing for purposes of infection control. However, annual testing for HBsAg is reasonable to detect the small percentage of HBV-infected patients who might lose their HBsAg.</p> <p><b>HBV-Immune Patients.</b> Annual anti-HBs testing of patients who are positive for anti-HBs (&gt;10 mIU/mL) and negative for anti-HBc determines the need for booster doses of vaccine to ensure that protective levels of antibody are maintained. No routine follow-up testing is necessary for patients who are positive for both anti-HBs and anti-HBc.</p> <p>HBV-immune patients can undergo dialysis in the same area as HBsAg-positive patients, or they can serve as a geographic buffer between HBsAg-positive and HBV-susceptible patients. Staff members can be assigned to care for both infected and immune patients on the same shift.</p>
129	<p><b>CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” as Adopted by Reference 42 CFR 494.30(a)</b></p> <p><b>Management of HBsAg-Positive Patients (cont.)</b></p> <p>Staff members caring for HBsAg-positive patients should not care for HBV-susceptible patients at the same time (e.g., during the same shift or during patient changeover).</p>	<p><b>CDC RECOMMENDED PRACTICES</b></p> <p>Most importantly, staff members who are caring for HBsAg-positive patients should not care for susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.</p>
130	<p>(2) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and</p>	<p><b>CDC RECOMMENDED PRACTICES:</b></p> <p><b>HBV-Infected Patients.</b> To isolate HBsAg-positive patients, designate a separate room for their treatment and dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV-</p>



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		<p>susceptible patients. Most importantly, staff members who are caring for HBsAg-positive patients should not care for susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.</p> <p>Newly opened units should have isolation rooms for the dialysis of HBsAg-positive patients. For existing units in which a separate room is not possible, HBsAg-positive patients should be separated from HBV-susceptible patients in an area removed from the mainstream of activity and should undergo dialysis on dedicated machines. If a machine that has been used on an HBsAg-positive patient is needed for an HBV-susceptible patient, internal pathways of the machine can be disinfected using conventional protocols and external surfaces cleaned using soap and water or a detergent germicide.</p> <p>Dialyzers should not be reused on HBsAg-positive patients. Because HBV is efficiently transmitted through occupational exposure to blood, reprocessing dialyzers from HBsAg-positive patients might place HBV-susceptible staff members at increased risk for infection.</p> <p><b>Survey Procedures:</b>  Observe if there is an isolation station at the facility. Ask which patients are dialyzed in the isolation station. The only patients that must be isolated are those with active Hepatitis B, (e.g., test positive for the Hepatitis B surface antigen [HBsAg-positive]).  New facilities should have separate rooms for isolating HBsAg-positive patients. For existing facilities without isolation rooms, ask how HBsAg-positive patients are managed.  A staff member may take care of an HBsAg-positive patient as well as an HBsAg-immune patient at the same time. However, a staff member caring for an HBsAg-positive patient may not take care of an HBV-susceptible patient on the same shift or during patient shift changeover.  Only HBV-positive patients can dialyze in a room that is dedicated to at least</p>



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		<p>one HBV-positive patient dialyzed at the facility Supplies used in the isolation room/area, such as multi-dose vials, clamps, blood-pressure cuffs, etc, should be labeled "isolation", and not routinely removed from the isolation room/area. Refillable dialysate containers should be kept in the isolation area and refilled at the door.</p> <p>The facility may have policies and procedures for isolation/additional precautions for patients with other infectious diseases, such as MRSA, VRE, HCV, etc.</p> <p><b>CDC RECOMMENDED PRACTICES:</b> <b>Prevention and Management of Bacterial Infections</b></p> <p>Follow published guidelines for judicious use of antimicrobials, particularly Vancomycin, to reduce selection for antimicrobial-resistant pathogens. Infection control precautions recommended for all hemodialysis patients (see Recommended Practices at a Glance) are adequate to prevent transmission for most patients infected or colonized with pathogenic bacteria, including antimicrobial-resistant strains. However, additional infection control precautions should be considered for treatment of patients who might be at increased risk for transmitting pathogenic bacteria. Such patients include those with either a) an infected skin wound with drainage that is not contained by dressings (the drainage does not have to be culture positive for VRE, MRSA, or any specific pathogen) or b) fecal incontinence or diarrhea uncontrolled with personal hygiene measures. For these patients, consider using the following additional precautions: a) staff members treating the patient should wear a separate gown over their usual clothing and remove the gown when finished caring for the patient and b) dialyze the patient at a station with as few adjacent stations as possible (e.g., at the end or corner of the unit)</p>
131	(3) Maintaining procedures, in accordance with applicable State and local laws and	<p><b>CDC RECOMMENDED PRACTICES:</b> Housekeeping staff members in the dialysis facility should promptly remove</p>

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	<p>accepted public health procedures, for the --</p> <p>(i) Handling, storage, and disposal of potentially infectious waste; and</p>	<p>soil and potentially infectious waste and maintain an environment that enhances patient care. All disposable items should be placed in bags thick enough to prevent leakage. Wastes generated by the hemodialysis facility might be contaminated with blood and should be considered infectious and handled accordingly. These solid medical wastes should be disposed of properly in an incinerator or sanitary landfill, according to local and state regulations governing medical waste disposal.</p> <p><b>Survey Procedures:</b> The surveyor should be familiar with State and local laws related to the handling, storage, and disposal of infectious waste</p> <p>The plan for the disposal of waste products should ensure that all waste destined for disposal is placed in appropriate leak-proof containers or bags that are properly color-coded or labeled as required. Sharps should be disposed of in closable containers which are puncture resistant, leak-proof and are labeled or color-coded accordingly. Sharps containers should be easily accessible and not overfilled, creating needle-stick hazards. When filled, Sharps containers should be securely closed. All infectious waste should be stored in non-patient areas, not accessible to the public .</p> <p>OSHA has related regulations for infection control and prevention for protection of the staff and the public. While CMS is responsible for rules that affect the health and safety of patients, there may be instances when a surveyor finds concerns that may be based on OSHA regulations for waste handling and disposal. If this occurs, contact your CMS Regional Office.</p>
132	(ii) Cleaning and disinfection of contaminated surfaces, medical devices and equipment.	<p><b>CDC RECOMMENDED PRACTICES:</b> <b>Cleaning and Disinfection.</b> Establish written protocols for cleaning and disinfecting surfaces and equipment in the dialysis unit, including careful mechanical cleaning before any disinfection process (Table 2). If the manufacturer has provided instructions on sterilization or disinfection of the</p>

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		<p>item, these instructions should be followed. For each chemical sterilant and disinfectant, follow the manufacturer's instructions regarding use, including appropriate dilution and contact time.</p> <p>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 should wear gloves, and the cloth should be placed in a bucket or other leakproof container. After all visible blood is cleaned, use a new cloth or towel to apply disinfectant a second time.</p> <p>Published methods should 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 bloodborne viruses. For single-pass machines, perform rinsing and disinfection procedures at the beginning or end of the day. For batch recirculating 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 should be performed according to the recommendations of the Association for the Advancement of Medical Instrumentation.</p>

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		<p><b>TABLE 2. Disinfection procedures recommended for commonly used items or surfaces in hemodialysis units</b></p> <table> <tr> <th data-bbox="932 347 1094 370">Item or Surface</th><th data-bbox="1436 324 1562 370">Low-Level Disinfection*</th><th data-bbox="1625 324 1814 370">Intermediate-Level Disinfection*</th></tr> <tr> <td data-bbox="932 376 1346 422">Gross blood spills or items contaminated with visible blood</td><td data-bbox="1499 376 1520 393"></td><td data-bbox="1730 402 1751 418">X</td></tr> <tr> <td data-bbox="932 435 1171 457">Hemodialyzer port caps</td><td data-bbox="1499 435 1520 451"></td><td data-bbox="1730 435 1751 451">X</td></tr> <tr> <td data-bbox="932 467 1310 490">Interior pathways of dialysis machine</td><td data-bbox="1499 467 1520 483"></td><td data-bbox="1730 467 1751 483">X</td></tr> <tr> <td data-bbox="932 500 1339 522">Water treatment and distribution system</td><td data-bbox="1499 500 1520 516">X</td><td data-bbox="1730 500 1751 516">X<sup>†</sup></td></tr> <tr> <td data-bbox="932 532 1289 578">Scissors, hemostats, clamps, blood pressure cuffs, stethoscopes</td><td data-bbox="1499 558 1520 574">X</td><td data-bbox="1730 558 1751 574">X<sup>‡</sup></td></tr> <tr> <td data-bbox="932 591 1360 636">Environmental surfaces, including exterior surfaces of hemodialysis machines</td><td data-bbox="1499 617 1520 633">X</td><td data-bbox="1730 617 1751 633"></td></tr> </table> <p>* Careful mechanical cleaning to remove debris should always be done before disinfection.</p> <p><sup>†</sup> Water treatment and distribution systems of dialysis fluid concentrates require more extensive disinfection if significant biofilm is present within the system.</p> <p><sup>‡</sup> If item is visibly contaminated with blood, use a tuberculocidal disinfectant.</p> <p><b>Survey Procedures:</b>  Determine how the dialysis and other equipment are disinfected between uses on different patients. Ask how is the disinfectant solution is mixed.  During observations, determine if the prime waste receptacle (prime bucket, container, Waste Handling Option [WHO], etc.) is adequately disinfected, with sufficient disinfectant contact time, between patients.</p>	Item or Surface	Low-Level Disinfection*	Intermediate-Level Disinfection*	Gross blood spills or items contaminated with visible blood		X	Hemodialyzer port caps		X	Interior pathways of dialysis machine		X	Water treatment and distribution system	X	X <sup>†</sup>	Scissors, hemostats, clamps, blood pressure cuffs, stethoscopes	X	X <sup>‡</sup>	Environmental surfaces, including exterior surfaces of hemodialysis machines	X	
Item or Surface	Low-Level Disinfection*	Intermediate-Level Disinfection*																					
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133	<p><b>(b) Standard: Oversight</b></p> <p>The facility must:  (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; and</p>	<p><b>Survey Procedures:</b>  The facility must develop, maintain, and incorporate into facility QAPI activities a log with sufficient information to track and address relevant infection control management in the facility. This should include, but not be limited to, patients' vaccination status (hepatitis, pneumonia, and influenza), hepatitis status (including ALT), bacteremia episodes, vascular access infections and vascular access loss due to infection. The log should include, at a minimum, the date of infection onset, site of infection, infecting organism(s), and antimicrobial susceptibility results.</p> <p>A record of adverse events (e.g., blood leaks, spills, machine malfunctions,</p>																					

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		<p>deaths) may be incorporated into the infection log or may be maintained and reviewed separately as part of QAPI.</p> <p>The facility should designate a staff person to promptly review the results of all routine testing and periodically review recorded episodes of bacteremia or vascular access infections to aid in tracking ,trending, and prompt identification of potential environmental/staff practices issues or infection outbreaks among patients.</p> <p>For tracking purposes, each patient treatment record should include the location of the dialysis station , machine number for each dialysis session, the name of staff members who initiate and discontinue dialysis as well as all staff who cared for the patient during the treatment.</p> <p>The facility should specify what actions are required when changes occur in test results or in the frequency of episodes of bacteremias or vascular access loss because of infection.</p>
134	(2) Designate a registered nurse as the infection control or safety officer, responsible for :	<p><b>Survey Procedures:</b> Determine who has been designated as the infection control officer. Ask how the facility infection control program meets the following requirements.</p>
135	(i) Maintaining current infection control information including the most current Centers for Disease Control and Prevention guidelines for the proper techniques in the use of vials and ampules containing medication;	<p>If a facility re-enters/re-punctures medication vials labeled for single use the following procedures, as outlined by the CDC, must be implemented:</p> <ol style="list-style-type: none"> <li>1. All doses must be drawn-up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.</li> <li>2. All doses from a given vial should be drawn-up and administered within a 4-hour period.</li> <li>3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.</li> </ol>

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		<p>4. Any opened vials or filled syringes (with epoetin alpha, iron, or vitamin D) must be discarded if not used within 4 hours of first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) during non-use.</p> <p>5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.</p> <p>6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.</p> <p><b>Reference S&amp;C Letter 02-43 (September 12, 2002)</b>  ESRD facilities will be expected to follow the revised CDC recommendations for injectable medications administered by ESRD facilities. The CDC has stated that failure to comply with the following recommendations poses a significant health and safety risk to patients. Therefore, we expect that either facilities will continue the practice of single use of single-use vials or facilities will follow the following recommendations: Page 2 – Associate Regional Administrator, DMSO; State Survey Agency Directors</p> <p>1. All doses must be drawn-up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.</p> <p>2. All doses from a given vial should be drawn-up and administered within a 4-hour period.</p> <p>3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.</p>

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		<p>4. Any opened vials or filled syringes (with epoetin alpha, iron, or vitamin D) must be discarded if not used within 4 hours of first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) during non-use.</p> <p>5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.</p> <p>6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.</p> <p><b>Survey Procedures:</b> Facilities will have different methods for adherence to the CDC guidelines for multiple uses of single dose medication vials (e.g., using multiple syringes for one dose, using a combination of single dose vials to obtain the ordered dose, etc.). Observe personnel preparing medications for administration to determine compliance.</p>
136	(ii) Reporting infection control issues to the dialysis facility's chief executive officer or administrator (see §494.180(a) of this part) and the quality improvement committee; and	<p><b>Survey Procedures:</b> The facility should be able to demonstrate that there is a reporting mechanism for infection control issues. Ask the infection control officer, administrator and medical director about the infection control program and reporting mechanisms. How are infection control issues reported and discussed in QAPI meetings?</p>
137	(iii) making recommendations regarding infection control training and improvements.	<p><b>CDC RECOMMENDED PRACTICES: INFECTION CONTROL TRAINING AND EDUCATION</b></p> <p>Training and education is recommended for both staff members and patients (or their family care givers). Training should be appropriate to the cognitive level of the staff member, patient, or family member, and rationales should be</p>



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		<p>provided for appropriate infection control behaviors and techniques to increase compliance. Regulations and recommendations regarding infection control training for health-care workers in general, and dialysis personnel in particular, have been previously published. The following recommendations are intended to highlight and augment the earlier recommendations.</p> <ul style="list-style-type: none"> <li>• Training and education for all employees at risk for occupational exposure to blood should be provided at least annually, given to new employees before they begin working in the unit, and documented. At a minimum, they should include information on the following topics: <ul style="list-style-type: none"> <li>– proper hand hygiene technique;</li> <li>– proper use of protective equipment;</li> <li>– modes of transmission for bloodborne viruses, pathogenic bacteria, and other microorganisms as appropriate;</li> <li>– infection control practices recommended for hemodialysis units and how they differ from Standard Precautions recommended for other health-care settings;</li> <li>– proper handling and delivery of patient medications;</li> <li>– rationale for segregating HBsAg-positive patients with a separate room, machine, instruments, supplies, medications, and staff members;</li> <li>– proper infection control techniques for initiation, care, and maintenance of access sites;</li> <li>– housekeeping to minimize transmission of microorganisms, including proper methods to clean and disinfect equipment and environmental surfaces; and</li> <li>– centralized record keeping to monitor and prevent complications, including routine serologic testing results for HBV and HCV, hepatitis B vaccine status, episodes of bacteremia and loss of access caused by infection, and other adverse events. Records of surveillance for water and dialysate quality should also be maintained.</li> </ul> </li> <li>• Training and education of patients (or family members for patients unable to be responsible for their own care) regarding infection control practices should be given on admission to dialysis and at least annually thereafter and</li> </ul>

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		<p>should address the following topics:</p> <ul style="list-style-type: none"> <li>– personal hygiene and hand washing technique;</li> <li>– patient responsibility for proper care of the access and recognition of signs of infection, which should be reviewed each time the patient has a change in access type; and</li> <li>– recommended vaccinations.</li> </ul> <p><b>Survey Procedures:</b> Determine what training staff receive in infection control and the prevention of the spread of blood-borne pathogens. Ask if direct care are staff periodically observed, to verify infection control procedures are followed. Ask how poor practices are identified and corrected.</p>
138	<p><b>(c) Standard: Monitoring:</b></p> <p>The facility must:</p> <p>(1) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; and</p>	<p><b>Survey Procedures:</b> This “Monitoring” standard is considered to be a component of the QAPI program for the facility. The facility must analyze, track, and trend specific information on outcomes related to infection incidence and potential sources to ensure patient safety.</p> <p>Pervasive problems in monitoring infection issues may also be cited at §494.110 Quality Assessment and Performance Improvement.</p>
139	<p>(2) Develop recommendations to minimize infection transmission and take actions to reduce future incidents.</p>	<p><b>Survey Procedures:</b> In developing recommendations, the facility must juxtaposition this standard with the staff training requirements, verification of infection control procedure implementation, and corrective actions for identified poor practices. Review records for evidence of corrective actions, such as staff re-education, revision of policies and procedures, adjustments to the dialysis environment, and audits to ensure compliance.</p>
140	<p><b>(d) Standard: Reporting</b></p> <p>The facility must report incidences of communicable diseases as required by</p>	<p><b>CDC RECOMMENDED PRACTICES:</b></p> <p><b>HBsAg Seroconversions.</b> Report HBsAg-positive seroconversions to the local health department as required by law or regulation. When a seroconversion</p>

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	Federal, State, and local regulations.	<p>occurs, review all patients' routine laboratory test results to identify additional cases. Perform additional testing as indicated later in this section. Investigate potential sources for infection to determine if transmission might have occurred within the dialysis unit, including review of newly infected patients' recent medical history (e.g., blood transfusion, hospitalization), history of high-risk behavior (e.g., injecting-drug use, sexual activity), and unit practices and procedures.</p> <p>In patients newly infected with HBV, HBsAg often is the only serologic marker initially detected; repeat HBsAg testing and test for anti-HBc (including IgM anti-HBc) 1–2 months later. Six months later, repeat HBsAg testing and test for anti-HBs to determine clinical outcome and need for counseling, medical evaluation, and vaccination of contacts Patients who become HBsAg negative are no longer infectious and can be removed from isolation.</p> <p><b>Survey Procedures:</b> The surveyor should be familiar with state and local infection/communicable disease incidence reporting requirements</p> <p>Ask if there have been any patients with seroconversions of HBV, HCV or tuberculosis? What actions did the facility take?</p> <p>The facility must report devices that cause infectious disease outbreaks to the FDA under their Medical Device Reporting, and to State and local authorities as required by law or regulation.</p>
200	<p><b>§494.40 Condition: Water Quality</b></p> <p>The facility must be able to demonstrate the following:</p>	<p>Cite this Condition if there are deficient practices identified under water or dialysate quality that have or could place patients at risk for exposure to unsafe water or dialysate. Examples include staff members assigned to testing water or preparation of dialysate that do not demonstrate competency for the assigned tasks; use of testing reagents that are expired or that are not sufficiently sensitive to discern unsafe levels of toxins; and failure to take action when tests results indicate unsafe water or dialysate may be in use.</p>

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<b>201</b>	<p><b>(a) Standard: Water purity.</b></p> <p>Water used for dialysis meets the following water quality standards and equipment requirements of the Association for the Advancement of Medical Instrumentation (AAMI) published in “Water Treatment Equipment for Hemodialysis Applications,” ANSI/AAMI RD 62: 2001, which are incorporated by reference. Incorporation by reference of the AAMI Water Treatment Equipment for Hemodialysis Applications was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.</p>	<p>The AAMI language incorporated by reference is included in the regulation column. Cite this Standard if there are major deficiencies identified related to water purity.</p>
<b>202</b>	<p>(1) Incorporated water quality requirements are those listed in sections—</p> <p>(i) 4.2.1 and 5.2.1 Water Bacteriology;</p> <p>(ii) 4.2.2 and 5.2.2 Maximum Level of Chemical Contaminants; and</p> <p>(iii) 4.3 Water Treatment Equipment requirements.</p>	<p>The referenced AAMI requirements follow this tag.</p>
<b>203</b>	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(i)</b></p> <p><b>4.2.1 Water bacteriology (requirements)</b> Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to reprocess dialyzers for multiple use, should contain a total viable microbial count of less than 200 CFU/mL and an</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>4.2.1 Water bacteriology</b> The supplier of water treatment equipment is responsible for recommending a method of cleaning the equipment so that product water meeting the microbial requirements of this standard can routinely be produced when typical feed water is presented. Beyond this qualification, it becomes the responsibility of the user of the system to monitor the system for ongoing compliance with the standard.</p>

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	<p>endotoxin concentration of less than 2 EU/mL. The action level for the total viable microbial count in the product water shall be 50 CFU/mL and the action level for the endotoxin concentration shall be 1 EU/mL. If these action levels are observed in the product water, corrective measures, such as disinfection and retesting, shall be taken promptly to reduce the levels into an acceptable range.</p> <p>The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete water treatment, storage, and distribution system is capable of meeting the requirements of this standard, including those related to action levels, at the time of installation.</p> <p>Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.</p>	<p>When this standard was initially developed, it was considered that neither the water used to prepare dialysate nor the dialysate itself needed to be sterile. However, several studies had demonstrated that the attack rates of pyrogenic reactions were related directly to the number of bacteria in dialysate (Dawids and Vejlsgaard 1976; Favero et al. 1974; Favero et al. 1975). These studies provided the rationale for setting the guidelines in the first edition of the hemodialysis standard at 2000 bacteria per mL in dialysate and at 200 bacteria per mL for the water used to prepare dialysate. In the latter case, it was known that if the level of contamination exceeded 200 bacteria per mL in water, this level could be amplified in the system and effectively constitute a high inoculum for dialysate at the start of a dialysis treatment. Even at low levels of bacterial contamination, pyrogenic reactions have been reported when the source of endotoxin was exogenous to the dialysis system (i.e. present in the community water supply) (Hindman et al. 1975). In addition, it had been shown that problems relating to microbial contamination in dialysis systems did not usually have a single cause, but rather were the result of a number of causes and factors involving the water treatment system, the water and dialysate distribution systems, and, in some cases, the type of hemodialyzer. Understanding the various factors and their influence on contamination levels is the key to preventing high levels of microbial contamination.</p> <p>Several groups of investigators have shown convincingly that pyrogenic reactions are caused by lipopolysaccharides or endotoxins that are associated with gram-negative bacteria. Furthermore, gram-negative water bacteria have been shown to have the capability of multiplying rapidly in a variety of hospital-associated fluids, including distilled, deionized, reverse osmosis, and softened water, all of which can be used as supply water for hemodialysis systems. The dialysate, which is a balanced salt solution made with this water, likewise provides a very good growth medium for these types of bacteria.</p> <p>Several investigators (Jones et al. 1970; Kidd 1964) have shown that bacteria</p>

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		<p>growing in dialysate produced products that could cross the dialysis membrane. It has also been shown (Gazenfeldt-Gazit and Eliahou 1969; Raij et al. 1973) that gram-negative bacteria growing in dialysate produced endotoxins that in turn stimulated the production of anti-endotoxin antibodies in hemodialysis patients. These data suggest that bacterial endotoxins, although relatively large molecules, do indeed cross dialysis membranes, either intact or as fragments. The use of the very permeable membranes known as high-flux membranes has raised the possibility of a greater likelihood of passage of endotoxins into the blood path. Several studies support this contention. Vanholder et al. (1992) observed an increase in plasma endotoxin concentrations during dialysis against dialysate containing <math>10^3</math> to <math>10^4</math> CFU/mL <i>Pseudomonas</i> species. In vitro studies using both radiolabeled lipopolysaccharide and biological assays have demonstrated that biologically active substances derived from bacteria found in dialysate can cross a variety of dialysis membranes (Laude-Sharp et al. 1990; Evans and Holmes 1991; Lonnemann et al. 1992; Urena et al. 1992; Bommer et al. 1996). Also, patients treated with high-flux membranes are reported to have higher levels of antiendotoxin antibodies than normal subjects or patients treated with conventional low-flux membranes (Yamagami et al. 1990). Finally, the Centers for Disease Control and Prevention have reported that the use of high-flux dialyzers is a significant risk factor for pyrogenic reactions (Tokars et al. 1996). Although other investigators have not been able to demonstrate endotoxin transfer across dialysis membranes (Bemick et al. 1979; Bommer et al. 1987), the preponderance of reports now supports the ability of endotoxin to transfer across at least some high-flux membranes under some operating conditions. In addition to the acute risk of pyrogenic reactions, there is increasing indirect evidence that chronic exposure to low amounts of endotoxin may play a role in some of the long-term complications of hemodialysis therapy. Patients treated with ultrafiltered dialysate for 5 to 6 months have demonstrated a decrease in serum <math>\beta</math>2-microglobulin concentrations (Quellhorst 1998) and a decrease in markers of an inflammatory response (Schindler et al. 1994; Akrum et al. 1997). In longer-term studies, use of microbiologically ultrapure dialysate has been associated with a decreased incidence of P2-</p>



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		<p>microglobulin-associated amyloidosis (Baz et al. 1991; Schwalbe et al. 1997; Kleophas et al. 1998). Consequently, it seems prudent to impose an upper limit on the endotoxin content of the water. A level of 2 EU/mL was chosen as the upper limit for endotoxin, since these levels are easily achieved with contemporary water treatment systems using reverse osmosis, ultrafiltration, or both. Because 48 hours can elapse between sampling water for the determination of microbial contamination and receiving results, and because bacterial proliferation can be rapid, action levels for microbial counts and endotoxin concentrations were introduced in this revision of the standard. These action levels allow the user to initiate corrective action before levels exceed the maximum levels established by the standard.</p> <p>In hemodialysis, the net movement of water is from the blood to the dialysate, although within the dialyzer there may be local movement of water from the dialysate to the blood through the phenomenon of back-filtration, particularly in dialyzers with highly permeable membranes (Leypoldt et al. 1991). In contrast, hemofiltration and hemodiafiltration feature infusion of large volumes of electrolyte solution (20 to 70 L) into the blood. Increasingly, this electrolyte solution is being prepared on-line from water and concentrate. The large volumes of fluid infused in hemofiltration and hemodiafiltration, and general concerns about the transfer of endotoxin and endotoxin fragments across highflux membranes, have given rise to the concept of "ultrapure" fluids for use in dialysis applications. An "ultrapure fluid" is defined as one having a bacterial content of less than 0.1 CFU/mL and an endotoxin content of less than 0.03 EU/mL using sensitive assays (Ledebø and Nystrand 1999). This definition is now widely accepted, particularly in Europe, as the standard for use in on-line convective therapies. During the 2000 revision of this document, the committee considered adopting this standard for water to be used in hemofiltration and hemodiafiltration. However, because of insufficient experience with on-line therapies, the committee could not reach a consensus on the need for the more stringent requirements. On-line hemofiltration and hemodiafiltration systems use sequential ultrafiltration as the final step in the preparation of infusion fluid.</p>



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		<p>Several committee members felt that these point-of-use ultrafiltration systems should be capable of reducing the bacteria and endotoxin burden of solutions prepared from water meeting the requirements of this standard to a safe level for infusion.</p> <p><b>Survey Procedures:</b> Review water culture results for the previous 6-12 months. Expect results to be within these limits or action to be taken.</p>
204	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(i)</b></p> <p><b>5.2.1 Water bacteriology (tests)</b> Samples shall be collected at a point where water enters the equipment used to prepare concentrates and dialysate, or the equipment used to reprocess dialyzers, or any other point where product water is dispensed. Samples shall be assayed within 30 minutes of collection or shall be immediately stored at 4-6 °C and assayed within 24 hours of collection. Total viable counts (standard plate counts) shall be obtained using the membrane filter technique, which can include commercial water-testing devices, or spread plates. The calibrated loop technique shall not be used. Culture media should be tryptic soy agar or equivalent. Blood agar and chocolate agar shall not be used. Incubation is at 35-37°C and colonies shall be counted after 48 hours of incubation. Product water should not contain a total viable microbial count of <math>\leq 200</math> CFU/mL. Endotoxin concentrations shall be</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>5.2.1 Water bacteriology</b> A.5.2.1 Water bacteriology The low total viable microbial counts permitted under the provisions of this standard require that sensitive culturing methods be used. The membrane filter technique is particularly suited for this application because it permits large volumes of water to be assayed (Bland 1995). Since the membrane filter technique may not be readily available in clinical laboratories, the spread plate assay can be used as an alternative (Bland 1995). However, if the spread plate assay is used, this standard prohibits the use of a calibrated loop as the means of applying sample to the plate. This prohibition is based on the low sensitivity of the calibrated loop. A standard calibrated loop transfers 0.001 mL of sample to the culture medium, so that the minimum sensitivity of the assay is 1000 CFU/mL. This sensitivity is unacceptable when the maximum allowable limit for microorganisms is 200 CFU/mL. Therefore, when the spread plate method is used, a pipette must be used to place 0.1 to 0.5 mL of water on the culture medium.</p> <p>During the evolution of this standard, there has been a continuing discussion within the committee regarding the most appropriate culture medium and incubation conditions to be used for determining total viable microbial counts. Nutrient-rich media, such as blood agar and chocolate agar, are top rich for</p>

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	<p>determined by the LAL assay and in no case should be <math>\leq 2</math> EU/mL.</p>	<p>growth of the fastidious organisms found in water, and their use is specifically prohibited by this standard'. The original clinical observations on which the microbiological requirements of this standard were based used standard methods agar (SMA), a medium containing relatively few nutrients (Favero et al. 1974). In later versions of this standard, the use of tryptic soy agar (TSA), a general-purpose medium for isolating and cultivating fastidious organisms, was recommended because it was thought to be more appropriate for culturing bicarbonate-containing dialysate. However, several studies have shown that the use of nutrient-poor media, such as R2A or tryptone glucose extract agar (TGEA), results in an increased recovery of bacteria from water (Ledebø and Nystrand 1999; van der Linde et al. 1999; Pass et al. 1996; Reasoner and Geldreich 1985). The original standard also specified incubation for 48 hours at 35 to 37°C before enumeration of bacterial colonies. Extending the culturing time up to 168 hours and using incubation temperatures of 23 to 28°C has also been shown to increase the recovery of bacteria (Ledebø and Nystrand 1999; Pass et al. 1996; Reasoner and Geldreich 1985). On the basis of these results, some committee members felt that a change in culture medium and/or culturing conditions was warranted. However, other investigators have not found such clear-cut differences between culturing techniques (Arduino et al. 1991a; Arduino et al. 1991b). Moreover, culturing systems based on TSA are readily available from commercial sources, whereas those based on media, such as R2A, are not. After considerable discussion, the committee could not reach a consensus regarding changes in the assay technique, and the use of TSA or equivalent for 48 hours at 35 to 37°C remains the recommended method.</p> <p>Users and manufacturers of water purification and distribution systems should recognize, however, that the culturing conditions required by this standard may underestimate the bacterial burden in the water and fail to identify the presence of some organisms. Specifically, the recommended method may not detect the presence of various nontuberculous mycobacteria that have been associated with several outbreaks of infection in dialysis units (Bolan et al. 1985; Lowry et al. 1990). Also, the recommended method will not detect fungi and yeast, which</p>

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		<p>have been shown to contaminate water used for hemodialysis applications (Klein et al. 1990). Finally, biofilm on the surface of pipes may hide viable bacterial colonies, even though no viable colonies are detected in the water using sensitive culturing techniques (Man et al. 1998). Many disinfection processes poorly remove biofilm, and a rapid increase in the level of bacteria in the water following disinfection may indicate significant biofilm formation. Therefore, although the results of microbiological surveillance obtained using the test methods outlined in this standard may be useful in guiding disinfection schedules and in demonstrating compliance with the provisions of 4.2.1, they should not be taken as an indication of the absolute microbiological purity of the water.</p> <p><b>Survey Procedures:</b> Interview the responsible staff member regarding where samples are collected and how the tests are run. The testing may be performed on site or samples may be sent to a laboratory. Since these are not human samples, CLIA certification of the laboratories used is not required.</p> <p>“Dip” (“Millipore”) samplers are commonly used by facility staff to collect and perform water and dialysate cultures. While the use of these is allowed, you should be aware of the following concerns:</p> <ol style="list-style-type: none"> <li>1. The AAMI Action limit of 50 CFU/ml approaches the sensitivity of the Dip sampler, as these devices require between 30–300 CFU in order to have a valid result (countable paddle). When performing membrane filtration technique this can be addressed by increasing the sample volume to 10 mls; the sample volume on the dip paddles is limited to 1 ml.</li> <li>2. User Error: <ol style="list-style-type: none"> <li>a. Not following manufacturer's instructions for performing the test: Not filling with enough sample; not allowing the paddle to be in contact with sample long enough; not emptying the sample container and incubating paddle and sample together; not shaking off excess water, reading errors (e.g., reading TNTC or</li> </ol> </li> </ol>

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		<p>confluent growth as No growth) and not using a magnifying lens thus missing small colonies, etc. The surveyor can observe the practice or interview the responsible staff member concerning these issues.</p> <p>b. Not doing any sort of quality assurance to ensure the results they are getting accurate. One way to do this would be to send a duplicate sample quarterly to a microbiology lab that will actually perform the membrane filtration technique. Results of the two test methods should be comparable (not necessarily the same).</p> <p>Observe culture collection or reading of cultures if available during the survey. Interview the responsible staff member regarding these practices. If you identify a concern, review the manufacturer's guidance and facility policy and procedure.</p>
205	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(ii)</b></p> <p><b>4.2.2 Maximum level of chemical contaminants (requirements)</b>  Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to reprocess dialyzers for multiple use, shall not contain chemical contaminants at concentrations in excess of those in Table 1. The manufacturer or supplier of a complete water treatment system shall recommend a system capable of meeting the requirements of this clause given the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality. The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.2.2 Maximum level of chemical contaminants</b>  Contaminants identified as needing restriction on the allowable level that may be present in water for dialysis are divided into three groups for the purposes of this standard. The first group includes chemicals shown to cause toxicity in dialysis patients. These chemicals include fluoride, aluminum, chloramines, sulfate, nitrate, copper, and zinc. Chlorine is included here because of its potential toxicity.</p> <p>Toxicity of fluoride in dialysis patients at the levels usually associated with fluoridated water, 1 part per million (ppm), is questionable. In the absence of a consensus on fluoride's role in uremic bone disease, the committee initially thought it prudent to restrict the fluoride level of dialysate (Rao and Friedman 1975). Subsequently, illness in 8 of 8 dialysis patients, with the death of 1 patient, was reported as a result of accidental over fluoridation of a municipal water supply (COC 1980). Fluoride levels of up to 50 ppm were found in water used for dialysis that was treated only with a water softener. Probably these</p>

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	<p>water treatment, storage, and distribution system is capable of meeting the requirements of this standard at the time of installation.</p> <p><b>Table 1-Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple use<sup>a)</sup></b></p> <table><tr><th>Contaminant</th><th>Maximum Concentration (mg/L)<sup>b)</sup></th></tr><tr><td>Calcium</td><td>2 (0.1 mEq/L)</td></tr><tr><td>Magnesium</td><td>4 (0.3 mEq/L)</td></tr><tr><td>Potassium</td><td>8 (0.2 mEq/L)</td></tr><tr><td>Sodium</td><td>70 (3.0 mEq/L)</td></tr><tr><td>Antimony</td><td>0.006</td></tr><tr><td>Arsenic</td><td>0.005</td></tr><tr><td>Barium</td><td>0.10</td></tr><tr><td>Beryllium</td><td>0.0004</td></tr><tr><td>Cadmium</td><td>0.001</td></tr><tr><td>Chromium</td><td>0.0014</td></tr><tr><td>Lead</td><td>0.005</td></tr><tr><td>Mercury</td><td>0.0002</td></tr><tr><td>Selenium</td><td>0.09</td></tr><tr><td>Silver</td><td>0.005</td></tr><tr><td>Aluminum</td><td>0.01</td></tr><tr><td>Chloramines</td><td>0.10</td></tr><tr><td>Free Chlorine</td><td>0.5</td></tr><tr><td>Copper</td><td>0.10</td></tr><tr><td>Fluoride</td><td>0.20</td></tr><tr><td>Nitrate (as N)</td><td>2.00</td></tr><tr><td>Sulfate</td><td>100.00</td></tr><tr><td>Thallium</td><td>0.002</td></tr><tr><td>Zinc</td><td>0.01</td></tr></table> <p><sup>a)</sup> The physician has the ultimate responsibility for ensuring the quality of water used for dialysis.</p> <p><sup>b)</sup> Unless otherwise noted</p>	Contaminant	Maximum Concentration (mg/L) <sup>b)</sup>	Calcium	2 (0.1 mEq/L)	Magnesium	4 (0.3 mEq/L)	Potassium	8 (0.2 mEq/L)	Sodium	70 (3.0 mEq/L)	Antimony	0.006	Arsenic	0.005	Barium	0.10	Beryllium	0.0004	Cadmium	0.001	Chromium	0.0014	Lead	0.005	Mercury	0.0002	Selenium	0.09	Silver	0.005	Aluminum	0.01	Chloramines	0.10	Free Chlorine	0.5	Copper	0.10	Fluoride	0.20	Nitrate (as N)	2.00	Sulfate	100.00	Thallium	0.002	Zinc	0.01	<p>illnesses would have been less severe, if not prevented, if the dialysis water had been treated with deionization or reverse osmosis. If deionization is used, implementation of the monitoring requirements listed in 4.3.4 must be closely adhered to. In one case, where deionizers were allowed to exhaust, 12 of 15 patients became acutely ill from fluoride intoxication (Arnow et al. 1994). Three of the patients died from ventricular fibrillation. Fluoride concentrations in the water used to prepare the dialysate were as high as 22.5 ppm.</p> <p>The suggested maximum aluminum level has been specified to prevent accumulation of this toxic metal in the patient (Kovalchik et al. 1978). Aluminum is particularly likely to increase suddenly to high levels caused by changes in the method of water treatment to include aluminum-containing compounds. As with fluoride, water treatment would provide a measure of safety should the aluminum levels increase dramatically between chemical tests of the product water.</p> <p>The toxicity of chloramines is undisputed (Eaton et al. 1973). Although the role of free chlorine in oxidative blood damage is unclear, its high oxidation potential and ability to form chloramines suggests the avoidance of highly chlorinated water in preparation of dialysate.</p> <p>Sulfate at levels above 200 mg/L has been related to nausea, vomiting, and metabolic acidosis. The symptoms disappear when the level remains below 100 mg/L (Comty et al. 1974). Nitrates are a marker for bacterial contamination and fertilizer runoff, and have caused methemoglobinemia (Carlson and Shapiro 1970). They should, therefore, be permitted only at very low levels. Both copper and zinc toxicity have been demonstrated when these substances are present in dialysate at levels below those permitted by the U.S. Environmental Protection Agency (EPA) standard (Ivanovich et al. 1969; Petrie and Row 1977). Hence, a lower level has been chosen.</p> <p>The second group of chemical contaminants is based on the EPA's Safe</p>
Contaminant	Maximum Concentration (mg/L) <sup>b)</sup>																																																	
Calcium	2 (0.1 mEq/L)																																																	
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Antimony	0.006																																																	
Arsenic	0.005																																																	
Barium	0.10																																																	
Beryllium	0.0004																																																	
Cadmium	0.001																																																	
Chromium	0.0014																																																	
Lead	0.005																																																	
Mercury	0.0002																																																	
Selenium	0.09																																																	
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Fluoride	0.20																																																	
Nitrate (as N)	2.00																																																	
Sulfate	100.00																																																	
Thallium	0.002																																																	
Zinc	0.01																																																	

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		<p>Drinking Water Act (see 2.6). When this standard was initially developed, the Safe Drinking Water Act included barium, selenium, chromium, lead, silver, cadmium, mercury, and arsenic. Selenium and chromium levels were set at the "no-transfer" level (Klein et al. 1979). The "no-transfer" level was chosen even though it is above the EPA limit for selenium and 28 % of the EPA limit for chromium, because a restriction is not needed below the level at which there is no passage from the dialysate to the blood. The standard specified the maximum allowable limits for the other contaminants in this group at one tenth of the EPA maximum allowable limits because the volume of water used for dialysis far exceeds that used for drinking water, because protein binding of these solutes may occur in the blood, and because there is reduced renal excretion of these substances. These reduced limits were selected using the following assumptions: (1) feed water entering dialysis systems typically meets the EPA Safe Drinking Water Act (see 2.6); (2) typically, reverse osmosis treatment removes 90 % to 99 % of dissolved inorganic solids; and (3) reverse osmosis-treated water is a suitable standard for safety of water used in dialysis. These assumptions are based on the recommendations of Keshaviah et al. (1980). The committee recognized that these assumptions are questionable but reasoned that setting standards in this way will cause little or no economic impact, even though some feed water exceeds the EPA maximum allowable levels. It should be noted that the level for arsenic, 0.05 mg/L, in the Keshaviah report is a typographical error. The correct value is 0.005 mg/L as given in Table 1 of this standard (E. Klein, personal communication).</p> <p>At the time of the 2000 revision of this standard, several changes had occurred in the Safe Drinking Water Act. Specifically, antimony, beryllium, free cyanide and thallium had been added to the list of contaminants covered by the Act and the maximum allowable levels for cadmium and lead had been decreased. For consistency, the committee chose to add antimony, beryllium, and thallium to the standard. The maximum allowable levels of antimony and thallium were set at values above one-tenth of the EPA maximum allowable level because of limitations in the sensitivity of commonly available analytical methods for these</p>



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		<p>two contaminants. After considerable discussion, the committee chose not to add free cyanide to the standard. There was concern that special requirements for sample collection and shipment, together with the need to pre-treat the sample before analysis to eliminate interfering substances, would impose a burden on dialysis facilities that could not be justified in the absence of specific toxicity data. More generally, the committee recognized that little, if any, data existed to indicate hemodialysis patients are at particular risk from the four contaminants noted above solely by virtue of their inclusion in the Safe Drinking Water Act. Therefore, the committee agreed that a comprehensive review of the toxicity of these contaminants in hemodialysis patients should be undertaken before the next scheduled review of ANSI/AAMI RD62:2001, Water treatment equipment for hemodialysis applications. The committee also decided not to decrease the maximum allowable levels of cadmium and lead in the standard. This decision was based on the absence of toxicity data in dialysis patients treated with water that meets the current standard and the minimum detection levels of currently used analytical methods.</p> <p>The third group of substances addressed in 4.2.2 and Table 1 consists of physiological substances that can adversely affect the patient if present in the dialysate in excessive amounts. Calcium, potassium, and sodium are examples of these substances.</p> <p>Of the physiological substances that can be harmful when present in excessive amounts, calcium has been reduced from the 10 ppm originally selected to 2 ppm, on the basis of the critical role of calcium in bone disorders associated with renal disease. A level of 10 ppm would have allowed a potential 20 % error in dialysate calcium, whereas a level of 2 ppm reduces that error risk to less than 5 %. Table 1 of this standard should not be taken as a definitive list of harmful substances, but as a partial listing of those that might reasonably be expected to be present and have clinical implications. Iron is not included because it does not enter the patient's blood in sufficient quantities to cause toxicity. Iron may, however, cause fouling of water purification devices (see</p>

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		<p>4.3.1) or dialysate supply systems. While the AAMI Renal Disease and Detoxification Committee chose not to set a specific limit, water treatment equipment suppliers are encouraged to consider the iron content of the feed water when recommending suitable equipment. During the first revision of this standard, a concern was raised regarding the injection of formulated phosphates (known as polyphosphates) primarily to bind iron and manganese to avoid the staining of fixtures and clothing. The concern was raised that this practice could cause significant problems in water purification. At the time of the 2000 revision of the standard, some municipal water suppliers were considering the use of chlorine dioxide as a disinfectant for potable water supplies. Chlorine dioxide breaks down in water to yield chlorite, chlorate, and chloride ions. The committee could find little information about the potential for chlorine dioxide and its daughter products to be toxic to hemodialysis patients. A limited study of 17 patients unknowingly treated with purified water prepared by carbon adsorption and reverse osmosis from water disinfected with chlorine dioxide showed no evidence of adverse effects (Ames and Stratton 1987). In that study, the purified water used to prepare dialysate contained 0.02 to 0.08 mg/L of chlorite ions and no detectable chlorate ions. However, the patient population was small, and potentially important hematological parameters were not measured. Further, there was only sparse data included on the removal of chlorine dioxide, chlorite ions, and chlorate ions by carbon adsorption and reverse osmosis, and it was not clear that sufficiently sensitive methods were available for their analysis in a dialysis facility. Therefore, the committee concluded that there was no basis for setting maximum allowable levels of chlorine dioxide, chlorite ions, or chlorate ions in water to be used for dialysis applications, or for making recommendations on methods for their removal at that time. However, in specifying water purification systems, manufacturers of such systems should be aware of the possibility that municipal water suppliers may add chlorine dioxide to the water.</p> <p>When the standard was originally developed, limits could not be set for toxic organic substances or for radioactive materials (Keshaviah et al. 1980).</p>

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		<p>However, the committee noted that the EPA drinking water standard (see 2.6) lists maximum contaminant levels (MCL) for more than 50 toxic organic substances. Following the rationale used in establishing levels for other potentially toxic contaminants that have not been shown to be harmful to dialysis patients (see previous paragraph), it is reasonable that these levels should be reduced tenfold if they are monitored. This data is provided for information purposes only, because these substances are only representative of a vast number of contaminants that occur in tap water, all of whose toxic effects are largely unknown (Keshaviah et al,1980). The committee also agreed with the Keshaviah report that systems including reverse osmosis and carbon filtration would adequately remove most organics.</p> <p><b>Survey Procedures:</b> Use the survey tasks of staff interview, observation of testing, and review of facility records to determine compliance with this regulation.</p>																																							
206	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(ii)</b></p> <p><b>5.2.2 Maximum level of chemical contaminants (tests)</b> Chemical analyses of the water contaminants listed in Table 1 of 4.2.2 shall be obtained by using methods referenced in the American Public Health Association's Standard Methods for the Examination of Water and Wastewater (see 2.3), methods referenced in the U.S. Environmental Protection Agency's Methods for the Determination of Metals in Environmental Samples (see 2.4), and/or other equivalent analytical methods. Samples shall be collected at the end of the water purification cascade and at the most distal</p>	<p><b>Table 2-Analytical tests for chemical contaminants</b></p> <table> <tr> <th>Contaminant</th><th>Test Name</th><th>Applicable Document, Test Number</th></tr> <tr> <td>Aluminum</td><td>Atomic Absorption (Electrothermal)</td><td>2.3, #3113</td></tr> <tr> <td>Antimony</td><td>Atomic Absorption (Platform)</td><td>2.4,#200.9</td></tr> <tr> <td>Arsenic</td><td>Atomic Absorption (gaseous hydride)</td><td>3.3, #3114</td></tr> <tr> <td>Barium</td><td>Atomic Absorption (Electrothermal)</td><td>2.3, #3113</td></tr> <tr> <td>Beryllium</td><td>Atomic Absorption (Platform)</td><td>2.4,#200.9</td></tr> <tr> <td>Cadmium</td><td>Atomic Absorption (Electrothermal)</td><td>2.3, #3113</td></tr> <tr> <td>Calcium</td><td>EDTA Titrimetric Method, or Atomic Absorption (direct aspiration), or ion specific electrode</td><td>2.3, #3500-Ca D 2.3, #3111B</td></tr> <tr> <td>Chlorine and Chloramines</td><td>DPD Ferrous Titrimetric Method, or DPD Colorimetric method</td><td>2.3, #4500-CL F 2.3, #4500-CL G</td></tr> <tr> <td>Chromium</td><td>Atomic Absorption (Electrothermal)</td><td>2.3, #3113</td></tr> <tr> <td>Copper</td><td>Atomic Absorption (direct aspiration) or Neocuproine Method</td><td>2.3, #3113 2.3, #3500 Cu D</td></tr> <tr> <td>Fluoride</td><td>Ion Selective Electrode method or SPADNS method</td><td>2.3, #4500-F<sup>-</sup> C 2.3, #4500-F<sup>-</sup> D</td></tr> <tr> <td>Lead</td><td>Atomic Absorption (Electrothermal)</td><td>2.3, #3113</td></tr> </table>	Contaminant	Test Name	Applicable Document, Test Number	Aluminum	Atomic Absorption (Electrothermal)	2.3, #3113	Antimony	Atomic Absorption (Platform)	2.4,#200.9	Arsenic	Atomic Absorption (gaseous hydride)	3.3, #3114	Barium	Atomic Absorption (Electrothermal)	2.3, #3113	Beryllium	Atomic Absorption (Platform)	2.4,#200.9	Cadmium	Atomic Absorption (Electrothermal)	2.3, #3113	Calcium	EDTA Titrimetric Method, or Atomic Absorption (direct aspiration), or ion specific electrode	2.3, #3500-Ca D 2.3, #3111B	Chlorine and Chloramines	DPD Ferrous Titrimetric Method, or DPD Colorimetric method	2.3, #4500-CL F 2.3, #4500-CL G	Chromium	Atomic Absorption (Electrothermal)	2.3, #3113	Copper	Atomic Absorption (direct aspiration) or Neocuproine Method	2.3, #3113 2.3, #3500 Cu D	Fluoride	Ion Selective Electrode method or SPADNS method	2.3, #4500-F <sup>-</sup> C 2.3, #4500-F <sup>-</sup> D	Lead	Atomic Absorption (Electrothermal)	2.3, #3113
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	point in each water distribution loop. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials (see 4.3.2). Appropriate containers and pH adjustments shall be used to ensure accurate determinations. Table 2 lists the test for each element, along with a reference to the appropriate normative reference.	Magnesium	Atomic Absorption (direct aspiration)	2.3, #3111
		Mercury	Flameless Cold Vapor Technique (Atomic Absorption)	2.3, #3112
		Nitrate	Cadmium Reduction method	2.3, #4500-NO <sub>3</sub> E
		Potassium	Atomic Absorption (direct aspiration), or Flame Photometric Method, or Ion Specific electrode	2.3, #3111 2.3, #3500 K D 2.3, #3500-K E
		Selenium	Atomic Absorption (gaseous hydride) or Atomic Absorption (Electrothermal)	2.3, #3114 2.3, #3113
		Silver	Atomic Absorption (Electrothermal)	2.3, #3113
		Sodium	Atomic Absorption (direct aspiration), or Flame Photometric Method, or Ion Specific electrode	2.3, #3111 2.3, #3500-Na D
		Sulfate	Turbidimetric method	2.3, #4500-SO <sub>4</sub> <sup>2-</sup> E
		Thallium	Atomic Absorption (Platform)	2.4, 200.9
		Zinc	Atomic Absorption (direct aspiration) or Dithizone Method	2.3, #3111 2.3, #3500-Zn D
		<b>Survey Procedures:</b> Review the results of the water analysis. Interview the responsible staff member regarding where the samples are taken.		
207	<b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b>  <b>4.3 Water treatment equipment requirements</b>  <b>4.3.1 General</b> The supplier of a water treatment system or a laboratory specified by the physician shall perform chemical analyses on feed water to determine the compatibility of the system with the feed water and the suitability of the system for providing product water meeting the requirements of 4.2.2. The result of the	<b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b>  <b>A.4.3.1 General</b> The supplier of the complete water treatment system is responsible for assuring that the water produced by the system can routinely meet the maximum allowable chemical contaminant levels specified in Table 1, or the prescription of the physician, at installation. Beyond this qualification, it becomes the responsibility of the physician in charge of dialysis to monitor the system to assure that the treatment device or devices maintain an acceptable level of purity of the water. Variations in water quality or the presence of as-yet-unidentified toxic substances will obviously compromise the system's safety (Keshaviah et al. 1980). Such variations typically do occur, and while the supplier cannot be held accountable for the performance of the water treatment		

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	<p>chemical analyses shall be available to the physician in charge of dialysis. In the case of an individual device, the person incorporating the device into the water treatment system is responsible for ensuring that incorporation of the device does not compromise the ability of the overall system to deliver product water capable of meeting the requirements of 4.2.2.</p>	<p>system during such variations, selection of water purification equipment should include careful consideration of methods to cope with such changes, many of which may be anticipated through consultation with state and local water authorities.</p> <p>The medical director has the ultimate responsibility for the selection and use of water purification devices on the basis of the supplier's recommendations. If a supplier is convinced that the local water quality is such that the selection of a minimum system does not provide an adequate margin of safety, then the supplier should recommend additions to the system or alternative systems with corresponding rationale. Continued monitoring of the water supply is necessary to maintain treatment methods consistent with safety.</p> <p><b>Survey Procedures:</b> Review water analysis results. How does the physician director demonstrate review of these results? This could be by signing the lab report, or could be by including this review in the QAPI records. If any of the values are outside parameters, expect immediate notification of the physician director, and action to be taken.</p>
208	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.2 Materials compatibility</b> The materials of any components of water treatment systems (including piping, storage, and distribution systems) that contact the purified water shall not interact chemically or physically so as to adversely affect the purity or quality of the product water. Such components shall be fabricated from unreactive materials (e.g., plastics) or appropriate stainless steel. The use of</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.2 Materials compatibility</b> Nontoxicity of construction materials for hemodialysis equipment is of major importance. Data is now available that demonstrates that materials once regarded as inert may in fact be toxic in this application (e.g., copper leaches from copper conduits, especially in the presence of low pH, which may result when a deionizer is exhausted) (Keshaviah et al, 1980). Other materials have been documented as being hazardous to the patient (e.g., brass, zinc, iron, and aluminum), and these materials should also be avoided. Some well-recognized nontoxic materials include certain stainless steel formulations, silicon rubber, borosilicate glass, polypropylene, polyvinylchloride (PVC), and</p>

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	<p>materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is specifically prohibited. Chemicals infused into the water, such as iodine, acid, flocculants, and complexing agents, shall be shown to be nondialyzable or shall be adequately removed from product water; monitors or specific test procedures to verify removal of additives shall be provided.</p>	<p>polytetrafluorethylene (PTFE). The hidden hazard with respect to construction materials derives from long-term cumulative toxicity. Patients on hemodialysis may well have a life expectancy in excess of 10 years, and this fact must be acknowledged when selecting construction materials. Direct testing for chemicals leached from components cannot be specified at this time because of a lack of suitable procedures.</p> <p>Repeated exposure to ozone or hot water may have a deleterious effect on some plastic or metal materials. Therefore the committee chose to require manufacturers to include warnings that only ozone- or heat-compatible materials be used in piping systems intended for use with ozone or hot water disinfection devices, respectively.</p> <p><b>Survey Procedures:</b> Interview responsible staff members (e.g., chief technician, area technical manager) regarding precautions in place to protect the water system from incompatible materials.</p>
209	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.3 Disinfection protection</b> When the manufacturer recommends chemical disinfectants (see 4.1.2(26)), means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications. When recommending chemical disinfectants, the manufacturer shall also recommend methods for testing for residual levels of the disinfectants. When disinfection is accomplished automatically by chemical</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.3 Disinfection protection</b> Disinfection procedures may render product water unsafe because of toxic chemicals or excessive temperatures. Therefore, the committee felt that provision should be made for restoring the water treatment system to a safe condition after disinfection. Although the committee recognized that the user is responsible for carrying out manual disinfection procedures, the committee believes that the manufacturer should demonstrate that recommended disinfection procedures meet the requirements of 4.3.3.</p> <p><b>Survey Procedures:</b> Interview responsible staff regarding methods used to ensure the system is clear of disinfectant prior to use for patient treatment. If there is an automated</p>



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	disinfectant, including ozone, or by high temperature procedures, activation of the disinfection system shall result in activation of a warning system and measures to prevent patient exposure to an unsafe condition.	disinfection system, interview staff and make observations to ensure the system includes a warning system.
<b>210</b>	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.4 Safety requirements</b> Each water treatment device shall exhibit the following minimum safety requirements (additional safety requirements specific to individual types of devices are listed in the appropriate subclauses of 4.3):</p> <ol style="list-style-type: none"> <li>1. Monitors shall be designed so that the monitor cannot be disabled while a patient is at risk, except for brief, necessary periods of manual control with the operator in constant attention.</li> <li>2. The sound emitted by audible alarms shall be at least 65 decibels ("A" scale) at 3 meters and it shall not be possible to silence these alarms for more than 180 seconds.</li> <li>3. Resistivity, conductivity, or totally dissolved solids (TDS) monitors shall be temperature compensated.</li> <li>4. Operating controls shall be positioned so as to minimize inadvertent resetting.</li> <li>5. Electrical circuits shall be separate from hydraulic circuits and adequately protected from fluid leaks.</li> </ol>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.4 Safety requirements</b> Although some of these requirements may seem obvious, the committee felt that all safety requirements should be specified. The question of whether or not audible alarms should be capable of being silenced provoked some discussion. On one hand, some felt that audible alarms should not be capable of being silenced because the alarm condition could be overlooked, allowing a dangerous situation to ensue. On the other hand, an audible alarm capable of being temporarily silenced was suggested so that the operator would have a relatively unharried period of time to correct the fault condition. The committee concluded that silencing an audible alarm for up to 180 seconds was a reasonable requirement.</p> <p><b>Survey Procedures:</b> Use the survey tasks of observation, staff interview and review of facility records to determine compliance with this requirement.</p>
<b>211</b>	<b>AAMI RD 62 Requirements as Adopted by</b>	<b>AAMI Rationale for the Development and Provisions of this Recommended</b>

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	<p><b>Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.5 Regenerated or reconstituted devices</b> All devices that are regenerated or reconstituted off-site, such as deionizers, shall be disinfected at the time of regeneration or reconstitution so that contaminated water is not reintroduced into the system after regeneration or reconstitution. Separate processes shall be employed to ensure no intermixing of devices or their components between devices returned from medical or potable water users and devices returned from nonpotable water users.</p>	<p><b>Practice</b></p> <p><b>A.4.3.5 Regenerated or reconstituted devices</b> Regenerated or reconstituted devices are subject to bacterial contamination that can cause excessive bacterial counts in product water (see 4.2.1). Disinfection procedures are required to minimize this risk. When devices are regenerated at a central facility, there is a risk of cross-contamination and improper disinfection and rinsing (Keshavlah et al. 1980): Some exchange-type deionizers are used for both dialysis and industrial recovery of plating metals, such as chromium and silver, from effluent process water. In some regeneration facilities, resins from both process and non potable users and from medical or potable users are regenerated together as a batch. Traces of these toxic metals will remain bound to the resins and may be eluted into water during subsequent use. For that reason, the committee felt that such mixed use shall be prohibited.</p> <p><b>Survey Procedures:</b> If exchanges tanks are used review documentation that provides evidence of disinfection at the time of regeneration or reconstitution, and that the device and its components are segregated from non-medical/ nonpotable use devices.</p>
212	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.6 Deionization</b> Deionization systems, when used to prepare water for hemodialysis applications, shall be monitored continuously to produce water of one megohm/cm or greater specific resistivity (or conductivity of, one microsiemen/cm or less) at 25°C.</p> <p>An audible and visual alarm shall be activated when the product water resistivity falls below</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.6 Deionization</b> Deionizer systems, during exhaustion, have the capability of releasing into the water potentially harmful contaminants at levels much higher than are present in the untreated feed water (Johnson and Taves 1974; Bland et al. 1996). The monitor level of 1 megohm/cm specific resistivity was selected as the point at which most of the useful capacity of the deionizers used in dialysis water treatment has been consumed and below which rapid degradation of Ion removal efficiency takes place. One megohm/cm specific resistivity is not the minimum safe value for dialysis water, but deionizer systems producing water dropping below this value are in danger, during the following dialysis</p>

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	<p>this level and the product water stream shall be prevented from reaching any point of use, for example by being diverted to drain. (Deionizers used to prepare water for home hemodialysis or, for portable dialysis systems are exempt from the requirement for diversion of flow.) The alarm must be audible in the patient care area.</p> <p>Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.</p> <p>If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device.</p>	<p>treatment, of producing water high in toxic contaminants as final deterioration of resin accelerates. A requirement that the product water be diverted to drain was included because of the acute danger that an exhausted deionizer can pose to patients (Amow et al. 1994). The requirement for activated carbon adsorption in advance of the deionizer prevents generation of possibly carcinogenic nitrosamines (Simenhoff et al. 1983). Deionizers are subject to bacterial contamination because of the porous structure of the resins. Although the level of bacterial contamination in product water from deionizers varies widely, it is generally highest after the deionizer has been idle for some time and lowest after continuous use. Because deionizers are usually placed last in a purification cascade, they should be followed by an ultrafilter to prevent bacterial contamination of the water storage and distribution system.</p> <p><b>Survey Procedures:</b> Use the survey tasks of observation during inspection of the water treatment system and staff interview to determine compliance with this requirement for systems which include DI.</p>
213	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.7 Reverse osmosis</b> The following requirements shall apply to reverse osmosis systems:</p> <p>1. When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of AAMI RD 62, 5.2.2.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.7 Reverse osmosis</b> A reverse osmosis system should demonstrate delivery of water meeting the requirements of 4.2.2; otherwise, additional treatment devices should be recommended to the user. Monitoring requirements for reverse osmosis systems are recommended on the basis of totally different degradation characteristics of these systems as compared with deionizer systems. On initial setup, the reverse osmosis device should have a rejection rate that ensures that the product water of the water treatment system meets the requirements of 4.2.2. Because this rejection rate varies with different installations, an absolute level is not required. Monitoring is defined in terms of the salt passage rate, or percent rejection, and a threshold level of product water resistivity or conductivity.</p>

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	<p>2. Reverse osmosis devices shall be equipped with on-line monitors that allow determination of rejection rates and product water conductivity. The product water conductivity monitor should activate audible and visual alarms when the product water conductivity exceeds the preset alarm limit. The audible alarm must be audible in the patient care area when reverse osmosis is the last chemical purification process in the water treatment system. Monitors that measure resistivity or TDS may be used in place of conductivity monitors.</p> <p>In addition, it is recommended that when a reverse osmosis system is the last chemical purification process in the water treatment system, it includes a means to prevent patient exposure to unsafe product water, such as diversion of the product water to drain, in the event of a product water conductivity or rejection alarm.</p>	<p>Compliance with both monitored parameters is required, since an increase in feed water contaminants may result in product water unsuitable for hemodialysis applications even though the percent rejection of the membrane modules remains high.</p> <p>The committee could not reach consensus on how to establish the alarm limits for rejection and product water resistivity or conductivity. As noted above, changes in feed water quality will result in changes in product water quality even though rejection remains constant. Also, a significant change in the feed water concentration of one trace inorganic contaminant may not appreciably alter the product water resistivity even though the product water concentration of that contaminant exceeds the allowable limit. For that reason, some committee members felt that routine analysis of feed water quality should be emphasized. Other committee members felt that the rejection alarm limit could be set based on the reduction ratio for each contaminant that can be achieved by reverse osmosis (Luehmann et al. 1989) and the assumption that the feed water would meet the requirements of the Safe Drinking Water Act. Either approach may be effective when incorporated into an overall monitoring program designed to protect the patient against exposure to contaminant levels in excess of those listed in Table 1.</p> <p>The committee could not reach consensus regarding the inclusion of a requirement that reverse osmosis systems incorporate a means of diverting the product water to drain in the event of a product water conductivity or rejection rate alarm. Some committee members felt that a divert-to-drain should be required because reverse osmosis is frequently the primary means of water purification. However, other committee members felt that including a divert-to-drain should be optional. They pointed out that, because reverse osmosis membranes tend to fail gradually, the risk is different from exhaustion of a deionizer where very high levels of contaminants, such as fluoride, may occur abruptly in the product water because of competitive binding at the ion exchange sites of the deionizer resin. Furthermore with direct feed water</p>

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		<p>distribution systems, a divert-to-drain would cause an immediate alarm condition with all dialysis machines as a result of interrupting their water supply. Under such circumstances, the ability to discontinue dialysis electively may pose the least risk to the patients. Therefore, a divert-to-drain was included as a recommendation and not as a requirement.</p> <p><b>Survey Procedures:</b> Use the survey tasks of observation during inspection of the water treatment system and staff interview to determine compliance with this requirement for RO systems.</p>
214	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.8 Sediment filters</b> Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.8 Sediment filters</b> Accumulation of organics, bacteria, algae, etc., on filters can lead to proliferation of bacteria to the point of overloading downstream elements or producing dangerous endotoxin levels. Use of opaque housings to reduce the light that promotes algae growth and differential pressure monitoring can reduce this risk.</p> <p><b>Survey Procedures:</b> Observe the filter housings during your inspection of the water treatment system. All housings should be opaque.</p>
215	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.9 Carbon adsorption media</b> Carbon adsorption systems shall be adapted specifically to the maximum anticipated water flow rate of the system. Two carbon adsorption beds shall be installed in a series configuration. A means shall be provided to</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.9 Carbon adsorption media</b> Carbon adsorption beds are particularly prone to bacterial infection because of their porosity and affinity for organics. More stringent requirements for the installation of carbon adsorption beds and their monitoring were included in the second revision of this standard because of continued reports of clusters hemolysis related to insufficient removal of chloramines from municipal water</p>

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	<p>sample the product water from the first bed. Exhausted carbon adsorption media shall be discarded and replaced with new media according to a replacement schedule determined by regular monitoring. For example, when testing between the beds shows that the first bed is exhausted, the second bed should be moved into the first position, the second bed replaced with a new bed, and the exhausted bed discarded. When granulated activated carbon is used as the adsorption medium, the carbon shall have a minimum iodine number of 900 and each adsorption bed shall have an empty bed contact time (EBCT) of at least 5 minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes). When other forms of carbon are used, the manufacturer shall provide performance data to demonstrate that each adsorption bed has the capacity to reduce the chloramine concentration in the feed water to less than 0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines. Regenerated carbon shall not be used. (Carbon adsorption systems used to prepare water for home dialysis or for portable dialysis systems are exempt from the requirement for the second carbon and a 10-minute EBCT, provided that removal of chloramines to below 0.1 mg/L is verified</p>	<p>supplies (Caterson et al. 1982; Tipple et al. 1991; Ward 1996). Changes to the Safe Drinking Water Act, designed to eliminate lead and copper from tap water (Petersen et al. 1991), reinforce the need for careful monitoring of carbon adsorption beds, since the increase in water pH which may accompany institution of these changes may decrease the adsorptive capacity of carbon for chloramines.</p> <p>Activated carbon may be regenerated by a number of techniques, including oxidation at high temperatures and stripping with low-pressure steam or solvents. Regeneration of activated carbon, also known as reactivation, is used in industrial applications where activated carbon may be used to remove organic and inorganic substances, such as pollutants, from process streams. The Committee could find no evidence that regenerated carbon was being used for hemodialysis applications. However, the Committee felt that it was prudent to prohibit the use of regenerated carbon in hemodialysis applications to avoid any potential hazard resulting from residual toxins that may remain in the carbon following regeneration.</p> <p>Depending on the source material used for its manufacture, and the manufacturing process, granular activated carbon may contain carbon fines and other contaminants, such as aluminum. If present, these substances will leach out of a carbon adsorption bed during the initial stages of operation. Carbon fines may contribute to fouling of reverse osmosis membranes downstream of the carbon adsorption beds and any metal ions may add to the burden of contaminants which must be removed from the water. Acid washing of carbon minimizes the amount of fines and other contaminants, and some committee members felt that use of acid-washed carbon should be required. No consensus could be reached on this issue, because rinsing of carbon adsorption beds before they are placed on-line in a water purification cascade will also effectively remove fines and other contaminants.</p> <p>The requirement for two adsorption beds in series and a 10-minute empty bed</p>



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	before each treatment.)	<p>contact time was waived for portable dialysis systems because of the impracticality of providing these features while retaining the portability of the system. However, when a single adsorption bed is used, it is important to ensure that the bed has adequate capacity to remove chloramines for the duration of an entire treatment given the typical feed water concentration of chloramines in the setting where the bed is being used.</p> <p>Although treatment of water by carbon adsorption is the usual method of meeting the requirement of 4.2.2 for chloramines, the committee recognized that in certain situations, such as acute or home dialysis with portable water treatment systems, it may not be practical to use the volume of carbon required for this purpose. In such circumstances, combining limited carbon adsorption with the addition of ascorbic acid to the acid concentrate has been used to eliminate chloramines from the final dialysate (Ward 1996). It should be noted that some minimum contact time is required for ascorbic acid to neutralize chloramines in water. If ascorbic acid is being used to neutralize chloramines, and unexplained red cell destruction or anemia occurs, the effectiveness of the ascorbic acid neutralization of chloramines should be investigated.</p> <p><b>Survey Procedures:</b>  Observe for two carbon tanks (or banks of tanks) during your inspection of the water treatment system. Interview the responsible staff member regarding EBCT and the type of carbon used in the tanks.</p> <p>When the first tank is exhausted, the facility may move the second tank into the first position and replace the second tank, or may choose to replace the carbon in both tanks. Either is acceptable.</p>
216	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.10 Automatically regenerated water softeners</b></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.10 Automatically regenerated water softeners</b>  The process by which "hard" water (containing high levels of calcium and</p>

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	<p>Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration. It is recommended that the face of the timers used to control the regeneration cycle be visible to the user.</p>	<p>magnesium) is made "soft" involves the exchange of sodium ions for the calcium and magnesium in the water supply. The resin must be regenerated with brine to sustain capacity for exchange. Regeneration may be either manual or automatic with a timer to regenerate outside operating hours. During regeneration, excess sodium may enter the product water stream if there is a temporary interruption of power, a malfunction in regeneration control, or inadequate water pressure. There are no monitors on a softener to detect excess sodium in the product water stream, and the physiological effects of excess sodium in the patient are severe (Nickey et al. 1970; Robson 1978). Therefore, the committee felt strongly that a protection against such excessive levels of sodium, as may occur during regeneration of a water softener, should be required. An automatic bypass valve most easily provides this protection during the regeneration cycle.</p> <p><b>Survey Procedures:</b> Interview the responsible staff member regarding how highly concentrated salt solution is prevented from entering the product water line. Observe that faces of the timers can be seen.</p>
217	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.11 Storage tanks</b> When used, storage tanks should have a conical or bowl-shaped base and should drain from the lowest point of the base. Storage tanks should have a tight-fitting lid and be vented through a hydrophobic 0.2-micron air filter. Means shall be provided to effectively disinfect any storage tank installed in a water distribution system.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.11 Storage tanks</b> The large volume and low water velocities in storage tanks predispose them to bacterial contamination. As a consequence, these tanks must be designed with features to prevent entry of bacteria and to facilitate disinfection procedures.</p> <p><b>Survey Procedures:</b> Use the survey tasks of observation and staff interview to determine compliance with this regulation.</p>
218	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p>

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	<p><b>4.3.12 Ultrafilters</b></p> <p>When used in a water purification system for hemodialysis applications, an ultrafilter shall be shown to reduce the concentrations of bacteria and endotoxin in the feed water to the ultrafilter by factors at least as great as those specified in the manufacturer's labeling. It is recommended that ultrafilters be configured in a cross-flow mode. However, dead-end filters that have validated endotoxin and bacterial removal characteristics may also be used. It is recommended that ultrafilters have an opaque housing or that other means be used to inhibit proliferation of algae.</p>	<p><b>A.4.3.12 Ultrafilters</b></p> <p>Ultrafilters are increasingly being used to provide water of high microbiologic purity for dialysis applications. In general, ultrafilters are characterized by their molecular weight cut-off. However, in hemodialysis applications, the principal role of ultrafilters is to remove bacteria and endotoxins. Therefore, the committee chose to define ultrafilters in these terms. This choice also provides a basis for monitoring the performance of ultrafilters after they have been installed in a water purification system. The committee could not reach consensus regarding minimum criteria for the removal of bacteria and endotoxins by an ultrafilter. Therefore, the committee chose to require that manufacturers disclose the minimum performance of their device and that the device be required to perform to at least this level. Individual members of the committee considered that an ultrafilter should be able to reduce the concentration of bacteria in the feed water to the ultrafilter by a factor of at least <math>10^7</math> and that of endotoxin by a factor of at least <math>10^3</math>. The recommendation to use an ultrafilter in a cross-flow configuration is aimed at preventing excessive replacement of membrane modules, which may result from rapid fouling if the filter is operated in the dead-end mode. However, a dead-end configuration may perform satisfactorily in situations where the water quality is generally good (for example, as final filtration of purified water immediately before its use in dialyzer reprocessing equipment). Differential pressure measurements can be used to monitor fouling of both cross-flow and dead-end filters.</p> <p><b>Survey Procedures:</b></p> <p>Interview the responsible staff (e.g., chief technician, area technical manager) regarding the monitoring of the function of the ultrafilter. Observe for an opaque housing.</p>
219	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.13 Ultraviolet irradiators</b></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.13 Ultraviolet irradiators</b></p>

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	<p>When used to control bacterial proliferation in water storage and distribution systems, UV irradiation devices shall be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm<sup>2</sup>. The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions and shall be equipped with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp must be replaced. It is recommended that UV irradiators be followed by an ultrafilter.</p>	<p>The effectiveness of UV irradiation depends on the dose of radiant energy. Several studies have demonstrated that a dose of 30 milliwatt-sec/cm<sup>2</sup> will kill greater than 99.99 % of a variety of bacteria, including <i>Pseudomonas</i> species, in a flow-through device (Martiny et al. 1988; Martiny et al. 1990). However, certain gram-negative water bacteria appear to be more resistant to UV irradiation than others, and use of sub-lethal doses of UV radiation, or an insufficient contact time, may lead to proliferation of these resistant bacteria in the water system (Carson and Petersen 1975). The radiant energy emitted by the mercury vapor lamps used in UV irradiators decreases with time. If the lamp is not replaced before its radiant energy decreases below the effective threshold, resistant bacteria may also develop. Therefore, the requirement for an on-line monitor of the radiant energy emitted by the lamp was included in the standard. Because the effectiveness of UV irradiation depends on the geometry of the device and the exposure time of water to the radiation, the manufacturer of a UV irradiation device is required to provide information on the killing of specific bacteria under specified operating conditions. Because UV irradiators do not eliminate endotoxin and may even increase endotoxin concentrations by killing bacteria, the committee recommended that they be followed by an ultrafilter. Use of an ultrafilter was not made a requirement, however, because reliance on an ultrafilter to remove endotoxin should not be considered an alternative to identifying and eliminating the source of bacterial contamination.</p> <p><b>Survey Procedures:</b> Observe for an on-line monitor of any UV light in use.</p>
220	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.14 Hot water disinfection systems</b> When used to control bacterial proliferation in water treatment, storage, and distribution systems, the water heater of a hot water disinfection system shall be capable of</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.14 Hot water disinfection systems</b> At the time of the 2000 revision of this standard, hot water disinfection of purified water storage and distribution systems was being introduced as a new means of controlling bacterial proliferation. The committee recognized that this new technology might have widespread applicability in dialysis facilities in</p>

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	<p>delivering hot water at the temperature and for the exposure time specified by the manufacturer.</p>	<p>light of the increased concern about endotoxin contamination of dialysate (see A.4.2.1). However, at the time of the 2000 revision of the standard, insufficient data was available to set performance standards for such systems, such as water temperature and exposure time. Therefore, the committee chose to require that the manufacturer of a hot water disinfection system disclose the operating specifications of the system until such time as performance criteria could be established. The manufacturer of a hot water disinfection system should validate the recommended operating conditions to demonstrate that they provide adequate reduction in bacterial levels. Repeated exposure to hot water may have a deleterious effect on some plastic piping. Therefore, a requirement that manufacturers of hot water disinfection systems include a warning in their product labeling about the need to use heat-resistant materials in piping systems to be disinfected with hot water was added to the standard.</p> <p><b>Survey Procedures:</b> If a hot water disinfection system is in use, interview the responsible staff (e.g., chief technician, area technical manager) as to how they assure the system meets this requirement.</p>
221	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.15 Ozone disinfection systems</b> When used to control bacterial proliferation in water storage and distribution systems, an ozone generator shall be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer. When ozone disinfection systems are used, it is recommended that an ambient air ozone monitor be installed in the area of the ozone generator.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.15 Ozone disinfection systems</b> At the time of the 2000 revision of this standard, ozonation was being introduced as a new means of controlling bacterial proliferation in purified water storage and distribution systems. The committee recognized that this new technology might have widespread applicability in dialysis facilities in light of the increased concern about endotoxin contamination of dialysate (see A.4.2.1). However, at the time of the 2000 revision of the standard, insufficient data was available to set performance standards for such systems, such as ozone concentration and exposure time. Therefore, the committee chose to require that the manufacturer of an ozone disinfection system disclose the operating specifications of the system until such time as performance criteria could be</p>

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		<p>established. The manufacturer of an ozone disinfection system should validate the recommended operating conditions to demonstrate that they provide adequate reduction in bacterial and, if applicable, endotoxin levels. The presence of ozone in product water may be harmful to patients. Therefore, the committee chose to require manufacturers to include a warning that product water should not be used until ozone produced in the disinfection process has dissipated (see 4.1.2(19)). The manufacturer should validate that residual ozone in the product water falls to acceptable levels at the end of the recommended minimum elapsed time between disinfection and use of the product water. Alternatively, the manufacturer of an ozone disinfection system may provide the user with a means of verifying that the residual ozone is within acceptable limits before product water is used.</p> <p><b>Survey Procedures:</b> As of late 2007, ozone disinfection systems had been approved by the FDA for use in bicarbonate delivery systems but not for use in product water distribution systems.</p> <p>Interview the staff member responsible for using ozone to disinfect the bicarbonate delivery system regarding how he/she determines the ozone is delivered in the concentration and for the time period required by the manufacturer. Review records of use of ozone, and any air sampling done for ambient air ozone.</p>
222	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.16 Tempering valves</b> Tempering valves shall be sized to accommodate the anticipated range of flow rates of hot and cold water. They shall be fitted with check valves to prevent backflow of water into the hot and cold water lines and</p>	<p><b>Survey Procedures:</b> During your observations in the water treatment room, determine whether tempering valves are in use. If so, interview the responsible staff member regarding how backflow of water is prevented. Observe for a means to monitor the outlet water temperature.</p>



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	with a means to monitor the outlet water temperature.	
223	<p><b>AAMI RD 62 Requirements as Adopted by Reference 42 CFR 494.40(a)(1)(iii)</b></p> <p><b>4.3.17 Piping systems</b>  The product water distribution system shall not contribute chemicals (such as aluminum, copper, lead, and zinc) or bacterial contamination to the treated water. Both direct and indirect water distribution systems should be configured as a continuous recirculation loop and designed to minimize bacterial proliferation and biofilm.</p> <p><i>End AAMI RD 62</i></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4.3.17 Piping systems</b>  The distribution system has been implicated in several bacterial contamination episodes involving dialysis patients (Petersen et al. 1978). The AAMI Renal Disease and Detoxification Committee discussed including specific design criteria, such as minimum flow velocities, to minimize bacterial proliferation and biofilm formation (Chapman et al. 1983). Differences in system configuration (for example, direct feed versus indirect feed) made it difficult to reach consensus on specific design criteria. However, the committee recommends a minimum velocity of 3 ft/s in indirect feed distribution systems. This velocity is sufficient to ensure non-laminar flow, which helps protect against biofilm formation by impairing bacterial adhesion to pipe surfaces. Other desirable design criteria include use of a distribution loop, an absence of multiple branching and dead-ended pipes, and the use of simple wall outlets with the shortest possible fluid path and a minimum of pipe fittings.</p> <p><b>Survey Procedures:</b>  Interview responsible staff (e.g., chief technician, area technical manager) regarding what safeguard they have in place to prevent insertion of non-compatible metals in the distribution loop or contamination of the loop.  Observe for any evidence of dead ended pipes in the water distribution system.</p>
224	(2) The requirements for frequency of water purity testing to insure meeting the AAMI limits specified in paragraphs (a)(1)(i) and (ii) of this section are as follows;	Cite this tag if the testing frequency is not as required under paragraphs (a)(1)(i) and (ii) below.
225	(A) Bacteria and bacterial endotoxin levels of water/dialysate must be monitored in established systems at least monthly;	For a resurvey, expect both bacteria and endotoxin levels of water and dialysate to be determined and reviewed monthly at a minimum.

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226	(B) Bacteria and bacterial endotoxin levels of water/dialysate must be monitored in newly-installed systems at least weekly until an established pattern of compliance can be demonstrated;	For an initial survey, or in the case where a water treatment or distribution system has been replaced, expect weekly monitoring until there are at least three weeks in a row with water/ dialysate testing results within the acceptable levels. After this pattern of compliance is demonstrated, the testing can be done monthly.
227	(C) In accordance with the requirements of AAMI published in “Dialysate for Hemodialysis” ANSI/AAMI RD 52:2004 section 7.2.1, which are incorporated by reference. Incorporation by reference of the AAMI Dialysate for Hemodialysis was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.	The specifics of these requirements are provided in the following tags.
226	<p><b>AAMI RD 52 Requirements as Adopted by Reference 42 CFR 494.40(a)(2)(i)(C)</b></p> <p><b>7.2 Microbial monitoring methods</b></p> <p><b>7.2.1 General</b> The microbial quality of water should be monitored at least monthly to validate the effectiveness of the disinfection program. Monitoring can be accomplished by direct plate counts, in conjunction with the measurement of bacterial endotoxin.</p>	<p><b>Survey Procedures:</b> Expect monthly microbial monitoring of the water. See “204” for discussion of concerns with the use of dip samplers.</p> <p>Endotoxin testing should be done at the same time as the bacterial culture is done.</p>
228	<p><b>AAMI RD 52 Requirements as Adopted by Reference 42 CFR 494.40(a)(2)(i)(C)</b></p> <p><b>7.2.1 Water Sample Sites:</b> Samples of water should be collected from several places to give an indication of the microbial quality of</p>	<p><b>Survey Procedures:</b> Interview the responsible staff member to determine where water culture and endotoxin samples are obtained. Expect samples to be taken from the sites listed in this regulation, generally, with the additional testing sites listed being used during initial qualification of a new system or for troubleshooting when the cause of contamination is not easily identified. .</p>

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	<p>the water throughout the water distribution system. In general, samples should be collected in the following areas: from the first and last outlets of the water distribution loop, where water enters equipment used to reprocess dialyzers, and where water enters equipment used to prepare bicarbonate concentrate or from the bicarbonate concentrate mixing tank. Additional testing, such as at the end of the water purification cascade and at the outlet of the storage tank, if one is used, may be necessary during initial qualification of a system or when troubleshooting the cause of contamination within the distribution loop.</p>	
229	<p><b>AAMI RD 52 Requirements as Adopted by Reference 42 CFR 494.40(a)(2)(i)(C)</b></p> <p><b>7.2.1 Dialysate Sample Sites:</b> Dialysate samples should also be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year.</p>	<p>Interview the responsible staff member and review documentation of dialysate culture /endotoxin testing to validate this requirement is met. Expect some system to be in place to assure every machine is tested at least annually.</p>

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230	<p><b>AAMI RD 52 Requirements as Adopted by Reference 42 CFR 494.40(a)(2)(i)(C)</b></p> <p><b>7.2.1 Investigation of positive microbial testing:</b> If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1 in the guidance.</p>	<pre> graph TD     Start([Review dialysate culture results]) --&gt; D1{Results &lt; 50 CFU/mL?}     Start --&gt; D2{Results 50-199 CFU/mL?}     Start --&gt; D3{Results ≥ 200 CFU/mL?}      D1 -- Yes --&gt; End1([Resume/Continue Routine Monthly Testing])     D1 -- No --&gt; Repeat[Repeat this site in next regular monthly sample collection]      D2 --&gt; N1[Notify Facility Manager &amp; Biomedical Technician]     N1 --&gt; R1[Review culture &amp; disinfection logs]     R1 --&gt; D1_1[Disinfect equipment or water system if necessary]     D1_1 --&gt; R2[Redraw sample]     R2 --&gt; D2_1{Results &lt; 50 CFU/mL?}     D2_1 -- Yes --&gt; Repeat     D2_1 -- No --&gt; End1      D3 --&gt; N2[Notify Medical Director, Facility Manager &amp; Biomedical Technician]     N2 --&gt; R3[Review culture &amp; disinfection logs]     R3 --&gt; D3_1[Disinfect equipment or water system if necessary]     D3_1 --&gt; R4[Redraw sample]     R4 --&gt; D3_2{Results &lt; 50 CFU/mL?}     D3_2 -- Yes --&gt; Repeat     D3_2 -- No --&gt; N3[Notify Medical Director, Facility Manager &amp; Biomedical Manager]     N3 --&gt; T1[Initiate troubleshooting protocol]     T1 --&gt; L1[-Evaluate/correct sample collection technique -Evaluate/correct bicarbonate preparation/distribution technique -Evaluate/correct water system components -Evaluate/replace equipment ultrafilters -Evaluate/implement biofilm removal protocols]     L1 --&gt; R5[Redraw sample]     R5 --&gt; D4{Results &lt; 50 CFU/mL?}     D4 -- Yes --&gt; Repeat     D4 -- No --&gt; N4[Notify Medical Director, Facility Manager &amp; Biomedical Manager]     N4 --&gt; D5{Determine whether equipment should be removed from patient use}     D5 --&gt; End1     D5 -- No --&gt; Repeat   </pre> <p>Figure 1—Example of decision tree that can be used to evaluate culture results and initiate corrective action, if necessary</p>

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		<p>The testing of sample dialysis machines is to represent ALL of the machines. If a sample machine is positive, the investigation must address procedures used in the facility to maintain all machines free of contamination. Expect to see the physician director involved in the oversight and review of the activities.</p>
231	<p><b>AAMI RD 52 Requirements as Adopted by Reference 42 CFR 494.40(a)(2)(i)(C)</b></p> <p><b>7.2.1 Repeat Cultures:</b> Cultures should be repeated when bacterial counts exceed the allowable levels. If culture growth exceeds permissible standards, the water system and dialysis machines should be cultured weekly until acceptable results are obtained. Additional samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia, and following a specific request by the clinician or the infection control practitioner.</p>	<p>When bacterial counts exceed the allowable levels, cultures must be repeated. If the system is disinfected to address the positive culture result, the machine and system must be thoroughly rinsed prior to collection of the repeat culture sample.</p> <p>If the repeat culture again shows growth exceeding the allowable limits, the facility must return to weekly cultures of a sample of the machines until acceptable results are obtained.</p> <p>Additional cultures must be taken of the involved machine if a patient experiences a pyrogenic reaction or demonstrates symptoms of septicemia (e.g., fever, chills, or diagnosis by a clinician), or if additional samples are requested by the patient's clinician or for the purposes of an investigation related to infection control.</p>
232	<p><b>AAMI RD 52 Requirements as Adopted by Reference 42 CFR 494.40(a)(2)(i)(C)</b></p> <p><b>7.2.1 Timing of Sample Collection:</b> Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines. If repeat cultures are performed after the system has been disinfected (e.g., with formaldehyde, hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before collecting samples. Drain and flush storage tanks and the distribution system until residual disinfectant is no longer</p>	<p>Interview the responsible staff member and review logs of disinfection and culture/ endotoxin reports. Compare the dates of disinfection with the dates of the samples; disinfection dates should be AFTER the sample dates.</p> <p>Interview the responsible staff member regarding procedures to ensure repeat cultures are free from potential exposure to residual disinfectant,</p>

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	detected before collecting samples.  <i>End AAMI RD 52</i>	
233	(ii) Chemical analysis of water purity must be done at least once a year and when --	Review results of chemical analysis to validate at least annual testing.
234	(A) The system is installed;	If a new system is installed, review the chemical analysis of the new system
235	(B) Membranes are replaced, if using a reverse osmosis system;	If the Reverse Osmosis (RO) system is in use, and the membranes are replaced, a water analysis must be done after installation of the new membranes. Interview the responsible staff member to determine if the RO membranes have been replaced since the last survey; if so, ask for evidence of a water chemical analysis after the new RO membranes were installed.
236	(C) Seasonal variations in source water suggest worsening water quality;	Interview the responsible staff member, recognizing in this case the responsible individual may be the chief technician, the area technical manager, or the physician director. If there has been flooding or a drought in the area of the dialysis facility, ask how the facility monitors for seasonal variations in water quality. Have there been times when the water quality worsened?
237	(D) Reverse osmosis rejection rates, which are monitored daily using continuous-reading monitors that measure product water conductivity, fall below 90 percent.	Expect RO rejection rates to be calculated at least daily if the RO monitoring system does not include this information as an automated function. The RO must be continuously monitored for quality using product water conductivity. Cite this tag if the RO is not continuously monitored.  Cite this tag if a water analysis is not done when the RO rejection rate falls below 90 percent.
238	<b>(b) Standard: Reverse Osmosis or deionization.</b> Each water treatment system must include reverse osmosis membranes of a deionization component with resistivity monitors.	Observe the water treatment components in use. Each dialysis facility must have an RO system or a deionization (DI) system. If a DI system is the final water treatment component, the product water quality must be continuously monitored using resistivity monitors.  Resistivity monitors of DI systems must incorporate audible and visual alarms that can be heard in the patient treatment area. If the facility routinely uses an RO system, but has DI tanks on site for use in emergencies, a resistivity meter should also be present and available for use in that emergency. If the facility



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		plan is to obtain DI tanks in the event of emergent need, the plan should address procuring and using a resistivity meter should DI be put in use.
<b>239</b>	<b>(c) Standard: Chlorine/chloramines.</b> The facility must ensure, on a daily basis, that the source water does not contain chlorine/chloramines or the facility must ensure that --	If the facility is not using carbon filtration, expect to see a letter from the applicable water treatment plant/ municipality stating that chlorine/ chloramine is not used in the water treatment. This letter should be current; that is dated within the previous 6 months. In addition, the facility must test the incoming water at least daily for the absence of chlorine and chloramines. Expect that this scenario would be rare.
<b>240</b>	(1) The water treatment system includes a component or carbon tank which removes chlorine/chloramines along with a backup component or second carbon tank for chlorine/chloramines removal; and	Expect each facility to have a primary and a secondary method to remove chlorine and chloramine from the incoming water. Generally, the method used will be carbon filtration.
<b>241</b>	(2) The water from the exit port of the first component or carbon tank which removes chlorine/chloramines is tested for chlorine/chloramines levels, at a minimum, before each patient shift or every 4 hours, whichever is shorter, during operation of the water treatment system.	Interview the responsible staff member to determine where the sample for chlorine/chloramine testing is collected. Validate this testing site is between the primary and secondary chlorine/chloramine removal systems.  Review logs of testing to validate that the testing is done before each patient shift or every four hours. If the facility does not have a set patient shift, but rather starts the next patient as a treatment chair is available, testing every four hours may be expected.
<b>242</b>	(i) If the test results are greater than 0.50 mg/L for free chlorine or 0.10 mg/L for chloramines from the port of the initial component or carbon tank then the second component or carbon tank which removes chlorine/chloramines must be tested; and	One test may be done if the test reagent used is sufficiently sensitive to identify results of 0.10 mg/L and less and if the policy requires the test result to be less than 0.10 mg/L.  Interview the responsible staff member regarding the test method used. Observe testing. Review logs of testing to validate the results are within the required limits.  Interview the responsible staff member to determine expected actions if the test result from the first testing port is greater than these limits.
<b>243</b>	(ii) If the test results from the last component	Interview the responsible staff member: what action would they take if the test

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	<p>or carbon tank are greater than the parameters for chlorine or chloramines specified in paragraph (c)(2)(i) of this section the facility must --</p> <p>(A) Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;</p> <p>(B) Immediately notify the medical director; and</p> <p>(C) Take corrective action.</p>	<p>results from the last component were greater than the accepted parameters? Their answer should include these components.</p> <p>Review the log of testing results to determine if any results were recorded outside the parameters; if so, is there evidence these actions were taken?</p>
244	<p><b>(d) Standard: Corrective action plan.</b></p> <p>Water testing results, including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.</p>	<p>Review results of the water chemical analysis and microbial and endotoxin testing for water and dialysate. Expect a corrective action plan to be developed if any of the results meet the AAMI action levels or if the results are outside the AAMI standards. Expect water and dialysate monitoring to be reported in the QAPI materials. Expect the physician director to be involved in analyzing and addressing test results outside of expected parameters. Does the plan ensure patient safety?</p>
245	<p><b>(e) Standard: Adverse events.</b></p> <p>A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must --</p>	<p>Interview responsible staff (licensed and unlicensed) regarding what symptoms would indicate a patient might be having a potential pyrogenic reaction, and what actions they would take in the event of a reaction. Ask staff to identify any patients who have had a suspected pyrogenic reaction.</p> <p>Include in patient interviews questions to determine if that patient has experienced a pyrogenic reaction.</p> <p>In reviewing clinical records, be alert to indications in the daily treatment records, in progress notes and in the plan of care of evidence of pyrogenic reactions (e.g., fever, chills, or a diagnosis of infection). Include any patients identified as having had a suspected pyrogenic reaction in your record review.</p>
246	<p>(1) Obtain blood and dialysate cultures;</p>	<p>Did the results of your interviews and record reviews (described above) demonstrate this action would be taken? Does the facility have standardized orders to require blood and dialysate cultures to be taken in the event of a</p>

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		suspected pyrogenic reaction?
247	(2) Undertake evaluation of the water purification system; and	Interview the responsible staff (e.g., chief technician, area technical manager, physician director) regarding action to be taken if patient experienced adverse reactions potentially related to the water system. Do their answers indicate recognition of the need to evaluate the water system?
248	(3) Take corrective action.	Interview the responsible staff (e.g., chief technician, area technical manager, physician director) regarding action to be taken if patient experienced adverse reactions potentially related to the water system. Do their answers indicate recognition of the need to take corrective action?
249	<b>(f) Standard: Unused bicarbonate.</b> Once mixed, bicarbonate concentrate must be used within the timeframe specified by the manufacturer of the concentrate.	Review the manufacturer's guidance for the maximum storage time of the mixed bicarbonate solution. Interview responsible staff members as to the mixing and storage of bicarbonate. Observe the bicarbonate mixing, storage and distribution systems. Review the logs of mixing and disinfection of the system. Do the logs include dates of mixing and disinfection? Do these dates demonstrate the manufacturer's guidance is followed?
300	<b>§494.50 Condition: Reuse of hemodialyzers and bloodlines.</b> The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.	Survey this Condition if the facility reuses hemodialyzers or bloodlines. If a facility does not reuse, this Condition does not apply.  Cite this Condition if there are major deficient practices that have or could potentially affect patient health and safety (e.g., staff members assigned responsibility do not demonstrate competency; less than sufficient concentration of germicide is in use; or direct care staff do not test for the absence of germicide prior to reusing a dialyzer).
301	<b>(a) Standard: General requirements for the reuse of hemodialyzers and bloodlines.</b> Certain hemodialyzers and bloodlines – (1) May be reused for certain patients with the exception of Hepatitis B positive patients;	Hepatitis B positive patients must be excluded from any reprocessing program.
302	(2) Must be reused only for the same patient; and	Cite this tag if there is a dialyzer mix-up and the wrong patient gets another patient's dialyzer. Observe set up of dialyzers for reuse; what precautions are in place to assure that each dialyzer is only used for one patient?

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303	(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 501(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.	Inspect dialyzers stored for reuse. Does the manufacturer's label indicate each dialyzer may be used multiple times?
304	<p><b>(b) Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.</b></p> <p>A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:</p> <p>(1) Meet the requirements of AAMI published in "Reuse of Hemodialyzers." Third edition, ANSI/AAMI RD47:2002/A1:2003, which is incorporated by reference. Incorporation by reference of the "in "Reuse of Hemodialyzers." Third edition, RD47:2002/A1:2003, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.</p>	The AAMI "Reuse of Hemodialyzers." Third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference. The recommendations are provided in the "Regulation" column and carry the full weight of regulation. The AAMI Rationale for the development and provisions of the recommended practice (where available) are provided in the "Guidance to Surveyors" column as an aide in understanding the recommendations which have been incorporated as regulation.
305	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>(4) Records</b></p> <p>All records described in this recommended practice shall meet the requirements for medical records, including completeness, legibility, and security. A place should be provided for the signature or other unique mark of identification of the person completing each step of the reprocessing</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.4 Records</b></p> <p>Documentation is essential to a safe, effective hemodialyzer reprocessing program. The overall dialyzer reuse procedure documentation includes reference materials, procedures, and policies, some of which may be distributed in the facility for operating purposes. The other records serve to document aspects of the reuse procedure for each dialyzer, along with QC and QA measures, so that a complete history of the reprocessing of each dialyzer and</p>

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	<p>procedure (i.e., the person performing preventive maintenance procedures, the person[s] investigating complaints, and the person[s] conducting quality assurance [QA] and quality control [QC] activities). Maintaining these records is the responsibility of the medical director.</p>	<p>QC/QA procedures exists. The committee felt that when the useful life of a dialyzer is over and no notable events have occurred, the reprocessing records for that dialyzer need not be kept. Allowance is made for keeping the reprocessing record data in the reprocessing log, the patient's chart, or a combination of the two, because both of them are traceable, permanent records, and it may be inconvenient to record all of the information in one location. The committee decided not to include a specific recommendation for a checklist for initiating dialysis because, although a checklist is a convenient way to ensure that the procedure is followed, the same purpose can be served by completing the recommended documentation for preparing the reprocessed dialyzer for dialysis (see 12.1, 12.2, and 12.4.1).</p> <p><b>Survey Procedures</b> Review records of reprocessing to ensure the records are complete, legible and secure. Recognize that the record of use of a dialyzer may be included in the patient record, in computer listings, and in separate records of reprocessing. You should be able to follow each dialyzer from first use to discard. If records are incomplete or missing, cite this tag and consider citing the physician director in egregious cases.</p>
306	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>4.1 Dialyzer reprocessing manual</b> The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures that may be integrated into the dialysis facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and files may be kept separate from</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b> <b>A.4.1 Dialyzer reprocessing manual</b></p> <p>The committee rejected a proposal to include a statement that the dialyzer reprocessing manual should not recommend or describe any methods for which the dialyzer or disinfectant manufacturer has indicated a contraindication.</p> <p><b>Survey Procedures:</b> The reprocessing manual must be complete for the reprocessing method, germicide and system in use, and address test procedures, maintenance and calibration of the reprocessing equipment and training and competency testing of personnel. The manual may be separate or combined with the general policy</p>

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	the dialyzer reprocessing manual. The dialyzer manufacturer's labeling should be consulted to determine if a specific dialyzer requires special considerations.	and procedure manual. If a specific dialyzer in use requires special consideration, the reprocessing manual should reflect the manufacturer's guidance.
<b>307</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>4.2 Reprocessing record</b> Records shall be kept that identify the new dialyzer, the date of each reprocessing step, the person performing the procedure, his or her signature or other identifying mark, and the results of tests of device performance and safety. This information should be recorded in a reprocessing log or the patient's chart, whichever is more convenient. Patients must be permitted to read records pertaining to the reprocessing and reuse of their own dialyzers</p>	<p><b>Survey Procedures:</b> Review records of reprocessing to determine if all steps are recorded. A permanent record must be maintained; information recorded on the dialyzer label must also be recorded either in a log or in the patient record. Patients must be allowed access to the record of use of their dialyzer. Records of reprocessing of various patients' dialyzers must not be commingled.</p>
<b>308</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>4.3 Equipment maintenance record</b> Records shall be maintained of the dates of preventive maintenance procedures and the results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment.</p>	<p><b>Survey Procedures:</b> Review reuse equipment maintenance logs; does the maintenance done correspond with the set schedule? Recognize that daily testing of the equipment may be required and if so, should be documented. Interview the responsible staff member to determine what testing is routinely done.</p>
<b>309</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>4.4 Personnel health monitoring records</b></p>	<p><b>Survey Procedures:</b> Testing of personnel is dependent on the germicide in use. Consult MSDS sheets for applicable germicides. Include the reuse technician(s) in your personnel record review sample, and review health records for congruence with</p>



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	A file must be kept of the results of medical examinations of personnel that are required by OSHA or other regulatory agencies.	any required testing.
<b>310</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>4.5 Complaint investigation record</b> Records shall be kept of all complaints by patients and staff members about failures of preprocessed and reprocessed dialyzers or possible adverse reactions to any dialyzers; the results of a comprehensive investigation of these alleged problems; and, if appropriate, the corrective actions taken. The records should be reviewed periodically for trends of adverse reactions. Compliance with the FDA's Medical Device User Reporting procedures should be considered.</p>	<p><b>Survey Procedures:</b> Review any complaints related to reprocessing (dialyzer failures, patient reactions, excessive leaks, etc). Expect to see an investigation of each issue, and corrective action as indicated.</p> <p>Interview responsible staff (e.g., the chief technician, area technical manager, nurse administrator, medical director) to determine if any trends have been identified. Expect to see any reuse incidents reported in the QAPI records as well.</p>
<b>311</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>4.6 Quality assurance and quality control record</b> A record shall be kept of the date and results of QA and QC evaluations and the person or persons conducting the evaluations.</p>	<p><b>Survey Procedures:</b> Review all audits of the reuse program. These may be recorded as part of the QAPI materials or may be maintained separately. See XXXX (AAMI 14) for a schedule of required reuse audits. Audits should include direct observation of reprocessing, including set up for use.</p>
<b>312</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>5 Personnel qualifications and training</b></p> <p><b>5.1 Qualifications</b></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.5 Personnel qualifications and training</b></p> <p>The committee rejected a proposal to include curricula covering the entire range of technical activities related to dialysis. The committee felt that more limited</p>

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	<p>Personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual dialysis facility relevant to the facility's multiple-use program. New personnel range in knowledge from those with no medical background who are fully trained by the facility, to licensed practitioners with extensive medical background. Education should be geared to meet the needs of this wide range of personnel.</p>	<p>training is appropriate as a minimum for personnel who are not involved in other aspects of dialysis. A proposal to recommend that training could be less extensive for personnel with relevant previous training also was rejected because certification of training (see 5.2.2) renders the recommendation superfluous.</p> <p><b>Survey Procedures:</b> Interview the personnel assigned responsibility for reprocessing to validate they are competent to do this task. Recognize you may need to gear your questions to the educational level of the staff member, but will need to determine that the reuse education provided is sufficient to ensure patient safety and an effective and safe reuse program.</p>
313	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>5.2 Training</b></p> <p><b>5.2.1 Curriculum</b> The dialysis facility's physician or director shall establish a training course for the persons performing hemodialyzer reprocessing. A written document should give details about the curriculum and, in particular, address the potential risks to patients and staff members of not following correct procedures. The curriculum should include at least the following information:</p> <ul style="list-style-type: none"> <li>a) the facility's specific reprocessing procedure, including a rationale for each step;</li> <li>b) basic documentation requirements of the program;</li> <li>c) the operation and maintenance of the</li> </ul>	<p><b>Survey Procedures:</b> Interview the personnel responsible for reprocessing dialyzers to verify they are knowledgeable in these areas. Observe the entire reprocessing sequence. If you identify a concern related to training, review the available training materials to validate the required topics are included.</p>

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	<p>facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components;</p> <p>d) microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infectious hazards;</p> <p>e) the risks and hazards of multiple use of hemodialyzers;</p> <p>f) the consequences of not performing tasks properly;</p> <p>g) the risks and hazards associated with toxic substances used in reprocessing hemodialyzers, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances;</p> <p>h) the use and location of protective eyewear, respirators, masks, and special clothing;</p> <p>i) emergency procedures as required by the facility; and</p> <p>j) the principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on these characteristics.</p>	
314	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>5.2.2 Documentation</b></p> <p>Each person performing procedures for the multiple use of dialyzers should have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area</p>	<p><b>Survey Procedures:</b></p> <p>Observe reprocessing to evaluate the competence of the individuals assigned responsibility.</p> <p>Review personnel files of selected reuse personnel for:</p> <ul style="list-style-type: none"> <li>➤ evidence the medical director/designee has certified each of the reuse personnel has successfully completed the required training</li> <li>➤ annual competence review and applicable retraining</li> <li>➤ retraining if any major changes in the reuse program (e.g., a change in</li> </ul>

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	<p>covered by his or her training. Successful completion of training should be certified by the medical director or his or her designated representative and recorded in the trainee's personnel file along with verification of the trainee having received the instruction. Retraining is necessary when new procedures are undertaken. Annual review of competence is required with appropriate retraining if deficiencies are found.</p>	<p>equipment or germicide), have occurred.</p>
315	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>6 Patient considerations</b></p> <p><b>6.1 Medical issues</b>  An order to reprocess hemodialyzers shall be made by a physician knowledgeable about reprocessing and its medical and economic implications. Because the current human immunodeficiency virus (HIV), hepatitis B, or hepatitis C status of a patient cannot be known with certainty, all staff potentially exposed to the patient's blood shall observe Standard Precautions. Dialyzers should not be reprocessed from patients who have tested positive with hepatitis B surface antigens. Precautions for all infectious hazards should be emphasized and included in the reprocessing procedures. Written procedures should stipulate whether and how reprocessing will be done for patients who</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.6 Patient considerations</b></p> <p><b>A.6.1 Medical issues</b>  The committee's primary objective was not to recommend medical indications for reprocessing or evaluate the medical or economic implications of reprocessing but to provide recommendations for safe reuse practice.</p> <p>At the time of this writing, the Centers for Disease Control and Prevention (CDC) does not object to reprocessing and reusing dialyzers from patients with hepatitis C or patients with known HIV infection because of the low viral burden and transmission efficiencies. The committee recommends, however, that standard precautions be used in the reprocessing of all dialyzers. These precautions include the use of gowns, masks, and gloves. Each facility should be aware of the hazards of infection and set policies accordingly.</p> <p><b>Survey Procedures:</b>  Expect evidence that the physician director has made a decision to reprocess dialyzers. This may be documented in policy or in the minutes of the governing</p>

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	<p>have shown sensitivity to materials used in the reprocessing of hemodialyzers.</p>	<p>body. Dialyzers of patients who are positive for Hepatitis B must not be reprocessed.</p> <p>Standard precautions must be followed in reprocessing activities; PPE appropriate to the task must be worn; all blood spills must be immediately cleaned; gloves that are visibly soiled with blood must be changed, with appropriate hand hygiene used prior to donning fresh gloves. Be sure to wear protective gear during your observations of reprocessing.</p> <p>If a patient has shown sensitivity to the materials used in reprocessing, expect to see this problem addressed in the patient assessment and plan of care.</p>
316	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>6.2 Informed consent</b> The Centers for Medicare &amp; Medicaid Services (CMS) Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services states that all patients in a dialysis facility will be fully informed regarding reuse of dialyzers. Printed material such as brochures describing the facility's services should contain a statement about dialyzer reprocessing if reuse is performed. National renal organizations may have additional materials available.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b> <b>A.6.2 Informed consent</b></p> <p>The committee decided, upon legal advice, that it is not appropriate for an AAMI recommended practice to suggest elements of informed consent, although this section originally contained them. The committee considered the following arguments about this issue. Those who believe that specific informed consent for the use of reprocessed hemodialyzers ought to be required maintain that greater patient participation in the therapeutic process need not impair the physician's ability to deliver quality care. Rather, they say, involvement ensures that quality care will remain the primary impetus of decisions to reuse. Those who do not agree with informed consent specifically for multiple use of hemodialyzers point out that specific consent is not required for the other aspects of dialysis therapy and could be counterproductive because of the confusion that could be created by personal preferences for, as examples, length of dialysis, choice of blood flow, fluid removal rate, and the like. They argue that multiple use of hemodialyzers can properly be implied in the consent for hemodialysis therapy as are other therapy parameters. Those backing this view also assert that for most patients honest, trusting interaction with their personal physicians is a sufficient guarantee of quality, and imposing a dictatorial</p>

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		<p>relationship may lead patients to seek recourse through legal means.</p> <p>The topic of physician-patient relationships is important in view of the concerns of some patients about the adequacy and safety of reprocessing procedures and the possibility that financial savings from the multiple use of hemodialyzers might contribute to the economic benefit of others rather than to the improvement of the quality of care. The committee also considered the question of the patient's right to freely choose not to participate in a hemodialyzer reprocessing program. Consensus could not be reached on this issue because of the underlying conflict between individual self-determination and financial constraints imposed by society (Rettig, 1982).</p> <p>Some patients have expressed fear of increased risk, anger over presumed profits, and frustration surrounding consent issues. Establishing QA practices such as those recommended here and sharing information with patients, may aid in solutions to these problems.</p> <p>The fact that most of dialysis facilities reprocess hemodialyzers and the long history of this technique support the conclusion that multiple use of hemodialyzers is customary medical practice. Courts might find that consent for dialyzer reprocessing per se is not required, but this issue has not yet been adjudicated.</p> <p>The National Kidney Foundation's position paper and the American Association of Kidney Patients recommend that patient consent for dialyzer reuse be obtained.</p> <p><b>Survey Procedures:</b>  CMS does not require specific patient consent, but does require that patients be informed that the facility does reprocess dialyzers and about that process. Include questions about reprocessing in your interviews of patients. If you find patients do not understand their dialyzers are being reused, consider citing this tag, and review the facility policy defining its position with respect to informed</p>



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317	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7 Equipment</b> Each piece of equipment used for reprocessing shall be appropriately designed, constructed, and tested to perform its intended task. Types of reprocessing systems vary from sophisticated microprocessor-controlled systems to hand-operated valving systems. Satisfactory operation of manual and automated systems shall be ensured by appropriate functional tests. Strict QC and QA shall be maintained for any type of dialyzer reprocessing equipment. Additionally, complete documentation of system function, operating procedures, potential system failures, and dialyzer-reuse criteria shall be included in the dialyzer reprocessing manual, known to the operator, and available for review.</p>	<p>consent for dialyzer reuse.</p> <p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.7 Equipment</b></p> <p>Validation of dialyzer performance and of the concentration of germicide was initially recommended after the repair of automated equipment to guard against possible faulty functioning of this complex apparatus. The recommendation was tempered by the words “if appropriate” for manual systems because replacing hoses, valves, and the like in those simple systems will not affect performance. The recommendation was subsequently changed to include testing the function of the reprocessing system because the committee judged that demonstrating proper functioning of the system is an adequate QC measure.</p> <p>An earlier recommendation that the system prevent cross-contamination of water used for reprocessing and water used for dialysis was based on an episode in which water containing formaldehyde was introduced into water used for dialysis. The committee decided to delete this recommendation because the mishap was not attributable to a reprocessing system (the formaldehyde was put into the water system for dialysis to disinfect that system) and because it may be desirable to use the same source for the water used for dialysis as the water used for reprocessing hemodialyzers in order to achieve the recommended water quality.</p> <p>It is particularly important that all water that comes into contact with the fluid pathways for blood or dialysate be of recommended quality because the blood side of the dialyzer might take up endotoxin that could be released into the circulation during the subsequent dialysis.</p> <p><b>Survey Procedures:</b> Interview responsible staff (e.g., chief tech or area technical manager) regarding the testing of the equipment in use to ensure safe operation.</p>

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		Interview the reuse technician and nursing staff regarding reuse criteria (e.g., reasons for discard, any limit on the number of times a dialyzer may be reused).
<b>318</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7.1 Water systems</b> The system providing water for reprocessing shall meet all of the requirements for pressure and flow rate for operating the reprocessing equipment under minimal and peak load conditions. Product water used for rinsing, cleaning, filling, and diluting the germicide shall be shown to comply with the chemical and microbiological quality requirements specified in the current version of ANSI/AAMI RD62. Water bacteriology monitoring shall be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.</p>	<p><b>Survey Procedures:</b> The product water chemical and microbiological requirements outlined in these regulations meet those in the current version of ANSI/AAMI RD62.</p> <p>Expect that a water sample for microbial and endotoxin testing will be routinely taken from the water supplying each reuse system, as close as possible to the point where the dialyzer would be connected to the system. If more than one automated reuse system is use, expect that each be monitored monthly.</p>
<b>319</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7.2 Reprocessing systems</b></p> <p><b>7.2.1 Utility requirements</b> The quality, pressure, flow rate, and temperature of the water used for reprocessing should be specified in the dialyzer reprocessing manual, established before the initiation of a reprocessing program, and maintained thereafter. The manufacturer or designer's recommendations</p>	<p><b>Survey Procedures:</b> Interview the reuse technician related to these requirements. If you have concerns regarding the responses, ask for the policy and compare that with the operating parameters. Observe the reuse area for adequate drains, ventilation, and electrical power.</p>

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	<p>for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.</p>	
320	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7.2.2 Process control testing</b></p> <p><b>7.2.2.1</b> Dialyzer test methods (11.3) shall be established before clinical use of the reprocessed dialyzers. Verification of tests should be repeated after each significant change in the reprocessing system. For automated systems, adherence to the manufacturer's instructions can verify the tests. For manual systems, confirmation of the accuracy of total cell volume (TCV) measurement and the membrane integrity test can verify the tests.</p>	<p><b>Survey Procedures:</b></p> <p>A process control allows the user to ensure the equipment is functioning correctly. This can be done by testing for the expected parameters (e.g., accuracy of the TCV) or by adherence to the manufacturer's guidance for automated equipment.</p> <p>A "significant change" would include a change from a manual to an automated system, a change from one automated system to another, or a change in the germicide.</p>
321	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7.2.2 Process control testing</b></p> <p><b>7.2.2.2</b> The test for the concentration of germicide or chemical shall be established before clinical use of the reprocessed dialyzers (11.4.1.6 and 12.3.2). For systems using heat disinfection, verifiable evidence shall be available before the next use that dialyzers have been exposed to the appropriate temperature for the time required.</p>	<p><b>Survey Procedures:</b></p> <p>The reuse manual should document how the concentration of germicide will be tested. Interview the reuse technician; if you have concerns about the responses, review the reuse manual.</p> <p>If heat disinfection is the reprocessing method, records of each batch of dialyzers processed must include an indicator the dialyzers were exposed to the appropriate temperature for the time required. If a chemical, such as citric acid, is used to enhance heat disinfection, a presence test for citric acid is also required before clinical use of the dialyzers.</p>

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	<p>If chemicals are used to enhance heat disinfection, both a presence test and a verification of time and temperature shall be performed.</p>	
322	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7.2.3 Maintenance</b>  Written maintenance procedures and a schedule of preventive maintenance activities designed to minimize equipment malfunctions should be established. In the case of purchased reprocessing equipment or safety equipment, the recommendations of the vendor should be followed unless documented experience supports alternative approaches. If the manufacturer's recommendations are not available, reuse equipment and safety equipment should be inspected on a semiannual basis. A record shall be kept of preventive maintenance activities (see 4.3), accompanied by the signature of the person performing the maintenance.</p>	<p><b>Survey Procedures:</b>  Interview assigned staff (e.g., reuse technician, chief tech, or area technical manager) about the routine preventative maintenance of the reprocessing equipment. Review records of this work as part of your log review.</p>
323	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>7.2.4 Repairs</b>  If the reprocessing system fails to function as expected, qualified personnel should investigate and repair the problem. The reprocessing system function testing should be repeated after repairs of automated</p>	<p><b>Survey Procedures:</b>  Interview assigned staff (e.g., reuse technician, chief tech, or area technical manager) about the repair of reprocessing equipment. Review records of this work as part of your log review. Determine if the equipment was tested for expected function prior to being returned to service.</p>

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	equipment and, if appropriate, after repairs of manual equipment before either the dialyzer is reprocessed or the reprocessed dialyzer is used for clinical dialysis.																			
324	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>8 Physical plant and environmental safety considerations</b></p> <p><b>8.1 Reprocessing area and ventilation</b></p> <p>The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see 8.5).</p> <p><b>Table 1—OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated</b></p> <table><tr><th>Substance/material</th><th>Limits (PEL)<sup>a</sup></th></tr><tr><td>Acetic acid</td><td>10 ppm TWA<sup>b</sup></td></tr><tr><td>Chlorine dioxide (syn: chlorine oxide)</td><td>0.1 ppm TWA</td></tr><tr><td>Citric acid</td><td>None developed</td></tr><tr><td>Formaldehyde</td><td>0.75 ppm TWA 2 ppm STEL<sup>c</sup> (15 min) 0.5 ppm action level</td></tr><tr><td>Glutaraldehyde</td><td>0.2 ppm ceiling NIOSH/OSHA</td></tr><tr><td>Hydrogen peroxide</td><td>1 ppm TWA</td></tr><tr><td>Peracetic acid</td><td>None developed</td></tr><tr><td>Phenol</td><td>5 ppm TWA</td></tr></table>	Substance/material	Limits (PEL) <sup>a</sup>	Acetic acid	10 ppm TWA <sup>b</sup>	Chlorine dioxide (syn: chlorine oxide)	0.1 ppm TWA	Citric acid	None developed	Formaldehyde	0.75 ppm TWA 2 ppm STEL <sup>c</sup> (15 min) 0.5 ppm action level	Glutaraldehyde	0.2 ppm ceiling NIOSH/OSHA	Hydrogen peroxide	1 ppm TWA	Peracetic acid	None developed	Phenol	5 ppm TWA	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.8 Physical plant and environmental safety considerations</b></p> <p>A proposal that the reprocessing area be supplied with HEPA-filtered air, a laminar flow station, and positive pressure to surrounding areas was rejected. Such measures to control bacterial contamination were deemed inappropriate for reprocessing because the exposure of the dialyzer to bacterial contamination is limited to making connections comparable to setting up the device for dialysis. Another proposal that the reprocessing area be negatively pressurized to control odors was rejected because the committee agreed that other methods can achieve odor control. The committee also determined that it was not necessary to recommend facility design, because a number of configurations have been shown to be satisfactory, including use of automated equipment in the dialysis treatment area.</p> <p>The statement about personnel health monitoring was included in response to a comment referring to the CFR (Chapter 29, Part 1910.20), which addresses access to employee exposure and medical records. The committee is unaware of any state department of public health that requires personnel health monitoring in this area, but the states themselves are another possible source of information on this question.</p> <p><b>Survey Procedures:</b></p> <p>Use all your senses in observing reuse practices. If you smell fumes or have burning eyes possibly from reprocessing germicides, ask the responsible staff member to test the air quality. Expect the reuse area to be kept clean and free of</p>
Substance/material	Limits (PEL) <sup>a</sup>																			
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	<p>ppm = parts per million</p> <p><sup>a</sup>PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs.</p> <p><sup>b</sup>TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period.</p> <p><sup>c</sup>STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.</p>	<p>clutter. Blood splashes should be immediately cleaned and the affected surfaces disinfected.</p>
325	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>8.2 Storage area</b></p> <p>Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage. New, used, and reprocessed dialyzers should be segregated to make clear the status of each group of dialyzers. Environmental contamination of the storage area should be controlled and monitored, if the personnel determine those actions to be necessary. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA regulations, and other appropriate regulations.</p>	<p><b>Survey Procedures:</b></p> <p>During your tour and observations throughout the survey, observe how reprocessing materials and dialyzers are stored. “Clean” and “dirty” dialyzers must be stored separately; the status (in the reprocessing cycle) of any dialyzer must be clearly apparent at all times. Stock must be organized to allow rotation and prevent use of out of date materials. Reprocessed dialyzers in storage must be protected from casual access to prevent tampering and to protect the confidentiality of the patients involved in the reuse program.</p>
326	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>8.3 Laboratory area</b></p>	<p><b>Survey Procedures:</b></p> <p>Expect testing for absence of germicide to be done in the dialysis treatment area. Testing for presence of germicide may be done in the reprocessing area or in the treatment area. Other testing such as water cultures and endotoxin</p>



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	Tests that do not require special facilities, such as certain tests for germicide levels, may be done in the reprocessing or dialysis treatment area, whichever is appropriate.	testing, may be done in the facility or sent out to an appropriate laboratory.
327	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>8.4 Personnel protection</b> Personnel shall wear durable gloves and protective clothing when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Standard Precautions shall be observed. Personnel shall wear eye protection when performing steps that may result in spills or splashes of substances of known or suspected toxicity. These agents shall be handled only in areas with adequate ventilation, washing facilities, eyewash stations, appropriate respirators, and spill control materials. When personnel are handling concentrated toxic substances, they shall wear aprons impervious to these substances.</p>	<p><b>Survey Procedures:</b> During your tour and later observations, note whether reuse personnel use appropriate PPE while doing this work. Interview the reuse technician related to what protections are expected to be in use, and what action would be taken in the event of a spill of germicide. Recognize that various germicides require different precautions as to eyewash, respirators, and spill control materials. Consult the germicide manufacturer's guidance for this information.</p> <p>You will need to use appropriate PPE during your observations of the reuse processes.</p>
328	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>8.5 Environmental safety</b> The dialysis facility shall have written procedures for safe storage and handling of chemicals used in reprocessing (see National Institute for Occupational Safety and Health</p>	<p><b>Survey Procedures:</b> Material safety data sheets (MSDS) must be available for the germicide in use. Interview the reuse technician regarding air level testing: how often is it performed, what are the safe levels, and is there any circumstance that would lead the technician to do an unscheduled test?</p>

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	<p>[NIOSH]/OSHA, 1980; Sax, 1979; material safety data sheets [MSDS]). Vapors from reprocessing materials must be maintained below potentially toxic levels (see Table 1).</p>	
329	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>9 Reprocessing supplies</b></p> <p><b>9.1 Specifications and testing</b>  Each reprocessing material should meet a written specification. The fulfillment of that requirement may be determined by certification by the product's supplier that the product meets necessary specifications, labeling for its intended purpose, or by testing procedures by trained personnel, as appropriate. The requirement may also be complied with by purchasing a specific grade as specified by the process, such as USP citric acid. When the user performs testing, he or she should maintain a log of the date of test, the identifying number (lot number) of the batch, the person performing any testing, and the test results.</p> <p>Over the past few years, bleach (sodium hypochlorite) manufacturers have begun selling household bleach in many new formulas. The concentration of sodium hypochlorite has gone from 5.25 % to 6.15 % in many cases. The CDC has not changed its</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.9 Reprocessing supplies</b></p> <p><b>A.9.1 Specifications and testing</b>  Testing of all incoming materials had been proposed. In recognition of the fact that most medical supplies are certified by the vendor and not tested by the user, the committee decided to recommend that supplies need not be tested by the facility doing hemodialyzer reprocessing if they are marketed for hemodialyzer reprocessing.</p> <p><b>Survey Procedures:</b>  Interview responsible staff (e.g. reuse technician, chief technician) regarding how they determine that the supplies used are of acceptable quality.</p>

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	<p>recommendations for diluting the bleach to take into account these percentage changes. However, manufacturers of bleach have also begun using additives such as fragrances and scents in their products commercially marketed in grocery stores.</p> <p>When bleach is purchased from a commercial outlet, the labeled concentration should be between 5.25 % and 6.15 %, and the formula should not contain fragrances or scents.</p>	
<b>330</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>9.2 Inventory control</b> Reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.9.2 Inventory control</b> The committee suggested that supplies should be used on a first-in, first-out basis to avoid deterioration over time in storage.</p>
<b>331</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>10 Hemodialyzer labeling</b> Each reprocessed hemodialyzer shall be used for only one patient. Therefore, the labeling shall uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure.</p>	<p><b>Survey Procedures:</b> Each hemodialyzer must have a permanently affixed label uniquely identifying the patient using that dialyzer.</p>
<b>332</b>	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>10.1 Time of labeling</b></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.10 Hemodialyzer labeling</b></p>

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	<p>Each hemodialyzer shall be labeled before or at the first use of the device, and the label shall be updated after each use (see 10.3).</p>	<p><b>A.10.1 Time of labeling</b></p> <p>The committee recognized the importance of identifying the patient who will be exclusively using the dialyzer and required the dialyzer to be labeled at the time of first use.</p> <p><b>Survey Procedures:</b> During the tour and observations throughout the survey, observe reprocessed dialyzers labeling. If a patient is given a new dialyzer that is intended to be reprocessed, that dialyzer must be labeled with the patient's name before the first use for the patient. Dialyzers which are not labeled with the name of the patient using that dialyzer must be discarded.</p>
333	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>10.2 Label composition</b> Markings should be resistant to normal reprocessing and dialysis procedures. The dialyzer labeling should not obscure the manufacturer's model number, lot number, or indicators of the direction of blood or dialysate flow or other pertinent information unless provision is made for recording this information on the label. The label on hemodialyzers with transparent casings should permit the blood path to be readily inspected.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.10.2 Label composition</b></p> <p>The committee initially recommended using indelible ink to label the dialyzer, but changed the recommendation to any method resistant to normal reprocessing and use procedures; other satisfactory materials exist, and requiring indelible ink might preclude some techniques, such as bar coding.</p>
334	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>10.3 Information recorded</b> The dialyzer shall be labeled with the</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.10.3 Information recorded</b></p>

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	<p>patient's name, the number of previous uses, and the date of the last reprocessing. Dialyzers of patients with similar last names should have a warning to the user to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other unique means of identifying the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. If this information appears on the label, a permanent record should also be kept (see 4.2).</p> <p>Electronic records are acceptable. If records are electronic, the test results should be available to the user. Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a dialysis facility for reprocessing.</p>	<p>A proposal that the label contain all of the recommended information was rejected because space is limited on the label, and such extensive labeling is unnecessary. Displaying the number of previous uses on the label is recommended so that this information is readily available. Displaying the date of the last reprocessing facilitates verification that sufficient time has elapsed since the introduction of the germicide to achieve sterilization or disinfection.</p> <p>Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a dialysis facility for reprocessing. It is the intent of the committee to make certain that the correct dialyzer is used on the patient. Requiring special labeling for home patients would normally not be necessary, unless the dialyzer was being transported outside the home, because only one patient would have access to the dialyzer.</p> <p><b>Survey Procedures:</b> At a minimum, each dialyzer must be labeled with the patient's name, the number of previous uses, and the date of the last reprocessing. For patients with similar names, a warning label is required. Since the labels are discarded with the dialyzer, this information must also be kept in a permanent record, which may be electronic. The record of reprocessing of the dialyzer is considered part of the patient's medical record, and must be able to be kept separate from the records of reprocessing of dialyzers of other patients.</p>
335	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11 Reprocessing</b> The multiple use of a dialyzer begins with the labeling of the new dialyzer (see section 10) and then continues with the reprocessing procedures described in this section. Preparation of the reprocessed dialyzer for the</p>	<p><b>Survey Procedures:</b> Observe the reprocessing of several dialyzers. The order of your observations may vary dependent on schedules—both yours and the facility's. Inform the facility representatives at the entrance conference that you will need to see all the steps of the process during your survey, and enlist their assistance in accomplishing this. Review logs of reprocessing to see that the required testing is documented, and the persons responsible are identified. If the facility is using a method of reprocessing recommended by the dialyzer manufacturer, use the dialyzer package insert to ensure all instructions are followed.</p>

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	<p>next dialysis is described in section 12. The cycle is repeated after the next use of the dialyzer until the dialyzer does not meet the criteria for continued use. A systems diagram of these procedures is given in annex B (normative). The results of the tests and the signature or other unique means of identifying the person performing each step should be maintained in a permanent record (see 4.2). Completion of all reprocessing steps, tests, and inspections should be documented in the reprocessing record, accompanied by the signature or other unique means of identification of the person completing them. When appropriate for the reprocessing procedure in use, all dialyzer manufacturer's instructions regarding reuse should be carefully followed.</p>	
336	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.1 Transportation and handling</b> Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11 Reprocessing</b></p> <p><b>A.11.1 Transportation and handling</b></p> <p>It was recommended at first that only disinfected caps be used to occlude the ports of the dialyzer. This recommendation was modified to include caps from the same dialyzer maintained in a clean condition, because experience indicates that this method is acceptable. The committee later decided that this recommendation is adequately addressed by the general statement about handling the hemodialyzer in a clean and sanitary manner.</p>



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	<p>described in this recommended practice shall be validated and documented by the responsible party.</p>	<p>During the 2002 revision of this recommended practice, the committee recognized that the refrigeration temperature of the dialyzers stored for extended periods of time was not specified. It was decided to recommend that dialyzers not reprocessed within 2 hours should be refrigerated and not allowed to freeze. The committee believed that this was sufficient to retard bacterial growth.</p> <p>A suggestion was also made that unprocessed dialyzers be stored in bags until they were reprocessed to minimize the risk of cross-contamination between dialyzers. This method would accomplish the requirements in this section; other methods have also been successfully used.</p> <p><b>Survey Procedures:</b> Observe used and reprocessed dialyzers for safe handling. All ports should be capped when the dialyzer is not in use or not being currently reprocessed, to prevent spills of blood or blood products, leakage of germicide, and entrance of air into the dialyzer. Personnel should use gloves to handle used dialyzers until disinfection is complete. Dialyzers may be transported in a common carrier (e.g., a basket) as long as the ports are capped and there is no visible blood on the outer casing of any of the dialyzers. Question the practice of allowing dialyzers to remain at room temperature for prolonged periods during the reprocessing process (e.g., after rinsing and prior to filling the dialyzer with germicide) and expect evidence of validation of such practices to ensure patient safety is not impacted.</p>
337	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.2 Rinsing/cleaning</b></p> <p><b>11.2.1</b> Many facilities preclean dialyzers. This process is typically accomplished with an apparatus developed by users and is intended</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.2 Rinsing/cleaning</b></p> <p><b>A.11.2.1</b> The committee considered stipulating a period of time after dialysis within which reprocessing should begin. Consensus was not reached on the period of time, and the committee decided that meeting performance guidelines</p>

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	<p>to remove gross deposits of blood and products before rinsing and cleaning with a reprocessing machine or device. When precleaning is done, it is necessary to include it as part of the reprocessing procedures. All applicable requirements for design and maintenance of equipment included in this document should be adhered to for precleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should also be adhered to.</p>	<p>is the goal of such a specification. Aqueous liquids rather than gases such as air are the preferred fluid for rinsing and cleaning (Bass, et al., 1973).</p> <p><b>Survey Procedures:</b> Observe reprocessing, including any precleaning. The interior of the dialyzer should never be exposed to tap water. Recognize there should be a pressure gauge on the treated water source used for rinsing the used dialyzers, and maximum limits of the pressure to be used should be known to the operator. Use of higher pressures may cause breaks in the blood fibers and subsequent blood leaks.</p>
338	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.2 Rinsing/cleaning</b></p> <p><b>11.2.2</b> Dialyzer reprocessing should be initiated in sufficient time to produce a reprocessed device that meets the requirements of section 11.3. Each dialysis facility should establish its time limits. Staff involved in handling, transporting, or storing of dialyzers locally or at remote locations shall follow Standard Precautions to prevent exposure to the operator and contamination of the physical environment.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.2.2</b> A proposal that only treated water or physiological saline be used was not at first accepted, because some safe and effective techniques use untreated water or nonphysiological concentrations of solute in the rinsing solution. The committee thought that the important goals were meeting the recommendations for satisfactory performance (see 11.3) and ensuring the presence of a physiological solution in the dialyzer before starting dialysis (see 12.4). After further comment and review, the committee endorsed as a reasonable safeguard the use of water meeting AAMI bacteriological standards (AAMI, 1982) or having a maximum level of bacterial LPS of 1 ng/mL. In 2001, the committee created a separate standard, ANSI/AAMI RD62, Water treatment equipment for hemodialysis applications, which is now referenced throughout this document. Originally, the chemical quality of the water was not specified because of lack of consensus on this issue. Although the committee agreed that high-quality water is not necessary to protect the patient from chemical contamination, it recognized that data exist suggesting that reprocessing with water of reverse osmosis quality yields more reuses (F. Gotch, personal communication). ANSI/AAMI RD62, Water treatment equipment for hemodialysis applications,</p>

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		<p>now contains chemical standards for water for dialyzer reuse.</p> <p>The committee had included a recommendation that any device that interfaces between the blood compartment and the permanent equipment should be cleaned and disinfected between each hemodialyzer reprocessed. The recommendation was deleted because permanent equipment sometimes makes a direct connection with the hemodialyzer and because data demonstrating the need for the recommendation is lacking.</p> <p><b>Survey Procedures:</b> Observe reprocessing. Interview the reuse technician regarding the time limits for starting reprocessing. Note whether Standard Precautions are in use. If dialyzers are sent to an off-site location for reprocessing, plan to include a visit to that site in your survey schedule.</p>
339	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.2 Rinsing/cleaning</b></p> <p><b>11.2.3</b> Precleaning the dialyzer (rinsing and cleaning) shall be done with a fluid or fluids made with water that meets the specification of the current version of ANSI/AAMI RD62, Water treatment equipment for Hemodialysis applications.</p>	<p><b>Survey Procedures:</b> All water that is used in reprocessing the interior of the dialyzer must be AAMI quality water. Expect to review results of both cultures and endotoxin testing from the water supply of the reprocessing station(s).</p>
340	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.2 Rinsing/cleaning</b></p> <p><b>11.2.4</b> Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid,</p>	<p><b>Survey Procedures:</b> Observe reprocessing. Ask the reuse technician if bleach or other chemicals are used as cleaning agents? If so, how does the facility assure each chemical is rinsed to a safe level prior to another chemical being used? If bleach is used, exposure times must be limited to prevent damage to the membranes.</p>

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	<p>or other chemicals may be used as cleaning agents for the blood compartment, provided that the cleaning agent has been shown to be reduced to safe levels by subsequent flushing and has no significant adverse effects on the structural integrity and performance of the dialyzer.</p> <p>Each chemical shall be rinsed from the dialyzer before the next chemical is added, unless mixing is known to be safe and effective for reprocessing. For example, a cleaning agent, such as sodium hypochlorite, shall be rinsed from the dialyzer before adding formaldehyde in order to avoid noxious fumes and degradation of disinfectant. Combining sodium hypochlorite and peracetic acid may produce hydrochloric acid vapors, which are harmful if inhaled.</p>	
341	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.3 Performance measurements</b> The performance characteristics of dialyzers may change following reprocessing. The ultrafiltration coefficient may increase or decrease. Clearances of small or large molecular weight solutes may also increase or decrease depending on the chemicals, methods, and dialyzer membrane used. The dialyzer labeling and medical literature should be consulted for information related to</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.3 Performance measurements</b> As dialysis facilities have attempted to rigidly comply with the 1986 edition of this recommended practice after its adoption by the Centers for Medicare &amp; Medicaid Services (CMS), some personnel have misunderstood or expressed concern about the “validation” for indirect measures such as TCV as indicators of performance of reprocessed dialyzers. In vitro clearances require special measures and may expose the hemodialyzer to additional risks. In vivo clearances are subject to multiple confounding variables. In view of these misunderstandings and concerns, the emphasis of this requirement has been</p>

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	<p>changes in in vitro and in vivo performance.</p> <p><b>11.3.1 Performance test after each use</b></p> <p>A direct or indirect measure of the in vitro clearance of a small molecule such as sodium or urea shall be used as the actual rejection criterion. If clearance is used, a 10% loss is acceptable. Total cell volume (TCV) may be used for hollow-fiber dialyzers. The acceptable TCV is at least 80 % of the original TCV. The dialyzer prescription should take into account the 10 % loss in clearance (20 % loss in TCV) that may occur with dialyzer reuse. Whenever possible, dialyzers should be preprocessed to establish the original TCV. If it is not possible to preprocess the dialyzer to obtain a baseline total cell volume, other methods such as “volume averaging of the lot” should be used.</p>	<p>changed. The essential function of the hemodialyzer is mass transfer adequate to provide the prescribed care to the patient. Change in TCV has been documented in the medical literature (Deane and Bemis, 1981) as an indirect measurement having a close relationship to the retained mass transfer of small molecules by the hemodialyzer, and may be used for the routine test of residual dialyzer performance. An integral component of the ongoing verification of the proper performance of the hemodialyzer is the monitoring requirement of section 13.</p> <p><b>A.11.3.1 Performance test after each use</b></p> <p>Clearance, a measure of the solute transport of the hemodialyzer, should be maintained within acceptable limits to ensure that dialysis is adequate to prevent uremic complications. Because of the established clinical importance of lower molecular weight clearance (Lowrie, et al., 1981), the committee decided that the urea clearance should be the recommended criterion for rejecting a dialyzer. The alternative of sodium clearance was included because sodium and urea clearances are similar, and measuring the former may be more easily accomplished. In developing the first edition of this recommended practice, published in 1986, the committee adopted <math>\pm 10\%</math> of the initial value as the maximum acceptable change in the urea or sodium clearance of a reused dialyzer. The basis for this decision was the belief that a <math>\pm 10\%</math> change in urea clearance would not result in a clinically significant change in a patient’s predialysis blood urea nitrogen (BUN) concentration. Subsequently, it has been recognized that predialysis BUN is a poor marker of dialysis adequacy and that a 10 % decrease in urea clearance could lead to inadequate dialysis if the dialysis prescription was marginal. Therefore, in the 2002 revision of this recommended practice, the committee added a caveat that a <math>\pm 10\%</math> change in urea or sodium clearance was acceptable as long as the patient’s prescription took into account the possibility of a 10 % decrease in urea clearance.</p> <p>The committee recognized that the clearance of larger molecules is largely</p>

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		<p>membrane limited (Collins and Ramirez, 1979; Dorson, et al., 1983) as opposed to the clearance of small molecules, which is largely flow-rate limited. Larger molecule clearances will therefore be disproportionately decreased by loss of membrane area or increased membrane resistance caused protein coating of the membrane, as compared with clearances of small molecules (Pizziconi, 1985). In 1986, when this recommended practice was initially developed, the committee considered, but ultimately decided against, a proposal to include vitamin B12 clearance as a criterion for rejection. It decided not to include vitamin B12 clearance as a rejection criterion because of (a) uncertainty about the significance of protein coating of the membrane in reprocessed hemodialyzers (Gotch, 1985), (b) lack of evidence supporting the clinical relevance of vitamin B12 clearance when the change in clearance is within that observed with reprocessed dialyzers, and (c) extensive experience demonstrating the safety of either monitoring urea clearance or using an appropriate indirect test for the urea clearance (Deane and Bemis, 1981). By the time of the 2002 revision of RD47, it had become widely accepted that solutes much larger than vitamin B12 were involved in some of the long-term complications of end-stage renal disease. Further, the committee recognized that the clearance of larger molecules may be affected by the type of reuse cycle used, especially the cleaning agent. Specifically, failure to use a cleaning agent such as bleach that effectively strips adsorbed protein from the membrane may lead to a significant decrease in the clearance of large molecules by high-flux dialyzers, even though the clearance of urea and the TCV are maintained in an acceptable range (Westhuyzen, et al., 1992; Ouseph, et al., 1997; Leypoldt, et al., 1998; Cheung, et al., 1999). Using bleach with some high-flux dialyzers may actually increase the clearance of large molecules, and possibly albumin, through mechanisms that are not completely understood (Diaz, et al., 1993; Kaplan, et al., 1995; Murthy, et al., 1998; Cheung, et al., 1999). These effects appear to be membrane dependent (Westhuyzen, et al., 1992; Murthy, et al., 1998; Cheung, et al., 1999). The committee is unaware of any practical test method for routine monitoring of large molecule clearance, and users are advised to consult the manufacturer's literature for more information on the</p>



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		<p>effects of different reuse practices on the performance of specific membranes.</p> <p>Although direct clearance measurements could be used to demonstrate compliance with the <math>\pm 10\%</math> change in urea clearance, determining the urea clearance for each dialyzer reprocessed is impractical. Several dialysis machines now allow noninvasive, automated on-line measurement of the ionic clearance of a dialyzer. Because the ionic clearance has been shown to correlate closely with urea clearance (Steil, et al., 1993; Lindsay, et al., 2001), this technique can be used to follow directly the clearance of a reused dialyzer. There are also indirect tests that reflect the mass transfer characteristics of a dialyzer, which may be used in lieu of clearance measurements. A change in the residual TCV of hollow-fiber hemodialyzers is the most widely used indirect test for changes in small molecule clearance. This method has been shown to be a good index to monitor the solute transport capacity of the reprocessed hollow-fiber hemodialyzer (Gotch, 1985). The volume of a hollow-fiber hemodialyzer (TCV) is readily measured in the clinical setting. When methods of reprocessing are used that do not cause a significant change in the permeability or geometry of the membrane, a loss of TCV of 20 % corresponds to a loss of urea clearance of less than 10 % (Gotch, January 1984). Volume change is recommended as a QC test only for hollow-fiber hemodialyzers because other hemodialyzer geometries do not have the relatively noncompliant blood compartment necessary for the validity of this measurement in predicting solute transport.</p> <p>The question of the appropriate volume to use as the reference TCV has been asked many times. The answer is not quite as clear as it might seem. Each hemodialyzer manufacturer supplies information regarding the total blood volume. However, the techniques used by hemodialyzer manufacturers are often quite different from those employed during hemodialyzer reuse and may yield somewhat different results. For example, several manufacturers measure the volume using kerosene, a liquid that does not “wet” the membrane. The TCV of dialyzers can vary from the values used to develop the original</p>

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		<p>manufacturer's literature, from lot to lot, and from hemodialyzer to hemodialyzer within a lot. In general, these variations are of little consequence in providing the proper transport properties designed into the hemodialyzer. When the hollow-fiber diameter decreases, the internal volume and surface area also decrease. Although it might appear that this would cause lower urea clearance, it does not. The shorter diffusion distances of the smaller fiber diameter cause an increase in urea transport rate, offsetting the loss in surface area. Following similar scientific principles, when individual fibers become plugged as the hemodialyzer is repeatedly used, the surface area associated with those plugged fibers is lost to solute transport and overall clearance decreases. This loss in transport is not linear because the (now) higher velocity in the remaining fibers causes an increase in the diffusion rate inside each fiber. This is the reason that a 20 % loss in surface area only yields about a 10 % loss in urea clearance. Therefore, <b>what is important in the reuse setting is the loss in TCV relative to the original volume of the hemodialyzer.</b></p> <p>The committee recommended that, whenever possible, the user measure the original volume of each hemodialyzer before the first patient use and record that value as the reference TCV (reprocessing volume) for all subsequent reprocessings. The committee also recognized that obtaining this measurement is not always practical. <b>In the absence of a preprocessing volume measurement for an individual hemodialyzer, the user should use the calculated average preprocessing volume for that hemodialyzer model. The average preprocessing volume can be determined by averaging the preprocessing volume of approximately 10 dialyzers (or 20 % of the monthly usage of dialyzers, whichever is less) for each hemodialyzer model. This figure should be rechecked monthly. Substantial changes in average preprocessing volume should be investigated.</b></p> <p>Initially, a change in the in vitro ultrafiltration coefficient of the hemodialyzer (KUF) or its inverse, the membrane hydraulic resistance (<math>R_m</math>), was proposed as an alternative to a change in TCV as an indirect measure of a change in solute</p>

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		<p>clearance (Pizziconi, 1985). However, this method was never validated in a clinical setting, and at the time of the 2002 revision of this recommended practice, it was considered to have no utility as a QC measure for contemporary hemodialyzers.</p> <p>The committee recognized that other factors can influence the effective clearance of toxins during the dialysis session or can influence interpretation of the results. These factors include the following:</p> <ul style="list-style-type: none"> <li>a) fistula recirculation;</li> <li>b) accurate blood and dialysate flow rates;</li> <li>c) accurate time of dialysis;</li> <li>d) compliance with dietary limitations;</li> <li>e) selection of appropriate hemodialyzer type and blood and dialysate flow rates;</li> <li>f) membrane surface coating that may affect higher molecular weight toxins;</li> <li>g) variations in the original clearance of the hemodialyzer; and</li> <li>h) variations in the clearance of the hemodialyzer caused by reuse;</li> </ul> <p>Users should be aware that the HEMO Study (Cheung, et al., 1999) identified reductions as well as increases in the clearance of <math>\beta_2</math> microglobulin with the use of certain combinations of dialyzers, cleaning agents, and reuse germicides.</p> <p>Of particular concern to this committee were any variations in hemodialyzer functions related to reuse procedures. Although cases have been documented (Delmez, et al., 1989), they are rare, especially when compared to the frequency of other factors listed above. For this reason, the committee strongly felt that the monitoring requirements of section 13 are of great importance to use in conjunction with the individual hemodialyzer measurements recommended in 11.3.</p> <p><b>Survey Procedures:</b> Interview the reuse technician regarding his/her understanding regarding the</p>

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		<p>change in dialyzer clearance with reprocessing. At a minimum, expect understanding that a drop in the total cell volume below 80% of the original volume = unsafe for patient use as patient would not receive a “good treatment.”</p> <p>Every dialyzer expected to be reprocessed must have its original cell volume measured prior to the first use. See the requirement at 494.100(a)(2)(vi) which references the KDOQI Standard for the rationale for this requirement. Observe the performance test done for each dialyzer. For manual systems be sure the graduated cylinder is emptied completely between uses and is placed on a level surface to be read. The reading should be made at eye level. Look at the charts used to determine whether the remaining volume is sufficient to continue using that dialyzer.</p> <p>For automated systems, ask the reuse technician how the system is validated to assure the volume measurements are accurate.</p>
342	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.3.2 Ultrafiltration</b> In vitro ultrafiltration coefficients should not be used to predict in vivo results. If the expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.3.2 Ultrafiltration</b></p> <p>Ultrafiltration rate (UFR) is the flow rate of fluid that passes through the membrane under a given pressure gradient at a given temperature. It is the product of the ultrafiltration coefficient of the hemodialyzer (KUF) and the transmembrane pressure. The K<sub>UF</sub>, and thus the UFR at a given transmembrane pressure, may be affected by changes in the intrinsic permeability of the membrane, the surface area of the membrane, and the presence of hydraulically resistive deposits on the membrane. Cleaning agents such as sodium hypochlorite may affect the intrinsic water permeability of many types of dialysis membranes (Cheung, et al., 1999).</p> <p>In vitro K<sub>UF</sub> is not recommended to predict in vivo ultrafiltration performance</p>

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		<p>because the former overestimates the latter (Gotch, January 1984; Wineman, 1984) in hollow-fiber hemodialyzers. This difference occurs in part because of the additional hydraulic resistance of the formed elements and proteins in blood. Additionally, thrombus-occluding hollow fibers may be highly permeable to water, and ultrafiltration may occur from either water passage through the occluding thrombus or retrograde flow from the unoccluded end of the fiber. These factors give a higher ultrafiltration coefficient during aqueous perfusion in vitro, whereas in vivo ultrafiltration across clotted fibers results in hemoconcentration of blood in clotted fibers to the point where osmotic pressure and hydraulic pressure drop to equal the transmembrane pressure, thus decreasing the ultrafiltration coefficient in the occluded fiber to zero. Similar data are not available for other types of dialyzers, but because clotting also occurs in those devices, the committee decided that in vitro <math>K_{UF}</math> should not be recommended to predict in vivo ultrafiltration performance in those devices as well.</p> <p>The committee recognized that surface deposits can significantly affect ultrafiltration (Pizziconi, personal communication, August 1984). This subject is not included in the recommended practice because of the controversy surrounding the clinical significance of protein deposits on the membrane (see A.11.3.1) and the lack of evidence for a significant decrease of in vitro <math>K_{UF}</math> using present-day reprocessing techniques (Gotch, January 1984; Wineman, 1984).</p> <p>The committee also recognized that in vitro <math>K_{UF}</math> measurements in hollow-fiber dialyzers can be used to estimate in vivo ultrafiltration if they are corrected for the percentage change in priming volume to reflect the amount of clotting and the normal in vitro-to-in vivo drop caused by the ultrafiltration of blood rather than protein-free solution. The committee decided not to include this information in the recommended practice because of the lack of consensus on the utility of this approach.</p>

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		<p>Measurement of in vitro ultrafiltration is temperature dependent. In vitro aqueous KUF will change approximately 2 % per °C. Thus, care should be taken to know the actual temperature at which the measurement is made. If the measurement temperature is not 37 °C, the appropriate temperature compensation algorithm should be used to correct the reading to 37 °C (see Pizziconi [1983] for an appropriate algorithm).</p> <p><b>Survey Procedures:</b>  Expect the direct care staff to monitor the patient's pre and post treatment weights. If the patient fails to lose the expected fluid weight during dialysis treatment, one cause could be the reprocessed dialyzer. Ask the reuse staff how the facility monitors the dialyzer's effectiveness in removing fluid from the patient. Review clinical records to determine if target weights are routinely achieved. In reviewing QAPI, determine whether the facility monitors achievement of target weight as part of their quality oversight of the reprocessing program.</p>
343	<p><b>AAMI RD 47 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.3.3 Blood path integrity test</b>  A membrane integrity test such as an air pressure leak test shall be done between uses.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.3.3 Blood path integrity test</b></p> <p>The 1986 edition of this recommended practice did not include a blood path integrity test. Because of on recommendations by the Centers for Disease Control and Prevention (CDC), the committee agreed to add such a test to the second edition of the recommended practice. This test is based on the observation that only a small amount of air leaks through wetted membranes, resulting in a pressure drop of less than 10 % of the test pressure. A maximum allowable pressure drop is not given because of variations among test systems and dialyzers.</p> <p><b>Survey Procedures:</b>  Observe pressure leak testing. Manual system may require each dialyzer be</p>



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344	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4 Germicide</b></p> <p>The rinsed and cleaned dialyzer shall be treated by a process that prevents adverse effects caused by microbial contamination. The blood and dialysate compartments of the dialyzer shall be sterilized or subjected to high-level disinfection because an inadequate germicidal process may result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device. The user shall consult the dialyzer labeling for contraindications or warnings regarding methods and applicability of specific germicidal processes or chemicals.</p>	<p>tested separately.</p> <p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.4 Germicide</b></p> <p>Until 1996, chemical germicides used in the health care setting were regulated by two government agencies: the Environmental Protection Agency (EPA) and the FDA. Chemical germicides formulated as disinfectants or sterilants were regulated and registered by the Disinfectants Branch, Antimicrobials Division, EPA. The authority for this responsibility comes under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA required manufacturers of chemical germicides formulated as sanitizers, general disinfectants, or disinfecting or sterilizing (sporicide) products to test formulations by using specific protocols for microbicidal activity, stability, and toxicity to humans. If a germicidal chemical was advertised and marketed for use on a specific medical device (e.g., a hemodialysis machine or flexible fiberoptic endoscope), then the germicide came under the additional regulatory control of the FDA, Center for Devices and Radiological Health, which is the federal agency that regulates medical devices. Under the authority of the 1976 Medical Device Amendment to the Food, Drug, and Cosmetic Act, a germicide that was marketed for use on a specific medical device is itself considered a medical device in a regulatory sense, and the manufacturer was required, in addition to EPA registration, to contact the FDA and submit a Pre-market Notification—510(k)—before legally marketing the product.</p> <p>In the early 1990s, the FDA began actively regulating all liquid chemical germicides with health care indications. To avoid the potential problem of regulating the same product under multiple classes, the FDA decided to regulate liquid chemical germicides as a separate type of medical device; therefore, it determined that they were unclassified devices. In an effort to ease the burden of this dual regulation, a memorandum of understanding (MOU) was signed</p>

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		<p>between the FDA and the EPA, that gave the FDA primary responsibility for premarket efficacy data review of liquid chemical sterilants and high-level disinfectants and gave the EPA primary responsibility for premarket efficacy data review of general purpose disinfectants.</p> <p>Additionally, the FDA adapted the basic terminology and classification scheme described by Spaulding (1971) to categorize medical devices, and the four levels of processing as proposed by the CDC: sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection (Favero and Bond, 2000). Also, the FDA regulatory authority over a particular instrument or medical device dictates that the manufacturer is obligated to provide the user with adequate instructions for the “safe and effective” use of that instrument or device. Those instructions must include methods to clean and disinfect or sterilize the item if it is marketed as a reusable medical device. The FDA regulates chemical germicides formulated as antiseptics, preservatives, or drugs that are used on or in the human body or as preparations to be used to inhibit or kill microorganisms on the skin. However, the method used to regulate and assess potency for these formulations is significantly different from the methods used for sterilants and disinfectants. The FDA has an advisory panel that reviews nonprescription antimicrobial drug products. Manufacturers of such formulations voluntarily submit data to the panel, which in turn categorizes the products for their intended use (e.g., health care personnel hand washes, patient preoperative preparations, surgical hand scrubs).</p> <p><b>Survey Procedures:</b> Observe the reuse process and the germicide used. Interview the reuse technician regarding the disinfection process: the concentration of the germicide and the exposure time required. If you identify knowledge deficits, review the reuse training curricula and the applicable technician’s personnel record.</p>
345	AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)	<b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b>

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	<p><b>11.4.1 Interior (blood/dialysate compartment)</b></p> <p><b>11.4.1.1 Germicidal process</b></p> <p>Chemical germicides or other procedures used for disinfecting of hemodialyzers shall have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms. If formaldehyde is used as the sole germicidal agent, the CDC recommends that a concentration of 4 % (W/V) be used in both the blood and dialysate compartments with a minimum contact time of 24 hours at a temperature of at least 20°C; lower concentrations or shorter contact times are appropriate if equivalent results can be demonstrated under other conditions. Formaldehyde used for reprocessing dialyzers should not be cloudy. Concentrated formaldehyde stored under adverse conditions can polymerize to form paraformaldehyde, a white precipitate. Formaldehyde should be of United States Pharmacopoeia (USP) or better quality. When other germicides are used, the manufacturer's instructions should be followed. If the germicide has an expiration date from the manufacturer, staff members should be sure that the chemical is not outdated. Some germicides have recommendations for maximum storage time after dilution or activation and before usage. If this is the case, the expiration date of the</p>	<p><b>A.11.4.1 Interior (blood/dialysate compartment)</b></p> <p><b>A.11.4.1.1 Germicidal process</b></p> <p>The following discussion of germicidal agents is limited to the use of high-level germicides for reprocessing dialyzers. Sterilization is an appropriate option, if feasible, because sterilization has a greater potential for killing microorganisms.</p> <p>Over the years, many techniques and germicides have been employed in dialyzer reuse programs, ranging from simple refrigeration to the use of quaternary ammonium compounds (which are very low-level germicides) to formaldehyde concentrations of 1 % to 6 %, glutaraldehyde solutions, solutions containing peracetic acid as the active ingredient, and, more recently, heat disinfection with and without the use of citric acid.</p> <p>The reason, in part, for using formaldehyde at concentrations that are less than the sterilization cycle concentration (i.e., 8 % for 12 hours at 20 °C) is that the challenge of microorganisms is not normally composed of bacterial spores. After the hemodialyzer is removed from a patient, there are two main points at which a microbiologic risk can occur: when water is used to rinse and clean the dialyzer, and when water is used to prepare the chemical germicide used for disinfection. In each case, the water is usually treated in the dialysis center itself for purposes of preparing dialysis fluids. The water that is produced is not sterile and does contain water bacteria.</p> <p>Gram-negative bacteria contain LPS, or bacterial endotoxins, which cause pyrogen reactions in dialyzing patients if the endotoxins are introduced into the bloodstream. Outbreaks of pyrogenic reactions during dialysis have ceased when steps were taken to reduce the colony count in the dialysate when it was counted at the end of dialysis, to fewer than 2000 per mL. The maximum allowable colony count in the water used for dialysis was estimated to be 200 per mL (ANSI/AAMI RD5:1982). The committee initially recommended this limit for the water used to dilute the germicide used for reprocessing</p>

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	<p>prepared germicide solution should be marked on the outside of the germicide solution container, and that date should be checked at the beginning of each day, before reprocessing begins. If other germicides such as heat and citric acid are used, it is necessary to ensure that the correct time, temperature, and concentration are being used. If the temperature of the disinfection process is elevated, appropriate recording means shall be employed to ensure that this criterion has been met. If maximum storage temperature limitations exist, records should be maintained to document this criterion. The disinfection process shall not adversely affect the integrity of the dialyzer. Germicides shall be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see 12.4). To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite and formaldehyde.</p>	<p>hemodialyzers as a reasonable bioburden to be controlled by the germicidal procedure. Subsequently, it decided to add the alternative of a maximum bacterial LPS concentration of 1 ng per mL for the water used to dilute the germicide because the association of reprocessed hemodialyzers with pyrogenic reactions has been defined by the LAL test rather than by culture (Petersen, et al., 1981), and because the LAL test detects both viable and nonviable bacterial contamination. The committee acknowledged the evidence for cross reactions between certain LAL tests and cellulosic materials (Pearson, et al., 1984) and the concern about the reproducibility of LAL tests. There is no evidence that cross-reactions apply to reprocessed hemodialyzers, and, even so, patient safety would not be compromised because acceptable reprocessed hemodialyzers would be mistakenly discarded rather than excessively contaminated hemodialyzers used. The committee also recognized that the LAL test is the test specified by the United States Pharmacopoeia (USP) for detecting bacterial endotoxin in water. Furthermore, the committee believes that reliable, reproducible LAL tests are readily available.</p> <p>Another group of water bacteria that can constitute a hazard in a dialysis center, is the nontuberculous mycobacteria. They are acid-fast water bacteria and, much like the gram-negative bacteria, survive and are capable of excellent growth in all water, including reverse osmosis and deionized water. Nontuberculous mycobacteria do not contain lipopolysaccharide, and their presence in dialysis fluids would not tend to pose a serious pyrogenic risk to a dialyzing patient. But unlike the gram-negative bacteria, they are considerably resistant to chemical germicides (Carson, et al., 1978). For example, they are between 10 and 100 times more resistant to free chlorine than are <i>Pseudomonas aeruginosa</i> and other common gram-negative water bacteria. Some strains of nontuberculous mycobacteria studied can survive a 60 minute exposure to 2 % alkaline glutaraldehyde. By comparison, <i>Pseudomonas aeruginosa</i> at a concentration of 10<sup>6</sup> per mL would be inactivated within a matter of minutes. Using 8 % formaldehyde, some strains of nontuberculous mycobacteria have survived up to 6 hours of contact at room temperature; if the challenge had been</p>

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		<p>Pseudomonas aeruginosa, the kill rate would have been so fast that it could not have been measured.</p> <p>The source of nontuberculous mycobacteria in an outbreak of disease among patients dialyzed at a center in Louisiana appeared to be the water used in processing dialyzers. Laboratory studies conducted by the CDC have demonstrated that the nontuberculous mycobacteria associated with the water systems in the Louisiana center can readily survive 2 % formaldehyde after 24 hours of exposure; in other instances, some strains survived for up to 96 hours. Obviously, those rates do not constitute high-level disinfection. Further laboratory studies have shown that if the concentration of formaldehyde is increased to 4 %, none of the strains of nontuberculous mycobacteria found in the water systems of the dialysis center or, for that matter, any of the strains that the CDC has stockpiled including some extraordinarily resistant strains, survive beyond 24 hours. In another more recent outbreak of mycobacteria infections in a dialysis clinic in California (Lowry, et al., 1990), the CDC also showed incomplete kill of mycobacteria in manually reprocessed high-flux dialyzers using 2.5 % Renalin.</p> <p>From a conservative standpoint, one should assume that nontuberculous mycobacteria may be part of the microbiologic flora of water used for rinsing and cleaning dialyzers and for preparing aqueous chemical germicides for disinfection and sterilization. Given this assumption, a dialysis center is faced with two alternatives. It could rely entirely on aseptic techniques throughout the reprocessing procedure, use sterile rinse water and sterile germicides (membrane-filter sterilized), and employ strict QC. Most dialysis centers in this country do not have the capability to undertake such a closed-system and complex approach.</p> <p>The second option would be either to use 4 % instead of 2 % formaldehyde or to use other chemical germicides at concentrations sufficient to produce sterility or high-level disinfection. Although good QC and QA practices and adherence</p>

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		<p>to protocols would have to be maintained, this approach is much simpler. Moreover, a scientific basis apparently exists for considering 4 % formaldehyde at a 24-hour exposure as at least a high-level germicide process. All laboratory data acquired so far shows that 24 hours of exposure with 4 % formaldehyde at room temperature (20 °C) inactivates high levels of all strains of nontuberculous mycobacteria that have been tested; many of the test strains are among the most resistant in the CDC collection.</p> <p>When 4 % formaldehyde is used, both the dialysate and the blood compartments shall be filled with this concentration to prevent its reduction as a consequence of diffusion of formaldehyde from one compartment to another or of dilution by residual rinse water retained on and in the dialyzer membranes. Dilution can be prevented by passing at least three volumes of 4 % formaldehyde through each compartment before sealing the dialyzer for storage. The committee decided to specify an effluent within 10 % of the original concentration to avoid a design standard that might not be appropriate in the future.</p> <p>The committee limited the recommendation for 4% formaldehyde to processes that use formaldehyde as the sole germicide, because it is possible that combinations of germicides might give a satisfactory result with less than 4% formaldehyde. Concentrations of formaldehyde lower than 4 % and a contact time shorter than 24 hours are permitted if adequate disinfection can be demonstrated, because intermediate conditions have not been tested and might, on further evaluation, prove satisfactory.</p> <p>The committee is aware of published information regarding the use of 1 % formaldehyde with dialyzers stored at 40 °C for 24 hours (Hakim, et al., 1985). Many dialysis facilities have adopted this procedure without resulting difficulties and it seems to be an acceptable alternative to 4 % formaldehyde at 20 °C.</p>



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		<p>The committee is also aware of published information regarding the use of 1.5 % USP citric acid elevated to a temperature of 95 °C for 20 hours (Levin, et al., 1995). If that process is to be used, the user should consult the published data to ensure that citric acid is being applied appropriately and there is no negative effect on the dialyzer performance or integrity.</p> <p>Unfortunately, no realistic procedure exists whereby a dialysis center can monitor the effectiveness of the disinfection procedure. Such sophisticated microbiologic tests cannot be performed in dialysis centers, because the tests require the use of specialized equipment and highly trained microbiologists. Instead, a center should adhere rigidly to established protocols for QC and QA. Tests for total bacteria and endotoxin in the water used to make up the germicide should be conducted at least monthly. If there are problems in maintaining water quality at the level established by ANSI/AAMI RD62:2001, Water treatment equipment for hemodialysis applications, the testing may need to be performed more frequently. Testing the germicide's final-use concentration should be a part of the center's QC program as well as verifying that each dialyzer was filled with germicide.</p> <p>The committee considered a functional reverse osmosis unit and 2 % formaldehyde disinfection, but decided not to rely on this option because the CDC believes that reverse osmosis water might not be adequate to control contamination by nontuberculous mycobacteria, that there is a substantial chance that these highly resistant organisms may be in the source water, and that monitoring the water for nontuberculous mycobacteria is not clinically feasible.</p> <p>The committee considered a recommendation that the chemical quality of the water used to dilute the germicide should be the same as the water used to make the dialysate. This recommendation was deleted because of the lack of consensus on this issue, as noted earlier (see A.7). Water quality standards for dialysis and for dialyzer reprocessing were made the same in 2001 (see current</p>

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		<p>version of ANSI/AAMI RD62, Water treatment equipment for hemodialysis applications).</p> <p>Potency testing of each batch of germicide is specifically recommended for batches of manually prepared germicides regardless of whether they are used with a manual or an automated system. Germicide solutions that are diluted on-line by automated machines are to be checked for concentration at least monthly. Other requirements for verification of germicide presence are contained in section 12.</p> <p>The CMS requires (42 CFR 405.2150) that dialyzers not be subjected to multiple germicide solutions because of possible combined actions of the germicides on the hemodialyzer membrane. That requirement does not apply to the original sterilization process or chemical cleaning agents that the hemodialyzer might be exposed to for short periods during the cleaning process for reuse. Certain members of the committee felt that the requirement was unnecessary if each hemodialyzer is subjected to an air pressure leak test as part of the reuse process.</p> <p><b>Survey Procedures:</b>  If 4% formaldehyde is used, staff (and surveyors) must wear respirators when exposed to the germicide during the reprocessing cycle.</p> <p>Interview the reuse tech about the germicide used and what risks this germicide presents to him/her and to the patient. Is the germicide manually diluted or diluted on line? Observe whether containers of germicide are dated (if necessary) to indicate dilution and discard dates.</p> <p>If an incubator or oven is used to raise the dialyzer storage temperatures, a recording thermometer should be in use to assure sufficient temperature is consistently maintained. Review records of such devices if they are in use.</p>
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	<p><b>Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4.1.2 Dialyzer header cleaning and disinfection</b></p> <p>The cleaning and disinfection of the header space should be done only when necessary and only before the dialyzer is reprocessed. The manufacturer's instructions should be followed. Header caps and O-rings shall be kept with their respective dialyzers.</p> <p>If the header space is cleaned, it shall be done in a manner to prevent infection and damage to the dialyzer. If the header cap is removed to clean the header space, cleaning shall be done with water meeting the requirements of the 2001 version of ANSI/AAMI RD62, <i>Water treatment equipment for hemodialysis applications</i>, §4.2.1 and §4.2.2. If instruments or other materials (e.g., header caps and 4x4 gauze pads<sup>2</sup>) are used, they should be shown not to cause damage to the end of the dialyzer and shall be new or cleaned and disinfected between uses. Once the O-ring and the header cap are cleaned and before they are reassembled at the end of the dialyzer, they should be disinfected. The disinfectant shall not be rinsed and shall be allowed to remain on the dialyzer components as they are reassembled. This procedure is done before reprocessing the dialyzer. Over tightening the header caps may cause damage</p>	<p><b>Practice</b></p> <p><b>A.11.4.1.2 Dialyzer header cleaning and disinfection</b></p> <p>The practice of header removal to remove clotted material has increased over the years. Many dialyzers do not have removable headers, but there are enough dialyzers with removable headers that the practice should be fully addressed. If the headers cannot be removed, other methods are used to remove this clotted material. Those methods should also be addressed. Removing the header allows the user to remove the clotted material from the end of the fiber bundle and the O-ring header assembly. The method of removal of the clotted material has been of concern. Some facilities use running water (AAMI quality) to remove the clotted material, whereas others use 4x4s or instruments to scrape away the clotted material. The main concerns of using 4x4s or instruments to scrape away the clotted material are (1) infection, (2) plugging of fibers, and (3) damage to the end of the fiber bundle.</p> <p>In the past, removing the headers was associated with reported incidents of bacterial and pyrogenic reactions in patients (Flaherty, et al., 1993). The patient reactions no longer occurred when the headers were disinfected by dipping the O-ring, header, and end of the dialyzer into the appropriate disinfectant. The research on this problem pointed to a double-fault failure system: 1) the bacteria seemed to be coming from a contaminated water source, and 2) the bacteria were not killed by the normal disinfection process. Dipping the dialyzer corrected that situation.</p> <p>Another concern is that rags, 4x4s, or instruments that are used to clean the clotted material would re-infect the end of the dialyzer. This concern can be removed by using new rags or 4x4s for each dialyzer. When instruments are used, they can be disinfected between treatments.</p> <p>Plugging of fibers has also been a concern. Because the dialyzer is cleaned and</p>

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	<p>to the cap, and under tightening the cap may cause blood leaks. If any cracking of the header occurs, the process should be evaluated.</p> <p>If the header space is cleaned with the header cap in place, it is necessary to ensure that the end of the fiber bundle is not damaged. If water is used, it shall meet the requirements of the 2001 version of ANSI/AAMI RD62, <i>Water treatment equipment for hemodialysis applications</i>, §4.2.1 and §4.2.2. If an instrument such as a tie wrap is used, it should be made of soft plastic or other material that will not damage the end of the fiber bundle and be disinfected between uses.</p> <p>If automated equipment is used, the manufacturer's instruction for use shall be followed.</p> <p><sup>2</sup> The CDC recommends that only a stream of RO water be used to rinse clots from the headers of the dialyzer.</p>	<p>tested after the header cleaning, any plugged fibers would be detected and corrected before they became a problem.</p> <p>There is also a possibility that, if instruments are used, they could damage the end of the fiber bundle. The user should make certain that no damage occurs.</p> <p>Several concerns are raised when the headers are not removed and the user attempts to clear the header space of clots. These concerns include infection and damage to the end of the fiber bundle. A multitude of items are used to clean the header space, including water sprays, paper clips, tie wraps, and the like. With water sprays, the possibility of contaminated water always exists. Other items that are inserted can damage the end of the fiber bundle. If the item inserted into the dialyzer is not disinfected between uses, it can cause bacterial transmission; however, the dialyzer is usually disinfected after the header space is cleaned.</p> <p>Automated header cleaning devices are commercially available.</p> <p><b>Survey Procedures:</b> If the end caps of the dialyzer ("headers") are removed during reprocessing, facility staff must ensure that the O-ring and the end of the dialyzer are exposed to germicide prior to reassembly of the cap, and that the components are reassembled wet with germicide. Observe end cap and header cleaning closely for any breaks in technique which could put the patient at risk.</p>
346	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4.1.3 Chemical germicide diluent</b> The water used to prepare the germicide solution shall meet the requirements of the 2001 version of ANSI/AAMI RD62, <i>Water treatment equipment for hemodialysis</i></p>	<p><b>Survey Procedures:</b> Interview the responsible staff (e.g., reuse technician, water treatment staff, chief technician) related to the testing of the water used to dilute the germicide for microbiological contaminants and endotoxins.</p>

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	<i>applications</i> , §4.2.1 and §4.2.2.	
347	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4.1.4 Chemical germicidal procedure</b> If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90 % of the prescribed concentration. The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer.</p>	<p><b>Survey Procedures:</b> Observe reprocessing. If a manual system is in use, recognize that the blood and dialysate compartments will have to be filled three times (e.g., three compartment volumes) in order to reach at least 90% of the prescribed concentration. Review reuse logs for documentation of verification of the desired concentration of germicide. Observe the cleaning of ports and caps. If new caps are used, these should be disinfected prior to use.</p>
348	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4.1.5 Water quality monitoring</b> The water used to rinse and clean dialyzers and dilute the germicide should be tested for bacterial contamination and pyrogens according to the requirements of the 2001 version of ANSI/AAMI RD62, <i>Water treatment equipment for hemodialysis applications</i>, §4.2.1 and §4.2.2 before a reprocessing program is undertaken. Once dialysis with the reprocessed hemodialyzers has begun, testing for bacterial contamination should be frequent (e.g., weekly). Less</p>	<p><b>Survey Procedures:</b> Review water testing results. Expect these to be reported in the QAPI minutes and action to be taken if any results are outside the parameters spelled out in these regulations for cultures and endotoxins.</p>

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	frequent testing, but not less than monthly, may be appropriate if there is a documented history of at least 3 months of results consistently below the levels allowed in the 2001 version of ANSI/AAMI RD62, Water treatment equipment for hemodialysis applications, sections 4.2.1 and 4.2.2.	
349	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4.1.6 Chemical germicide concentration</b>  Reprocessing systems in which each batch of germicide is manually prepared, each batch of germicide shall be tested before use to verify the proper concentration of the germicide. This requirement does not apply in cases in which each dialyzer is tested for concentration before setup. When the germicide is diluted on-line, its concentration in the hemodialyzer immediately after reprocessing should be checked at least monthly for each reprocessing system. When the germicide is partially or fully diluted by the user, it is of great importance that the solution be thoroughly mixed.</p>	<p><b>Survey Procedures:</b>  Observe reprocessing:</p> <ul style="list-style-type: none"> <li>• If germicides are diluted by the user, is the solution thoroughly mixed before use?</li> <li>• If germicide is manually prepared, is each batch tested before use for concentration, or is each dialyzer tested for concentration before setup for use?</li> <li>• If germicide is diluted on-line, is the concentration in a dialyzer from each reprocessing system checked immediately after reprocessing monthly?</li> </ul>
350	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.4.2 Exterior</b>  The outside of the dialyzer should be soaked or wiped clean of visible blood and other foreign material. For chemically disinfected</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.4.2 Exterior</b></p> <p>Low-level germicides satisfactorily clean the exterior of the device to a degree comparable what a new dialyzer receives. For example, 1:100 dilution of</p>



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	<p>dialyzers, a low-level germicide that is compatible with the dialyzer's materials of construction should be used for this purpose. Sodium hypochlorite at a concentration of 0.05 % is usually suitable. Certain commercial low-level disinfectants may cause some plastics used for dialyzers to crack after repeated or prolonged exposure.</p>	<p>household bleach will achieve the concentration of sodium hypochlorite specified in 11.4.2.</p> <p><b>Survey Procedures:</b> Observe the reuse process, including the cleaning of the exteriors of the dialyzers. Spraying the dialyzer with germicide is generally unsatisfactory, unless all the surfaces of the dialyzer are covered with the spray.</p>
351	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.5 Inspection</b> The hemodialyzer shall be examined after reprocessing to ensure that the external surface is clean, the dialyzer is not damaged, and the rinsing of blood has been satisfactorily completed. The dialyzer should also be aesthetically acceptable in appearance to patients and staff.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.5 Inspection</b> The committee considered a recommendation not to accept hemodialyzers with visible clots because venous filters are not used for all hemodialyzer circuits, leading to the risk of embolization to the patient if a clot were to break loose. The committee decided to reject this proposal because the allowable clots are required to be small and in stagnant areas that are present during the first use of the hemodialyzer and because there is no evidence of embolization from reprocessed hemodialyzers that meet this criterion.</p> <p>A proposal that the number of dark, clotted fibers evident upon external inspection be limited to five was not accepted because a considerably larger number may be clotted without significant adverse effect on performance and because some authorities do not agree that this criterion is essential to an aesthetically pleasing appearance. A recommendation that hemodialyzers with a pink or brownish tint not be acceptable was also deleted because this condition is difficult to define and because glutaraldehyde disinfection results in a slight tan color of the membranes that has not been shown to impair the safety or performance of the hemodialyzer. The committee recognized that the patient should be included in the aesthetic evaluation of the hemodialyzer.</p>

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		<b>Survey Procedures:</b> Observe the inspection of the reprocessed dialyzers. Interview the reuse technician regarding criteria used to determine “pass” or “fail” of this inspection.
352	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>11.5.1 Inspection</b> The dialyzer jacket should be free of visible blood or other foreign material.	Survey Procedures Inspect the reprocessed dialyzers: do your own observations confirm the requirements of the following tags are met?
353	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>11.5.2 Inspection</b> There shall be no leaks or cracks in the dialyzer jacket or the blood or dialysate ports.	
354	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>11.5.3 Inspection</b> No more than a few dark, clotted fibers should be evident on inspection of the exterior of the hollow fibers.	
355	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>11.5.4 Inspection</b> The headers of hollow-fiber dialyzers should be free of all but small peripheral clots or other deposits.	
356	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>	

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	<p><b>11.5.5 Inspection</b> Blood and dialysate ports shall be capped without evidence of leakage.</p>	
357	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.5.6 Inspection</b> The label shall be properly filled out and legible.</p>	
358	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.6 Disposition of rejected dialyzers</b> Reprocessed dialyzers that have been rejected for failure to meet performance, inspection, or other release criteria should either be immediately discarded or further reprocessed and subjected to the performance requirements of 11.3, 11.4, and 11.5. If the dialyzer is to be further reprocessed, rather than discarded, it shall be labeled as rejected and stored in a quarantine area to preclude use until requirements are met.</p>	<p><b>Survey Procedures:</b> Interview the reuse technician to determine if dialyzers which initially fail criteria may be repeatedly reprocessed. If any dialyzers fail criteria during your observation of the process, note how these are handled until they pass or are discarded.</p>
359	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>11.7 Storage</b> Reprocessed dialyzers that meet the performance and inspection criteria for multiple use should be stored according to the provisions of 8.2. Prolonged storage (greater</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.11.7 Storage</b> The committee acknowledged that the selection of 1 month as the maximum storage period permitted without validation was arbitrary. The committee was, however, unaware of any adverse effects of storage for up to 1 month and, therefore, felt that this period of time was reasonable.</p>

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	<p>than 1 month) should be documented to be safe and effective.</p> <p>Dialyzers that have exceeded the facility's maximum storage time shall be reprocessed or discarded. The dialyzer and disinfectant labeling should be consulted regarding proper storage conditions.</p>	<p><b>Survey Procedures:</b></p> <p>Inspect the stored dialyzers. Look at dates of reprocessing; interview the reuse technician regarding a system for ensuring dialyzers are not stored longer than the set timeline.</p>
360	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues</b></p> <p>A written procedure that has been shown to be effective shall be followed.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues</b></p> <p>The committee considered methods other than direct testing of the germicide as a process control in each hemodialyzer. It noted that some automated systems add sodium chloride to the germicide and monitor conductivity. Brilliant Blue (FD&amp;C Blue #1) added to the germicide has also been used to confirm the presence of germicide by visual inspection. There is toxicological data supporting the safety of this method (E. Lowrie, personal communication, 30 December 1984).</p> <p>For the 1986 edition of this recommended practice, the committee recommended testing each hemodialyzer for the presence of germicide just before rinsing and priming. The committee noted in 1986 that certain germicide manufacturers recommended this procedure, and that their recommendation should be followed. If each hemodialyzer was not tested for the presence of germicide, then a combination of process control and sampling was considered to be adequate. By conducting the test before any dialyzer in a batch were used, all dialyzers from the batch could be quarantined or released at the same time.</p> <p>The committee recognized that a residual level of less than 3 ppm for formaldehyde is the guideline for reuse in the State of California (California</p>

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		<p>Code of Regulations, Title 22 §75207). This level apparently was chosen to coincide with the sensitivity of tests that detect formaldehyde. The committee decided to recommend a maximum residual level of formaldehyde of 5 ppm for the following reasons (Gotch, 1983).</p> <p>a) Anti-N-like antibody formation, the only established chronic toxicity caused by formaldehyde in reused dialyzers, does not occur below a residual formaldehyde level of 10 ppm (Howell and Perkins, 1972; White, et al., 1977; Crosson, et al., 1976). Subsequently, at least two published studies (Vanholder, et al., 1988; Ng, et al., 1995) report anti-N-like antibodies in 10 % to 11 % of patients treated with reused dialyzers when the residual formaldehyde level was less than 2 ppm to 3 ppm.</p> <p>b) The maximum daily dose of formaldehyde from dialysis is less than the California OSHA daily limit, which is based on a five day week, whereas dialysis patients usually dialyze three or fewer times a week (Gotch, 1984a).</p> <p>c) There is no evidence of toxicity from the long-term use of methenamine by mouth for urinary tract infections at doses that release considerably more formaldehyde to the patient than comes from reused dialyzers.</p> <p>d) Although tests are commercially available to test for formaldehyde at levels of 1 ppm, residual formaldehyde levels lower than 5 ppm increase the time required to prepare the dialyzer for dialysis.</p> <p>When the committee revised RD47 in 2002, it decided that there was sufficient information available to indicate that the residual level of formaldehyde should be reduced to less than 3 ppm. The testing technology for residual formaldehyde had also improved, and it was feasible to easily test to less than 3 ppm.</p> <p>The committee considered establishing maximum residual levels for germicides other than formaldehyde. Because these newer germicides are all cleared by the FDA and could have different allowable levels of residuals even for the same generic type of germicide, the committee determined that it is best to recommend that the manufacturer's instructions for use be followed. The</p>

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		<p>committee noted that toxicology studies are favorable for some of these agents, and the FDA reviews labeling information for them, which includes the maximum residual level.</p> <p>When checking for the presence or concentration of the germicide in the hemodialyzer, do not place anything into the blood or dialysate ports of the device (e.g., test strip or syringe) to withdraw the sample. Doing so may damage the fibers of the dialyzer and lead to blood leaks during dialysis. If a germicide test strip or kit is being used, the instructions provided by the manufacturer should be followed.</p> <p><b>Survey Procedures:</b> Observe testing of dialyzers prior to use. Interview responsible staff (e.g., reuse technicians and direct care staff) regarding the testing of reprocessed dialyzers prior to use. Observe the test methods: are these sensitive to the levels specified by the germicide manufacturer?</p>
361	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.1 Visual inspection</b> The dialyzer should be inspected before it is prepared for use. Completion of this inspection should be recorded in the reprocessing record (see 4.2), along with the signature or other unique means of identifying the person completing the inspection. The inspection should include the following:</p> <ul style="list-style-type: none"> <li>a) The reprocessed dialyzer shall be legibly labeled with the information recommended in 10.3.</li> <li>b) There should be no indication of structural damage or tampering with the dialyzer.</li> </ul>	<p><b>Survey Procedures:</b> Observe setup for reuse. Note whether staff visual inspect the dialyzers for these points, and how this inspection is documented. Each parameter does not have to be individually documented; however, the staff member should be able to describe each of these elements. Observe practice and interview the responsible staff members; if you identify a concern, review applicable policies.</p>



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	<p>c) The ports of the dialyzer should be properly capped.</p> <p>d) The presence of germicide in the dialysate and blood compartments, including headers, should be confirmed, and there should be no evidence of leakage from the ports or other portions of the dialyzer.</p> <p>e) The duration and conditions of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer; and</p> <p>f) The cosmetic appearance of the dialyzer should be aesthetically acceptable to the staff and the patient.</p>	
362	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.2 Verification of patient identification</b>  Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step shall be recorded, along with the signature or other unique means of identifying the person verifying patient identification.</p> <p>NOTE—This step may be done later in the procedure but shall precede initiation of dialysis.</p>	<p><b>Survey Procedures:</b>  Observe the verification of patient identify with his/her dialyzer. Standard of practice requires the final check be done when the patient is present for that treatment. Observe if patients check their dialyzers for their name. Ask patients if they check their dialyzer. If patients sign the treatment record for this item, ask the patient what their signature means.</p>

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363	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.3 Verification of germicidal contact</b> The contact time of the germicide or disinfection procedure shall comply with the facility's protocol and the manufacturer's recommendations. The presence of chemical germicide in each hemodialyzer shall be ensured through either direct testing or an on-line process and procedural control. If other disinfection (e.g., heat) procedures are used, there shall be methods to ensure that each hemodialyzer has been properly subjected to the disinfection process. A record shall be kept indicating that the dialyzer has undergone the appropriate storage time, and the record shall be appropriately verified.</p>	<p><b>Survey Procedures:</b> Interview responsible staff (e.g., reuse technician, direct care staff) regarding how they ensure the dialyzers have been exposed to the germicide for a sufficient contact time.</p>
364	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.3.1 Presence test of each hemodialyzer</b> Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed.</p>	<p><b>Survey Procedures:</b> Manufacturers of peroxyacetic acid (trade name Renalin<sup>®</sup>) and glutaraldehyde (trade name Diacide<sup>®</sup>) require every dialyzer be tested for presence of germicide after storage and before use. Observe the testing.</p>
365	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.3.2 Process control and sampling</b> In the absence of the requirement in 12.3.1, the presence of germicide may be ensured by</p>	

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	<p>a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide. Sections 12.3.2.1 and 12.3.2.2 provide examples of what can be used to comply with this requirement.</p>	
366	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.3.2.1 Process control</b></p> <p>a) Use hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process; or</p> <p>b) Use an indicator substance (e.g., FD&amp;C Blue #1), which has been added to the germicide, and that reliably indicates the presence of germicide. If blue dye is used, it should be added to the germicide concentrate before dilution, not to the fully diluted solution. Note that use of dye may be inappropriate with certain germicides such as peracetic acid.</p>	<p><b>Survey Procedures:</b></p> <p>If formaldehyde is used, the facility may use a blue dye to indicate the presence of germicide. The absence of blue coloring must not be used as an indicator of the absence of germicide.</p>
367	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.3.2.2 Sampling for process validation</b></p> <p>a) Sample at least one hemodialyzer per patient shift per reuse system with a direct presence test (do not use a Schiff test for formaldehyde for this purpose because it will detect the presence of inadequate concentrations of formaldehyde). Samples</p>	<p><b>Survey Procedures:</b></p> <p>If the germicide manufacturer does not require testing of each dialyzer, expect a procedure to test a sample that meets these requirements.</p>

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	<p>should be taken immediately after the dialyzers have been reprocessed.</p> <p>b) For germicide prepared in batches, sample at least one hemodialyzer from each batch with a direct presence test. Samples should be taken immediately after the dialyzers have been reprocessed.</p> <p>c) Sampling and testing are to be accomplished before patients use any hemodialyzers processed on this shift.</p> <p>NOTE—The requirements of this section are fulfilled if every dialyzer is subjected to post-storage/pre-priming direct presence testing.</p>	
<b>368</b>	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.4 Priming the dialyzer and rinsing the germicide</b></p> <p>If the manufacturer's instructions so require, a germicide presence test shall be performed before the germicide is rinsed from the dialyzer. The dialyzer shall be rinsed and primed according to a written procedure that has been documented to produce a reduction in the concentration of germicide to an acceptable level and result in a physiological solution in the blood and dialysate compartments. The dialyzer manufacturer's instructions should be considered in developing these procedures.</p>	<p><b>Survey Procedures:</b></p> <p>Observe the rinsing procedure. Refer to the germicide manufacturer's requirements for specific rinsing procedures, which vary by germicide. Interview the direct care staff regarding the specific rinsing and priming steps. If you identify a concern, review policies and add this staff member to your list for personnel record reviews.</p>
<b>369</b>	<b>AAMI Requirements as Adopted by</b>	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>

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	<p><b>Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.4.1 Testing for residual germicide</b> Residual germicide shall be measured by a test of appropriate sensitivity according to a written procedure to ensure that the germicide level is below the maximum recommended residual concentration. In the case of formaldehyde, the recommended maximum level is 3 ppm. Completion of this step shall be documented, along with the signature or other unique means of identifying the person performing the test. A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis. Certain germicides have been demonstrated to disperse into solid components or less rapidly exchangeable compartments of the hemodialyzer. The priming, removal, and residual testing process should be reinstituted after a delay sufficient to bring concentrations of germicide above the recommended level (rebound). Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration before initiating of dialysis. A rinse procedure should be defined and documented step by step, and all personnel should be familiar with and follow it. If heat disinfection is used, the dialyzer should be cool to the touch before it is primed with saline.</p>	<p><b>12.4.1 Testing for residual germicide</b> Residual germicide shall be measured by a test of appropriate sensitivity according to a written procedure to ensure that the germicide level is below the maximum recommended residual concentration. In the case of formaldehyde, the recommended maximum level is 3 ppm. Completion of this step shall be documented, along with the signature or other unique means of identifying the person performing the test. A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis. Certain germicides have been demonstrated to disperse into solid components or less rapidly exchangeable compartments of the hemodialyzer. The priming, removal, and residual testing process should be reinstituted after a delay sufficient to bring concentrations of germicide above the recommended level (rebound). Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration before initiating of dialysis. A rinse procedure should be defined and documented step by step, and all personnel should be familiar with and follow it. If heat disinfection is used, the dialyzer should be cool to the touch before it is primed with saline.</p>

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370	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>12.5 Written procedure for tests for germicide or other residues</b></p> <p>There shall be a written procedure for all tests employed in preparing the dialyzer for use, including mention of each test's sensitivity. The germicide manufacturer's instructions for use should be consulted in determining the maximum residual level. The physician in charge of the reuse program shall approve any alterations in the procedures.</p>	<p><b>Survey Procedures:</b></p> <p>Observe set up for use; if you identify a concern, review the written policy and the germicide manufacturer's instructions for use, If there is any variation from the manufacturer's instruction, expect to see physician approval, and interview the physician regarding the rationale and basis for the variation.</p>
371	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>13 Monitoring</b></p> <p><b>13.1 Dialysis</b></p> <p>The clinical course of the patient should be observed and recorded during each dialysis to identify possible complications caused by new or reprocessed dialyzers. Dialyzer failures should be recorded and systematically evaluated. Home dialysis patients and their assistants should be instructed in the appropriate observation, recording requirements, and reporting procedures.</p>	<p><b>Survey Procedures:</b></p> <p>Review clinical records for intradialytic monitoring. Recognize that adequacy, anemia management and patterns of infection may be related to reprocessing. If you identify any symptoms potentially related to reprocessing, determine whether action taken included review of the reuse processes. If reuse is being done for home patients, include applicable patients in your sample and interview them (by phone if necessary) regarding their responsibilities for reuse.</p>
372	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>13.2 Symptoms</b></p> <p><b>13.2.1 Fever and chills</b></p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.13.2 Symptoms</b></p>



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	<p>Patients' temperatures should be measured and recorded at least before and after dialysis with new and reprocessed dialyzers. A temperature of over 37.8°C or °F, taken orally, or chills should be reported to the physician. Any patient with an unexplained fever and/or chills should be evaluated for the possibility of a pre-existing infection (e.g., access site). The dialysis procedure should also be evaluated to rule out the use of contaminated water, errors in treatment delivery, or incorrect dialyzer reprocessing.</p>	<p>Evaluation by a physician is required to determine whether symptoms might constitute an adverse reaction to the reprocessed dialyzer because symptoms during dialysis are commonly the result of other factors, such as infections not attributable to dialysis, and to hypovolemia. First-use syndrome is a symptom complex characterized by nervousness, chest pain, back pain, palpitations, pruritus, and other usually mild symptoms, occurring minutes following the initiation of dialysis with a new dialyzer. The syndrome is defined by some authorities to include the anaphylactoid reaction occurring usually immediately after the initiation of dialysis in some patients using dialyzers sterilized with ethylene oxide. In addition to first-use syndrome, serious reactions have been reported in patients taking ACE inhibitors and dialyzed on certain synthetic membranes. This reaction is now known to involve increased bradykinin release accompanied by suppression of bradykinin degradation.</p> <p><b>Survey Procedures:</b> Review clinical records to verify that patient temperatures are checked pre and post treatment. In reviewing infection control data and the QAPI materials, look for any symptoms potentially related to reuse. Interview the responsible staff (e.g., nurse manager, infection control officer, medical director) regarding any areas of concern.</p>
373	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>13.2.2 Other symptoms</b> Other unexplained symptoms such as pain in the blood-access arm at the onset of dialysis should be evaluated by the physician and consideration given to the possibility that the symptom may be attributed to residual disinfectant in the new or reprocessed dialyzer or contamination of the water</p>	<p><b>Survey Procedures:</b> Include questions regarding symptoms such as pain in the blood access site in your patient interviews.</p>

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	treatment equipment. Suspected reactions to the residual germicide should prompt reevaluation of the rinsing procedure and a test for residual germicide (see 12.4.1).	
374	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>13.2.3 Recording</b> Any significant events such as the occurrence of symptoms listed in 13.2.1 and 13.2.2 should be recorded on an incident report form which would include the results of any evaluations conducted by the physician and others, and the event should be considered for reporting to the manufacturer(s) in accordance with the FDA's Medical Device User Reporting procedures. The resolution of actual or suspected problems caused by reprocessed dialyzers should be indicated. This form should be kept in the complaint investigation record file (see 4.5).</p>	<p><b>Survey Procedures:</b> Review the complaint investigation records. Are these included in the QAPI program?</p>
375	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>13.3 Dialyzer failures</b> Dialyzer blood leaks should be recorded in a log kept in the complaint investigation record file (see 4.5). If there is excessive deviation from the expected performance, testing should be repeated (see 11.3.1) and appropriate adjustments made in the reprocessing procedure.</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.13.3 Dialyzer failures</b> This section sets up conditions under which some of the tests given in section 11 should be conducted. The option of adjusting the algorithm for UFR refers to a significant change of UFR without a significant change of clearance.</p> <p><b>Survey Procedures:</b> Interview the reuse technician regarding actions taken when a dialyzer blood leak occurs. Review the complaint investigation file for evidence blood leaks</p>

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376	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>13.4 Clinical results</b> Monitoring of relevant patient results is recommended to ensure that all parameters relating to hemodialyzer clearance are being met. Specifically, examination of urea reduction ratio (URR) or Kt/V over time is necessary. The failure of these results to meet the expectations of the dialysis prescription should be investigated. Deterioration of a patient's clinical condition or variability of routine dialysis procedures (heparinization, ultrafiltration, erythropoietin requirement) requires investigation of all practices, including reuse. Reports of investigations should be filed in the complaint log.</p>	<p>are reported.</p> <p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.13.4 Clinical results</b> Critical assessment of chemistries and the delivered dose of dialysis (Kt/V or urea reduction ratio), as is done monthly, provides a clear trend line to assess treatment. This scrutiny of the patient's treatment and course is the primary confirmation that hemodialyzer performance anticipated from TCV or other indirect estimation is accurate and adequate. The overall effectiveness of the entire treatment, not only the clearance of the dialyzers, is measured. No other measure of the effectiveness of new or reused dialyzers is as clear or relevant. Trend lines developed from this data characterize the quality of therapy. Other professional assessments of patient well-being should be considered. If the practitioner has concerns for "middle molecules" or other clinical parameters, these factors should also be part of the assessment of the delivered therapy.</p> <p>There are many reasons for an apparent reduction in the mass transfer of urea, other than decreased hemodialyzer clearance as a result of inadequate reprocessing (such as recirculation, decreased dialysis time or blood flow rate, or an inappropriate dialysis prescription). To document adequate mass transfer, one may find parallel measurements of pre- and post-creatinine levels helpful. When problems develop with any patient or group of patients, monitoring intensity should be increased, and other methods should be used to analyze the problem and define corrective action.</p> <p>Techniques to compare survival among facilities and for individual facilities against national and regional standard mortality rates are an important instrument for a facility to use in self assessment (Wolfe, et al.,1992). The committee recommends periodic review of this outcome measure.</p> <p><b>Survey Procedures:</b></p>

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		<p>Review the Dialysis Facility Report prior to beginning the on-site survey. Note the standard mortality rate; if this is higher than the average for the state, add questions to your interviews of the medical director regarding the potential causes of this higher rate.</p> <p>Expect the QAPI program to review aggregate data for adequacy; if these data indicate a negative trend, facility staff should consider whether there is any potential negative impact from the reprocessing program.</p>
377	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>14 Quality assurance</b> It is the responsibility of all staff members to critically scrutinize all materials, practices, operations, and outcomes. Criteria that serve as the scale for evaluation may be drawn from local experience and practice relative to the specific activity under review, consensus documents such as AAMI guidelines or standards, aggregated regional or national data, or other accepted norms. The criteria chosen as the internal standards of a facility shall be documented in its policy and/or procedure manual. Process review should be part of the activity of the individual carrying out the process, and oversight of that review by another qualified member of the staff or a group of staff members should affirm, modify, or repeat these observations to confirm or improve the process. Clinical outcomes serve as the most important indicator of quality of all dialysis treatment</p>	<p><b>AAMI Rationale for the Development and Provisions of this Recommended Practice</b></p> <p><b>A.14 Quality assurance</b> The FDA's 1987 compliance policy guide (7124.16) advises reuse practitioners to establish the following: (a) adequate device cleaning and sterilization; (b) the lack of adverse effects on device quality or physical characteristics; and (c) certainty that the device remains safe, reliable, and effective for its intended use. The committee believes that compliance with those recommendations necessitates use of regularly examined reprocessing procedures that are based on methods of demonstrated effectiveness and are carried out under conditions safe to the patient and the personnel.</p> <p><b>Survey Procedures:</b> Expect the reuse audits to be performed on the required schedule and to be reported in the QAPI activities.</p>

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	<p>practices including reuse. Final oversight is the responsibility of the medical director. See Table 2 for a summary of the audit schedule.</p> <p><b>Table 2—Quality assurance audit schedule</b></p> <table><tr><th></th><th>Monthly</th><th>Quarterly</th><th>Semi-Annually</th><th>Annually</th></tr><tr><td>Patient information policy (14.3)</td><td></td><td></td><td></td><td>x</td></tr><tr><td>Equipment manuals and procedures (14.4)</td><td></td><td></td><td></td><td>x</td></tr><tr><td>Equipment maintenance and repair policies (14.4)</td><td></td><td></td><td></td><td>x</td></tr><tr><td>Environmental safety (8.1)</td><td></td><td></td><td></td><td>x</td></tr><tr><td>Environmental safety (8.2)</td><td></td><td>x</td><td></td><td></td></tr><tr><td>Environmental safety (8.4)</td><td></td><td>x</td><td></td><td></td></tr><tr><td>Reprocessing supplies (9)</td><td></td><td></td><td>x</td><td></td></tr><tr><td>Water treatment* (11.4.1.5)</td><td>x</td><td></td><td></td><td></td></tr><tr><td>Hemodialyzer labeling (10)</td><td></td><td>x</td><td></td><td></td></tr><tr><td>Reprocessing procedures** (14.8)</td><td>x</td><td></td><td>x</td><td></td></tr><tr><td>Procedures for preparation for dialysis (14.9)</td><td></td><td>x</td><td></td><td></td></tr></table> <p>* More frequent monitoring may be required initially as described in 11.4.1.5. ** These functions may allow for the less frequent review period indicated according to the circumstances specified in their respective sections.</p>		Monthly	Quarterly	Semi-Annually	Annually	Patient information policy (14.3)				x	Equipment manuals and procedures (14.4)				x	Equipment maintenance and repair policies (14.4)				x	Environmental safety (8.1)				x	Environmental safety (8.2)		x			Environmental safety (8.4)		x			Reprocessing supplies (9)			x		Water treatment* (11.4.1.5)	x				Hemodialyzer labeling (10)		x			Reprocessing procedures** (14.8)	x		x		Procedures for preparation for dialysis (14.9)		x			
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378	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>14.1 Records</b> A record of review, comments, trend analysis, and conclusions arising from QA practices will serve as a foundation for future review and as documentation to external evaluation.</p>	<p><b>Survey Procedures:</b> Do the QAPI minutes include review of reuse practices?</p>																																																												
379	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>14.2 Schedule of quality assurance activities</b> Problems in a particular aspect of operations</p>	<p><b>Survey Procedures:</b> Expect reuse procedures/ tasks/ logs to be audited according to Table 2 (above). The medical director is responsible to assure these audits are done, but may not routinely authorize less frequent audits than specified in this table. If problems are identified via the audits, expect to see an action plan operationalized for correction.</p>																																																												

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	<p>should be reviewed and tracked until a solution is in place and demonstrated to be effective. High-volume tasks that are recognized as hazardous should have frequent (weekly or daily) oversight. Practices with little potential for harm may need critical scrutiny on only a quarterly or annual basis. The medical director is responsible for scheduling review, endorsing findings, and, when appropriate, implementing changes.</p>	
<b>380</b>	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>14.3 Patient considerations</b> Personnel should audit at least annually compliance with the facility's policy to inform patients of the facility's reuse practices.</p>	<p><b>Survey Procedures:</b> Interview responsible staff (e.g., nurse manager, administrator) to determine the method of audit for this requirement. Review documentation of the completion of the audit.</p>
<b>381</b>	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>14.4 Equipment</b> Designated staff members should audit written procedures and manuals for relevance at least annually and whenever adverse findings could be attributed to equipment failure. Designated staff should also audit maintenance and repair policies at least annually.</p>	<p><b>Survey Procedures:</b> Review documentation of this audit.</p>
<b>382</b>	<p><b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b></p>	<p><b>Survey Procedures:</b> 8.1 Reprocessing area and ventilation: annually 8.2 Storage area: quarterly</p>



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	<b>14.5 Physical plant and environmental safety considerations</b> Designated staff members should audit the provisions of 8.1 at least annually. The provisions of 8.2 and 8.4 should be audited quarterly.	8.4 Personnel protection: quarterly
383	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>14.6 Reprocessing supplies</b> Designated staff members should audit the provisions of section 9 at least semiannually.	<b>Survey Procedures:</b> Section 9 audit should address: 9 Reprocessing supplies 9.1 Specifications and testing 9.2 Inventory control
384	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>14.7 Hemodialyzer labeling</b> Designated staff members should audit the provisions of section 10. quarterly	<b>Survey Procedures:</b> Section 10 audit should address: 10 Hemodialyzer labeling 10.1 Time of labeling 10.2 Label composition 10.3 Information recorded
385	<b>AAMI Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</b>  <b>14.8 Reprocessing</b> Initially, designated staff members should audit the written procedures for the various steps in this process and verify implementation at least monthly. Subsequently, semiannual audits may be sufficient if there is a documented history of favorable results. Trend analysis should be performed.	<b>Survey Procedures:</b> For a new reuse program, verify monthly audits of reprocessing steps were done at a minimum. For an established program, expect audits of the practice of reuse to be done semiannually, unless problems are identified, requiring more frequent audits until a pattern of compliance is established.
386	<b>AAMI Requirements as Adopted by</b>	<b>Survey Procedures:</b>

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	<p><b>Reference 42 CFR 494.50 (b)(1)</b></p> <p><b>14.9 Preparation for dialysis</b> At least quarterly, designated personnel should audit the written procedures and verify their implementation. At least quarterly, designated staff members should verify the tests for the presence of germicide and the test for residual germicide by using positive and negative control solutions, on those products that are not specifically intended for use in dialyzer reuse germicide indicator tests and which have not been cleared by the FDA.</p> <p>End AAMI Requirements</p>	<p>This regulation requires audits of the set-up for dialysis, including testing for presence of germicide, testing for residual germicide, and verification of the patient identify with the reprocessed dialyzers. These audits are required quarterly at a minimum. In addition, the tests for presence and residual germicide must be verified quarterly. Interview the responsible staff (e.g., nurse manager, administrator, medical director) regarding these audits and review documentation the audits were accomplished and that any concerns identified were addressed.</p>
387	<p>(2) Reprocess hemodialyzers and bloodlines–</p> <p>(i) By following manufacturer’s recommendations; or</p> <p>(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.</p>	<p>Review insert from dialyzer original packaging. Each manufacturer of dialyzers for multiple use is required by FDA to provide at least one acceptable method. The facility may use that method or choose an alternate method. If choosing an alternate method, expect to see documentation that the chosen method is safe and effective. Interview the responsible person (e.g., chief technician or area technical manager) to determine how the method for reprocessing was chosen.</p>
388	<p>(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach, during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.</p>	<p>Interview responsible staff to determine what germicide is currently in use, and if there has been any recent change in the germicide used. If there has been a change, determine what was done with the dialyzers reprocessing using the previous germicide. These should have been discarded.</p>
389	<p><b>(c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.</b></p>	<p>Interview responsible staff (licensed and unlicensed) regarding what symptoms would indicate a patient might be having a potential reaction to a reprocessed dialyzer or the germicide used in reprocessing, and what actions they would take in the event of a reaction. Ask staff to identify any patients who have had</p>

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	<p>In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:</p> <p>(1) Monitor patient reactions during and following dialysis.</p>	<p>a suspected reaction related to reprocessing.</p> <p>Include in patient interviews questions to determine if that patient has experienced any problems potentially related to reprocessing.</p> <p>In reviewing clinical records, be alert to indications in the daily treatment records, in progress notes and in the plan of care of evidence of reactions related to reprocessing (e.g., a funny taste, burning in the access limb, fever or chills). Include any patients identified as having had a suspected reprocessing reaction in your record review.</p> <p>Expect that patient's temperature pre and post treatment will be monitored and recorded.</p>
390	<p>(2) When clinically indicated (for example, after adverse patient reactions), the facility must –</p> <p>(i) Obtain blood and dialysate cultures; and</p>	<p>Did the results of your interviews and record reviews (described above) demonstrate this action would be taken? Does the facility have standardized orders to require blood and dialysate cultures to be taken in the event of a suspected reaction related to reprocessing?</p>
391	<p>(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.</p>	<p>Interview the responsible staff (e.g., chief technician, area technical manager, physician director) regarding action to be taken if patients experienced adverse reactions potentially related to the reprocessing system. Do their answers indicate recognition of the need to evaluate the water treatment and distribution systems as well as the reprocessing system?</p> <p>If a cluster of adverse patient reactions associated with reuse was identified, was reuse suspended?</p>
392	<p>(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.</p>	<p>The dialyzer manufacturer is not responsible for adverse outcomes related to reprocessing. The facility management would be responsible for reporting, as required by law. This might include a state licensing requirement for required reporting, as well as reporting to FDA and perhaps the Centers for Disease Control (CDC), in the event of adverse outcomes related to reprocessing.</p>
400	<p><b>§494.60 Condition: Physical environment.</b></p>	<p>The facility and equipment should provide comfort and safety for patients and staff.</p>

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	The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.	
<b>401</b>	<p><b>(a) Standard: Building.</b></p> <p>The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.</p>	<p>The building must be constructed following local building codes. The plumbing, electrical system, heating/air conditioning systems should be constructed according to local codes. All building and building systems must be in good working order and free from defects or hazards. The building and its component systems should be appropriately maintained for safety and functionality.</p> <p>In order to ensure safety, the building accesses to patient care areas, reprocessing areas, water treatment areas, storage/supply areas, and machine maintenance areas must be restricted to authorized personnel only.</p>
<b>402</b>	<p><b>(b) Standard: Equipment maintenance</b></p> <p>The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p>	<p>All equipment in the dialysis facility needs to be maintained in good working order. The facility must establish, implement, and maintain a planned program of preventive maintenance of equipment used in dialysis and related procedures in accordance with the manufacturer's recommendations. Documentation must reflect performance of preventive maintenance in accordance with the manufacturer's recommendations and the facility's planned preventive maintenance program.</p> <p>Examples of equipment that must be maintained and operational include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Dialysis delivery system (individual patient station): On the blood side the machine should have clean, functioning air detector, blood leak detector, arterial and venous pressure monitors/alarms, transducer protectors, and heparin pump. Use of a "dummy drip chamber," a water filled venous chamber, on the dialysis machine even during machine setup is not allowed. On the dialysate side expect a clean source of dialysate concentrate such as a jug, cartridge or a central source and a functional proportioning pump and</li> </ul>

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		<p>conductivity monitor.</p> <ul style="list-style-type: none"> <li>• Water treatment system: May have UV (ultraviolet) light, expect to find appropriately maintained/changed filters, carbon tanks, DI tanks, RO membranes, and light bulbs and timers in good order. Readily available and easily identifiable records should be at hand for tracking daily water treatment system checks, change of the components, disinfection of the system and any required interventions. Cite problems under applicable tags in the Condition of Water Treatment/ Dialysate.</li> <li>• Ancillary equipment : Expect to find clean and functional glucometer, scales, centrifuge, refrigerators, incubators, B/P monitoring equipment, infusion pump, thermometer, eye wash, portable conductivity and/or pH meters, equipment required to support in-unit laboratory testing which may include a heat block, and or materials for hemocue, guiac, or ACT (activating clotting times), Additionally some facilities will maintain emergency generators.</li> <li>• Reuse System: If reprocessing of dialyzers is performed in the facility expect to find clean and functional equipment for the safe rinsing, cleaning, testing, disinfecting, labeling and storing dialyzers</li> <li>• Emergency equipment: Based on facility protocols, look for clean, functional, and accessible AED or defibrillator, oxygen, generators, suction equipment, cardiac monitors, ambu bags.</li> </ul> <p>Exchange programs for maintenance are sometimes utilized with device manufacturers for PD cyclers, integrated hemodialysis systems, etc. The facility may utilize an exchange program rather than specifying maintenance by the user. In this case, expect the facility to receive and maintain evidence of the work performed by the manufacturer to maintain/refurbish/remanufacture the exchanged device.</p>
403	<p><b>(c) Standard: Patient care environment.</b>  (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to</p>	<p>Unless specified by state regulation, there are no specific space requirements. However, space must be sufficient to:</p> <ol style="list-style-type: none"> <li>1. Provide needed care and services;</li> <li>2. Prevent cross contamination; and</li> </ol>

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	accommodate medical emergency equipment and staff.	<p>3. Accommodate medical emergency equipment and staff.</p> <p>To provide needed care and service the dialysis station requires</p> <ul style="list-style-type: none"> <li>• Enough room for all dialysis equipment, supplies and items for individual stations</li> <li>• Sufficient space for the caregivers to provide emergency care including CPR procedures requiring use of medical emergency equipment, crash cart, emergency cart, stretcher, and emergency staff.</li> <li>• Personal care with privacy as required by the individual patient. Special privacy needs may include use of commode , care of access placed in an intimate area or sensitive communication among other needs.</li> </ul> <p>To prevent cross contamination there should be sufficient space and privacy to allow for:</p> <ul style="list-style-type: none"> <li>• Prevention of body fluid spatters between patient stations during the initiation and discontinuation of treatment as well as during the dialysis treatment;</li> <li>• Dialysis machines and chairs not to come in contact with other dialysis stations machines and chairs;</li> <li>• Patient belongings to remain contained at the patient's station;</li> <li>• Catheter dressing and care</li> <li>• Use of a commode</li> <li>• Emesis</li> <li>• Hazardous waste container</li> </ul>
404	<p>(2) The dialysis facility must –</p> <p>(i) Maintain a temperature within the facility that is comfortable for the majority of its patients; and</p> <p>(ii) Make reasonable accommodations for the patients who are not comfortable at the</p>	<p>The facility and equipment should provide comfort and safety for patients and staff.</p> <p>While the protective clothing and activity level required of the staff predicts a different desirable temperature range from that of the patient confined to a chair with a reduced blood volume a respectful approach to creating an acceptable environment for all is expected.</p>



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	temperature that is comfortable for the majority.	Observe patients for comfort with the temperature. If all patients are using blankets, caps and gloves, question the setting of the temperature. Interview patients for staff responsiveness to requests for change to the temperature.
<b>405</b>	<p><b>(d) Standard: Emergency</b></p> <p>The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p>	<p>Expect the facility to have developed procedures addressing medical and non-medical emergencies.</p> <p>For a dialysis patient timely regular treatment is essential. Should a natural or man-made disaster interrupt dialysis service, immediate action must be taken to ensure prompt restoration of service or transfer of patients. Each dialysis facility should have a facility-specific plan and be able to respond promptly and appropriately. For example, facility plans should address failure of basic plant systems such as power, municipal water, air conditioning or heating systems as well as treatment specific failures such as the facility water treatment or supply delivery.</p> <p>Dialysis facilities must consider the potential for natural and man-made disasters in their geographical location and plan for these. The facility should contact and develop a communicative relationship with the local Emergency Operations Center in order to expedite restoration of power and water supplies if these are interrupted due to an emergency or disaster. Facilities located in areas prone to natural disasters (e.g., the Gulf Coast for hurricanes, the West Coast for earthquakes, etc.) should collaborate with their ESRD Network in forming partnerships with suppliers, utility service providers, state agencies for survey and for emergency preparedness as well as with other dialysis facilities to ensure life saving dialysis services will be available in the event of an emergency or disaster.</p> <p>Observe emergency supplies. Interview responsible staff (e.g., nurse manager, administrator) regarding the facility's emergency plan. Review the written emergency plan.</p>
<b>406</b>	(1) Emergency preparedness of staff.	All personnel are trained, as part of their orientation and continuing education,

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	<p>The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:</p>	<p>in all aspects of preparedness for any emergency or disaster. Emergency training of staff should address medical and non-medical emergencies and include natural and man-made disasters. Review selected personnel files for documentation that staff receive training in these areas and show competency at least annually.</p>
407	<p>(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of –</p> <ul style="list-style-type: none"> <li>(A) What do to;</li> <li>(B) Where to go;</li> <li>(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility; and</li> <li>(D) How to disconnect themselves from the dialysis machine if an emergency occurs.</li> </ul>	<p>Staff must have sufficient knowledge of emergency procedures to inform patients of how to handle medical and non-medical emergencies, both in and out of the center.</p> <p>Many dialysis corporations have an 800 telephone number to provide information to patients in the event of an emergency. Such information may include what facilities are open / closed; their hours of operation; and other facilities where patients might receive for treatment. In addition, there are help lines from the National Kidney Foundation and from the Kidney Community Emergency Response Coalition (KCER) which will be operated in the event of a significant natural or man-made disaster.</p> <p>In the event of a significant natural or man-made disaster, the ESRD Network in that area (or its back-up Network) is responsible for hosting an open door conference call to allow facilities, personnel, support services, etc. to discuss problems and solutions. Contact your Network to be placed on a list to be informed of these calls.</p> <p>Use the survey tasks of staff and patient interviews to evaluate compliance.</p> <p>The patient should be able to describe what they would do if they are not able to get to their regular dialysis treatment. This would include dietary precautions and some instruction regarding safety (e.g., don't drive through water if it is over the road). Patients should not be told they must come for treatment no matter the weather or road conditions. In contrast, patients should understand they must seek treatment promptly in the event a natural or man-made disaster</p>

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		<p>closes their usual place of treatment.</p> <p>For emergencies occurring in the dialysis facility, expect patients to be able to verbalize how they would disconnect themselves from the machine, or if unable, if they have been told a staff member would assist them.</p> <p>If patient responses do not demonstrate knowledge in this area, review records for evidence of education and interview staff regarding efforts to provide patients with this information.</p> <p><b>Resource:</b> Kidney Community Emergency Response Coalition (KCER) <a href="http://www.kcercoalition.com/">www.kcercoalition.com/</a></p>
408	(ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and	All direct patient care staff must have current certification in CPR. Review selected personnel files for compliance.
409	(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs;	All nursing staff must be trained in the use of emergency equipment (e.g. suction machine, AED, cardiac monitor, oxygen, defibrillator, Ambu bag) and drugs. Emergency drugs are defined by facility policy, and are commonly limited to a small number of on site medications, such as 50%dextrose, Benadryl and epinephrine. Inspect emergency supplies; review selected personnel files for compliance.
410	(2) Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.	<p>Patients must have sufficient knowledge of emergency procedures to handle medical and non-medical emergencies, both in and out of the center.</p> <p>Many dialysis corporations have an 800 telephone number that patients can call in the event of an emergency.</p> <p>Information provided to patients may include what facilities are open / closed; their hours of operation; and other facilities where patients might receive for treatment. In addition, there are help lines from the National Kidney Foundation and from the Kidney Community Emergency Response Coalition (KCER) which will be operated in the event of a significant natural or man-</p>

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		<p>made disaster. Resources can be found at <a href="http://www.kcercoalition.com/">www.kcercoalition.com/</a></p> <p>Patients should be informed to contact their Network for emergency information. Use the survey tasks of patient interviews and clinical record review to evaluate compliance.</p> <p>Patients should be able to describe what they would do if they are not able to get to their regular dialysis treatment. This would include dietary precautions and some instruction regarding safety (e.g., don't drive through water if it is over the road). Patients should not be told they must come for treatment no matter the weather or road conditions. In contrast, patients should understand they must seek treatment promptly in the event a natural or man-made disaster closes their usual place of treatment.</p> <p>For emergencies occurring in the dialysis facility, expect patients to be able to verbalize how they would disconnect themselves from the machine, or if unable, if they have been told a staff member would assist them.</p> <p>If patient responses do not demonstrate knowledge in this area, review records for evidence of education and interview staff regarding efforts to provide patients with this information.</p>
411	(3) Emergency equipment and plans. Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. The facility must --	The emergency equipment listed here should be clean, accessible, operational and ready to use.
412	(i) Have a plan to obtain emergency medical system assistance when needed; and	On interview, all members of the staff must demonstrate knowledge of how to obtain emergency medical assistance (e.g., recognize the need to call 911 should an emergency situation occur).
413	(ii) Evaluate at least annually the	This process should include review of any medical or non-medical emergencies

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	effectiveness of emergency and disaster plans and update them as necessary.	which have occurred to determine any opportunities for improvement. If no emergencies have presented, the facility may choose to conduct a drill or mock emergency in order to test their plans. Interview responsible staff (e.g., nurse manager, administrator) to determine compliance.
<b>414</b>	<p><b>(e) Standard: Fire safety.</b></p> <p>(1) The dialysis facility must meet applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference in §403.744(a)(1)(i) of this chapter).</p>	Refer to the referenced requirements for guidance.
<b>415</b>	(2) Chapter 5 of the 2000 edition of the Life Safety Code does not apply to a dialysis facility.	
<b>416</b>	(3) If CMS finds that a State has a fire and safety code imposed by State law that adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.	
	(4) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:	
<b>417</b>	(i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and	
<b>418</b>	(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.	
<b>450</b>	<b>§494.70 Condition: Patients' Rights</b>	Survey of the Patients' Rights Condition should be coordinated by one

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	<p>The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.</p>	<p>surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the dialysis facility's compliance with the Patients' Rights Condition.</p> <p>Expect to see written documentation patients or their legal patient representatives were informed (generally within the first 3 treatments) of facility policies, their rights and responsibilities in a language and format that they can understand. Patients must be able to exercise their right to self-determination without fear of ridicule, reprisal or refusal of service. A Condition level citation should be considered when there are multiple or serious problems identified.</p> <p>To determine compliance with this Condition, use the tasks of patient interview, record review, staff interview, and observation. Review related policies and procedures if you have questions or identify any issues.</p>
451	<p><b>(a) Standard: Patients' rights.</b></p> <p>The patient has the right to</p> <p>(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD</p>	<p>In all verbal and nonverbal communications, staff must treat patients with respect, dignity, and sensitivity taking into consideration their physical condition, emotional state, and cultural differences. Patients must be able to exercise their right to self-determination without fear of ridicule, reprisal or refusal of service. Observe interactions between facility staff and patients and between patients. Patients should be treated with dignity and respect. Essentially this means that patients should be treated as you would expect to be treated if you were a dialysis patient (privacy should be respected and protected, and patients should be spoken with in a respectful manner). If a portion of the patient's body is exposed to deliver care, screening for privacy should be provided. Staff should not shout out patient weights or lab values across the room. Patients should not be restrained in treatment chairs. Staff should refer to patients by their names and not use diminutive names such as "grandma," "pops," "sweetie," etc. While hard to describe specific instances of disrespect, it is likely you will recognize it if you see it. Patient interviews are another good way of evaluating compliance with this requirement.</p>



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		<b>Resources:</b> NKF, Dialysis Patient's Bill of Rights at <a href="http://www.kidney.org/atoz/pdf/DialysisBillRights.pdf">www.kidney.org/atoz/pdf/DialysisBillRights.pdf</a> Life Options, How to Talk to Team at <a href="http://www.lifeoptions.org/catalog/pdfs/teaching/HowToTalk.pdf">www.lifeoptions.org/catalog/pdfs/teaching/HowToTalk.pdf</a>
452	(2) Receive all information in a way that he or she can understand;	<p>There must be evidence (obtain by observing, asking, or reviewing) that patients or their legal patient representatives receive information about current policies, rights, responsibilities, dialysis process, treatment options, diet, costs of treatment, paying for treatment, and right to be told if a significant medical error occurs, how the error could affect his/her health, and what is being done to restore health. Information related to patient rights must be presented in a format and language that the patient understands.</p> <p>Forms that must be available in other languages for applicable patients include consent, rights and responsibilities, grievance forms, and/or any document that requires a patient or legal patient representative signature. Staff should limit the use of technical words in oral and written communication with patients or legal patient representatives. It is not acceptable to use another patient as the interpreter, as this would be a breach of confidentiality. Use of a family member is also problematic, especially if a medical issue must be explained: the family member may not know the medical terms. Non-family interpreters, e.g. paid or volunteer medical interpreters, bilingual staff or telephone services, should be used to communicate with patients and family members with limited English proficiency. Staff should use oral communications or materials in Braille for patients who are visually impaired. Options for hearing impaired patients would include lip reading, sign language, pictograms or written communication.</p> <p>Written communications with patients must take into consideration content, health literacy, graphics, layout, learning stimulation, and cultural appropriateness. There should be printed material available in the major languages in the geographic area served to explain the basic dialysis process, treatment options, diet, and financing treatment. If written materials are not</p>

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		<p>available in alternate languages or formats, the facility must provide for an interpreter to explain this information to the patient.</p> <p><b>Resources:</b>  DHHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons - <a href="http://www.usdoj.gov/crt/cor/lep/hhsrevisedlepguidance.pdf">www.usdoj.gov/crt/cor/lep/hhsrevisedlepguidance.pdf</a>  DHHS, CMS, <i>Your Medicare Rights &amp; Protections</i> (page 8) - <a href="http://www.medicare.gov/Publications/Pubs/pdf/10112.pdf">www.medicare.gov/Publications/Pubs/pdf/10112.pdf</a>  Doak, Doak &amp; Root's <i>Teaching Patients with Low Literacy Skills</i>, Second Edition, J.B. Lippincott Company, 1996. (Suitability Assessment of Materials)  Institute of Medicine, <i>Health Literacy: A Prescription to End Confusion</i> (April 8, 2004) - <a href="http://www.iom.edu/CMS/3775/3827/19723.aspx">www.iom.edu/CMS/3775/3827/19723.aspx</a>  Institute of Medicine, <i>Preventing Medication Errors</i> (July 20, 2006) - <a href="http://www.iom.edu/CMS/3809/22526/35939.aspx">www.iom.edu/CMS/3809/22526/35939.aspx</a>  Language Line (interpreters) - <a href="http://www.languageine.com/">www.languageine.com/</a></p>
453	(3) Privacy and confidentiality in all aspects of treatment;	<p>Space between dialysis stations should be sufficient to prevent breaches in confidentiality when patients and staff converse in a normal tone of voice.</p> <p>The dialysis access should remain uncovered and in view of staff during dialysis for safety. Patient placement (e.g., end of aisle, corner station), screen or privacy curtain must be used if a patient's sensitive body area is exposed while on dialysis. The social worker and other staff members must have ready access to a private office or conference room where they can meet with patients and/or families confidentially.</p> <p><b>Resources:</b>  Several fact sheets on privacy  <a href="http://www.hhs.gov/ocr/hipaa/">www.hhs.gov/ocr/hipaa/</a>  <i>Protecting the Privacy of Patients' Health Information</i>  (<a href="http://www.hhs.gov/news/facts/privacy.html">www.hhs.gov/news/facts/privacy.html</a>)</p>
455	(4) Privacy and confidentiality in personal	A patient has the right to understand facility privacy policies and expect that the

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	medical records;	<p>facility will maintain confidentiality of his/her medical records. The sensitive notes may be maintained separately if so noted in the chart. The patient has the right to approve any non-employee who can view or receive a copy of his/her medical records unless access is required by law. The patient has the right to read his or her medical records, to have corrections made to his or her medical records, and to not be frustrated in legitimate efforts to read or obtain a copy of his or her medical records. The facility must actively seek to meet patients' requests to copy medical records as quickly as its recordkeeping system permits. The patient as the right to file a complaint to the HHS Office for Civil Rights for violation of his or her privacy rights.</p> <p><b>Resources:</b>  HHS Office of Civil Rights - HIPAA  <a href="http://www.hhs.gov/ocr/hipaa/">www.hhs.gov/ocr/hipaa/</a>  Protecting the Privacy of Patients' Health Information (fact sheet)  <a href="http://www.hhs.gov/news/facts/privacy.html">www.hhs.gov/news/facts/privacy.html</a></p>
456	(5) Be informed about and participate, if desired, in all aspects of his or her care, including advance directives, and be informed of the right to refuse treatment and to refuse to participate in experimental research;	<p>The patient has the right to participate in the development and implementation of his or her plan of care. The patient has the right to learn how to safely do as much of his/her dialysis treatment as desired, including but not limited to knowing how to tell if the dialyzer is his/hers, preparation for and self-cannulation, machine monitoring and recording vital signs. The facility must inform the patient about advance directives, including the right to request or refuse treatment, to formulate advance directives, and to have medical and ancillary staff honor his/her advance directives. If the patient asks for help establishing an advance directive, the facility must provide appropriate guidance.</p> <p>A patient who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her consent.</p>

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		<p>A patient who is asked to participate in experimental research must be fully informed of the nature of the experiment, possible benefits and possible consequences of participating. The patient has the right to refuse to participate in experimental research prior to the start of research. Aggregated patient statistics that do not identify individuals may be used for studies without patient permission.</p> <p>“<b>Treatment</b>” is defined as care provided for purposes of maintaining health, improving functional level, or relieving symptoms.</p> <p>“<b>Experimental research</b>” is defined as development and testing of interventions that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.</p> <p>“<b>Advance directive</b>” means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated or unable to communicate his or her wishes.</p> <p>Use the survey tasks of patient and staff interviews and clinical record reviews to determine compliance with this regulation.</p> <p><b>Resources:</b>  Dialysis Patient’s Bill of Rights (NKF)  <a href="http://www.kidney.org/atoz/pdf/DialysisBillRights.pdf">www.kidney.org/atoz/pdf/DialysisBillRights.pdf</a>  Clinical Practice Guideline on Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis (ASN/RPA)  <a href="http://www.guideline.gov/summary/summary.aspx?doc_id=2195&amp;mode=full&amp;ss=14">www.guideline.gov/summary/summary.aspx?doc_id=2195&amp;mode=full&amp;ss=14</a>  End-Stage Renal Disease Workgroup Full Report of <i>Promoting Excellence in End-of-Life Care</i>  <a href="http://www.promotingexcellence.org/files/public/esrd_full_report.pdf">www.promotingexcellence.org/files/public/esrd_full_report.pdf</a>  Kidney End of Life Coalition  <a href="http://www.kidneyeol.org/">www.kidneyeol.org/</a>  <i>Advance Directives</i></p>

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		<a href="http://www.kidney.org/atoz/atozItem.cfm?id=21">www.kidney.org/atoz/atozItem.cfm?id=21</a> <i>Dialysis: Choosing Not to Start</i> <a href="http://www.kidney.org/atoz/atozItem.cfm?id=28">www.kidney.org/atoz/atozItem.cfm?id=28</a> <i>Dialysis</i> <a href="http://www.kidney.org/atoz/atozItem.cfm?id=39">www.kidney.org/atoz/atozItem.cfm?id=39</a> <i>Dialysis: Deciding to Stop</i> <a href="http://www.kidney.org/atoz/atozItem.cfm?id=40">www.kidney.org/atoz/atozItem.cfm?id=40</a>
457	(6) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis;	<p>A patient or his/her legal representative must receive education about all treatment options for kidney failure. All patients must be evaluated for home dialysis and transplant as well as in-center hemodialysis. A patient interested in transplant or home dialysis (hemodialysis or peritoneal dialysis) must be evaluated by a transplant facility or home dialysis training facility as applicable. If the patient is interested and the current facility does not offer home dialysis, that facility must provide information about area facilities where home dialysis is provided. A patient has the right to know the reason(s) why home dialysis or transplantation is not appropriate in their case. A patient has the right to understand the benefits and consequences of method selection on the Beneficiary Selection Form (CMS 382).</p> <p>Use the survey tasks of patient and staff interview to determine compliance.</p> <p><b>Resources:</b>  American Association of Kidney Patients <a href="http://www.aakp.org">www.aakp.org</a>  American Kidney Fund <a href="http://www.kidneyfund.org">www.kidneyfund.org</a>  Home Dialysis Central <a href="http://www.homedialysis.org">www.homedialysis.org</a>  Life Options <a href="http://www.lifeoptions.org">www.lifeoptions.org</a>  National Institute of Diabetes and Digestive and Kidney Diseases <a href="http://www.niddk.nih.gov">www.niddk.nih.gov</a>  National Kidney Foundation <a href="http://www.kidney.org">www.kidney.org</a>  National Kidney Disease Education Program <a href="http://www.nkdep.nih.gov">www.nkdep.nih.gov</a>  CMS 382 (Beneficiary Selection Form) for home dialysis <a href="http://www.cms.hhs.gov/cmsforms/downloads/cms382.pdf">www.cms.hhs.gov/cmsforms/downloads/cms382.pdf</a></p>

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458	(7) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;	<p>A patient has the right to know and understand policies regarding patient care, including policies that the facility follows to protect patients from disease transmission. The facility must avoid breaching confidentiality of any patient who has a communicable disease.</p> <p>Use the survey tasks of patient and staff interviews to determine compliance. Review selected policies if concerns are identified.</p> <p><b>Resource:</b> Centers for Disease Control and Prevention, Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, MMWR, April 27, 2001 / 50(RR05);1-43 <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm">www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm</a></p>
459	(8) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;	<p>A patient must be informed of whether the facility practices reuse, what supplies are reused, and, if the facility practices reuse, what benefits and risks are associated with the practice. If a patient chooses to refuse to participate in the reuse program, the facility has the right to offer the patient a treatment option that does not require reuse of supplies, or to help the patient locate and transfer to another facility that does not practice reuse.</p> <p>Use the survey tasks of patient and staff interview to review this requirement.</p> <p><b>Resource:</b> From NKF What You Should Know About Dialyzer Reuse <a href="http://www.kidney.org/atoz/pdf/dialyzer_reuse.pdf">www.kidney.org/atoz/pdf/dialyzer_reuse.pdf</a></p>
460	(9) Be informed by a physician of his or her own medical status as documented in the patient's medical record unless the medical record contains a documented contraindication to do so;	<p>A patient has the right to be fully informed by a physician (or physician extender as allowed by federal or state regulation) of his or her medical health status. If a patient is incompetent, the legal patient representative should be informed of the patient's medical status. There should be few, if any, cases when a patient (or legal patient representative) is not informed of his/her medical status.</p>



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		<p><b>Medical status</b> includes but is not limited to diagnosis, clinical and functional status.</p> <p>Use the survey tasks of patient and staff interviews to evaluate compliance.</p>
461	(10) Be informed of services available in the facility and charges for services not covered under Medicare;	<p>A patient must be fully informed while he or she is a patient at the facility of the charge for services, including any charges for services not covered under Medicare. If Medicare or Medicaid is expected to deny a claim for services, the facility must inform the patient of the potential denial and the cost of the service, prior to providing the service.</p> <p><b>Resources:</b>  Medicare Coverage for Kidney Dialysis and Kidney Transplant Services  <a href="http://www.medicare.gov/Publications/Pubs/pdf/10128.pdf">www.medicare.gov/Publications/Pubs/pdf/10128.pdf</a>  NKF, Dialysis Patient's Bill of Rights at  <a href="http://www.kidney.org/atoz/pdf/DialysisBillRights.pdf">www.kidney.org/atoz/pdf/DialysisBillRights.pdf</a>  Kidney Medicare Drugs Awareness and Education Initiative (Part D)  <a href="http://www.kidneydrugcoverage.org">www.kidneydrugcoverage.org</a>  Your Guide to Medicare Prescription Drug Coverage (generic Part D)  <a href="http://www.medicare.gov/Publications/Pubs/pdf/11109.pdf">www.medicare.gov/Publications/Pubs/pdf/11109.pdf</a></p>
462	(11) Receive the necessary services outlined in the patient plan of care described in the patient plan of care described in §494.90 of this part;	<p>Cross reference to Patient Care Plan §494.90(b) Implementation of the patient plan of care</p> <p>A patient has a right to receive the care set forth in the care plan that was developed by the interdisciplinary team and patient or legal patient representative. Care must be individualized to the type of treatment and medical, dietary, psychosocial, and rehabilitation needs. For example, if all patients are prescribed the same dialyzer and treatment prescription, the patient may not be receiving individualized care. If any care plan goals are not achieved by timelines set in the written care plan, the patient has a right to participate with the team in revising the care plan to overcome the barriers that prevented achievement of the goals or develop new goals and new interventions to achieve them.</p>

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		Use the survey tasks of patient and staff interviews, clinical record reviews, and observation to determine compliance.
473	(12) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;	<p>The patient is informed of his/her responsibilities which may include such items as the importance of being on time for dialysis, notifying the facility if he/she will be late, miss dialysis, or if a change in appointment time is needed, any restrictions about eating, drinking, visitors, behavior, information about making payment arrangements or requesting financial help, and when a patient may legally be discharged from a facility.</p> <p><b>Resources:</b>  NKF, Dialysis Patient's Bill of Rights at <a href="http://www.kidney.org/atoz/pdf/DialysisBillRights.pdf">www.kidney.org/atoz/pdf/DialysisBillRights.pdf</a> (see responsibilities)  Decreasing Dialysis Patient Provider Conflict (DPC) - <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a></p>
464	(13) Be informed of the facility's internal grievance process;	<p>Recognize there are additional requirements under the Condition of Governance related to this issue</p> <p>The dialysis facility must establish a mechanism to address a patient's verbal or written concerns, complaints, and grievances. Patients should be given clear information regarding who to talk with about a complaint, and staff should know to refer any patient concern to the appropriate person for resolution. The social worker should be able to describe the facility complaint process and how complaint information is shared with the team. There should be a complaint resolution system within the facility to address patient issues/concerns. All staff must be informed about the process and who to refer a patient to if he/she has an inquiry, complaint, or grievance.</p> <p><b>Definitions:</b>  <b>Inquiry</b>  Any contact made to a resolving entity by a Medicare beneficiary or beneficiary representative via phone, fax, walk-in, email, or white mail (U.S. Postal Service) that does not fall into the category of being a complaint or grievance.</p>

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		<p>This could also be referred to as a general inquiry.</p> <p><b>Complaint</b> Any verbal or written report of dissatisfaction regarding administrative issues or how a beneficiary may feel he or she was treated within the health care/Medicare field.</p> <p><b>Grievance</b> Any verbal or written report of a health care risk of any kind.</p> <p>Use the survey tasks of patient and staff interviews to evaluate compliance with this requirement.</p> <p><b>Resource:</b> Decreasing Dialysis Patient/Provider Conflict <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a></p>
465	(14) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;	<p>Every patient must be given information on how to file a grievance with the applicable ESRD Network or state survey agency. Staff must be informed about the grievance process and how to refer the patient to the Network or state survey agency. It is common, though not required, for Network to provide a poster which includes contact information for facilities to place in their patient waiting rooms.</p> <p>Use the survey tasks of patient and staff interview and observation to determine compliance.</p> <p><b>Resources:</b> Decreasing Dialysis Patient/Provider Conflict <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a> MARC Patient Complaint/Grievance Policy <a href="http://www.esrdnetworks.org/networks/net5/grievbroch.pdf">www.esrdnetworks.org/networks/net5/grievbroch.pdf</a> Network Statement of Work, Task 2.b. Provision of Education Information-Patient (page 13)</p>

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466	(15) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of service; and	<p><a href="http://www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/SOWBaseYear.pdf">www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/SOWBaseYear.pdf</a></p> <p>Each patient must feel free to file a grievance without fear or ridicule, reprisal or refusal of service. All staff should be informed about the grievance process and who to refer a patient to if he/she has a concern, complaint, or grievance.</p> <p>Reprisal is defined as perceived punishment, e.g. isolation, reducing contact with caregivers, or perceived infliction of physical or emotional distress.</p> <p>Use the survey tasks of patient and staff interviews to determine compliance.</p> <p><b>Resources:</b> Decreasing Dialysis Patient/Provider Conflict <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a> Network Statement of Work, Task 2.b. Provision of Education Information-Patient (page 13) <a href="http://www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/SOWBaseYear.pdf">www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/SOWBaseYear.pdf</a></p>
467	(16) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.	<p>Patients must be informed that they can file an internal or external complaint personally, through a representative, or anonymously.</p> <p>Use the survey tasks of patient and staff interviews to determine compliance. Review related policies and procedures if you identify any issue or concern.</p> <p><b>Resources:</b> Decreasing Dialysis Patient/Provider Conflict <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a> Network Statement of Work, Task 2.b. Provision of Education Information-Patient (page 13) <a href="http://www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/SOWBaseYear.pdf">www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/SOWBaseYear.pdf</a></p>
468	<b>(b) Standard: Right to be informed regarding the facility's discharge and transfer policies.</b>	<p>Cross reference 494.180 (f) Standard: Discharge and transfer policies and procedures.</p> <p>Each facility must define situations under which a patient could be transferred,</p>

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	<p>The patient has the right to –</p> <p>(1) Be informed of the facility’s policies for transfer, discharge, and discontinuation of service to patients, and</p>	<p>discharged, or when dialysis could be discontinued.</p> <p>A patient (or legal patient representative) has the right to receive information about what notice the facility will provide and how far in advance this notice will be given if the facility will no longer provide his/her dialysis treatments or if the facility is closing.</p> <p>Use the survey tasks of patient and staff interview and clinical record review to determine compliance.</p>
469	<p>(2) Receive written notice 30 days in advance of the facility reducing or terminating ongoing care after following the procedure described in §494.180(f) of this part. In the case of immediate threats to the health and safety of others, a shortened discharge procedure may be allowed.</p>	<p>A patient (or legal patient representative) has the right to receive at least 30-days notice if the dialysis facility plans to discharge him/her or if the dialysis facility is voluntarily closing. A shortened discharge procedure may be allowed if the patient (or patient’s family member) present a credible threat to the health or safety of others (patients or staff).</p> <p>A credible immediate threat is a perceived likelihood and ability to carry out a written or verbal threat.</p> <p>Use the survey tasks of patient and staff interview and clinical record review to determine compliance.</p> <p><b>Resources:</b>  Decreasing Dialysis Patient/Provider Conflict  <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a> Grassley memo, Grassley Urges Improvements in Quality of Care for Kidney Dialysis Patients, November 6, 2003.  <a href="http://www.senate.gov/~grassley/releases/2003/p03r11-06.htm">www.senate.gov/~grassley/releases/2003/p03r11-06.htm</a></p>
470	<p><b>(c) Standard: Posting of rights.</b></p> <p>The dialysis facility must prominently display a copy of the patient’s rights in the facility, including the current State agency and ESRD network telephone complaint numbers, where it can be easily seen and read by patients.</p>	<p>The facility must post a copy of these rights in the facility. This may be in the form of a poster or an actual copy of the rights that is available for patients to read. The complaint phone contact information for both the state survey agency and the applicable ESRD</p> <p>Network must also be posted. The applicable Network may provide the facility with a poster with this information.</p>

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		Use the survey tasks of observation, patient and staff interviews to determine compliance. If concerns are identified, review applicable policy and procedure.
<b>475</b>	<p><b>§494.80 Condition: Patient Assessment</b></p> <p>The facility's interdisciplinary team, consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee, a registered nurse, a nephrologists or the physician treating the patient for ESRD, a social worker, and a dietitian, is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.</p>	<p>The interdisciplinary team staff members must meet the qualification definitions as outlined in §494.140. If any of the team members do not contribute to the assessment, a deficiency should be cited under the applicable Standard.</p> <p>A comprehensive assessment must meet the specific criteria as outlined in §494.80 (a) (1) through (13). The patient assessment may be one document or be composed of sections developed by each team member. If the latter is used the comprehensive assessment must be congruent and demonstrate integration of the assessments by each discipline.</p> <p>Use the survey tasks of patient and staff interviews and clinical record reviews to determine compliance. (If the patient chooses to), is there evidence that clearly reveals that the patient was invited to participate or has declined to participate?</p>
<b>476</b>	<p><b>(a) Standard: Assessment criteria.</b></p> <p>The patient's comprehensive assessment must include, but is not limited to, the following (1) Evaluation of current health status and medical conditions, including co-morbid conditions.</p>	<p>Expect to see documentation of a history of the etiology and progress of the patient's kidney disease and a history of co-morbid conditions.</p> <p>Appropriate physical assessment must include a physical exam to update any components of the patient's current medical status.</p> <p>If you see copies of histories and physicals (H&amp;P) from hospital admissions being used, the content should address the patient's current presentation and health status. The H&amp;P should address the renal disease aspects of the patient's medical history.</p> <p>H&amp;P are expected to be updated as part of the re-assessment requirement as</p>



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		<p>stated in §494.80(d).</p> <p>Physician extenders may conduct the medical portions of the H&amp;P, in accordance with State law and facility policy.</p> <p>Nursing documentation must include a nursing history of the patient, as well as evidence of assessment of the needs of the patient, conducted by the registered nurse.</p> <p>The nursing history is expected to be updated as part of the reassessment requirement as stated in §494.80(d).</p>
477	(2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.	<p>There should be evidence that the patient's individual dialysis needs have been assessed: dry weight, blood pressure.</p> <p>Is there evidence that the assessment resulted in the development of the comprehensive patient care plan as stated in §494.90(a)(1)?</p>
478	(3) Laboratory profile and medication history.	<p>Review for laboratory work-up consistent with accepted professional standards of practice.</p> <p>Expect to see a comprehensive metabolic panel, complete blood count, iron studies and hepatitis panel.</p> <p>Is there an accurate and complete medication history and a list of medications the patient is currently taking?</p>
479	(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoietin.	<p>Has the patient been assessed for individual anemia management needs, consistent with current accepted professional standards of practice?</p> <p>If indicated, did the facility identify the need for more frequent than monthly laboratory monitoring of the patient's anemia status?</p> <p>Cross-reference 494.90(a)(3)</p>
480	(5) Evaluation of factors associated with	Expect to see a review of the patient's laboratory values for calcium,

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	renal bone disease.	<p>phosphorous, and PTH.</p> <p>Expect to see a review of the current renal bone disease medications, such as phosphate binders, vitamin D analogs, Sensipar.</p> <p>Expect to see an assessment of the patient's dietary and nutritional status.</p>
481	(6) Evaluation of nutritional status.	<p>Must be done by a qualified dietitian as defined at §494.140(c). It must include assessment of the nutritional and dietetic needs of the patient. The dietary assessment should reflect the patient's lab work. The assessment should address those values that touch on nutritional needs include electrolytes, albumin level, iron stores, etc.</p> <p>The assessment should include information from the person that cooks and provides meals for the patient, whether this is the patient, spouse, family or nursing home. If the patient is in a nursing home, the dietitian should conduct the assessment with the input from the dietary personnel at the nursing home.</p>
482	(7) Evaluation of psychosocial needs.	<p>Must be done by a qualified social worker as defined at 494.140(d).</p> <p>Expect the psychosocial evaluation to include assessment of the psychosocial status and needs of the patient, including assessment of the patient's:</p> <ul style="list-style-type: none"> <li>• And family's ability to cope with and adjust to dialysis</li> <li>• Financial capabilities and resources.</li> <li>• Mental health history, capacities, and needs for counseling.</li> <li>• Family and social history and environment.</li> <li>• Cognitive status and capacity to understand</li> <li>• Home environment.</li> <li>• Access to available community resources</li> <li>• Current living situation;</li> <li>• Family composition and history;</li> <li>• Support system, willingness to ask for help when needed;</li> <li>• Knowledge of, interest in, and barriers to transplantation and all</li> </ul>

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		<p>hemodialysis and peritoneal dialysis treatment options;</p> <ul style="list-style-type: none"> <li>• Interest in and ability to participate in dialysis care in-center;</li> <li>• Expectations for the future and living with kidney failure and treatment;</li> <li>• Substance abuse history, if any;</li> <li>• Current coping, especially level of anxiety, hostility, depression;</li> <li>• Ability to perform activities of daily living with or without help;</li> <li>• Educational and employment status, concerns, and goals;</li> <li>• Legal issues, e.g. incarceration, court appointed guardian, advance directive status and healthcare proxy;</li> <li>• Need for advocacy with traditional (nursing home) and non-traditional housing (e.g., homeless shelters, group homes, etc.)</li> <li>• Ability to follow the treatment prescription</li> <li>• Ability to meet basic needs</li> <li>• Eligibility for Federal, State, or local resources</li> </ul> <p>If the assessment is done using a checklist or narrative, it must provide more than merely answers to questions, but should provide an assessment of need and plan for meeting those needs, including individual or group counseling for patients and/or their families to help them cope with the special problems associated with ESRD and helping them to access services from Federal, State, and local resources as needed.</p> <p><b>Resources:</b>  CNSW, Social Work: The Ideal Profession to Address the Psychosocial Issues of the Kidney Disease Patient (PowerPoint)  <a href="http://www.kidney.org/professionals/CNSW/teri_arthur_presentation02.htm">www.kidney.org/professionals/CNSW/teri_arthur_presentation02.htm</a>  CNSW Documentation Guidelines For Dialysis and Transplant Facilities  <a href="http://www.kidney.org/professionals/CNSW/pdf/documentation.pdf">www.kidney.org/professionals/CNSW/pdf/documentation.pdf</a>  National Kidney Foundation, Social Work Services for the Person with Kidney Failure  <a href="http://www.kidney.org/professionals/CNSW/pdf/swservices.pdf">www.kidney.org/professionals/CNSW/pdf/swservices.pdf</a></p>

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		<p>CNSW Care Plan  <a href="http://www.kidney.org/professionals/CNSW/pdf/cnswcareplan.pdf">www.kidney.org/professionals/CNSW/pdf/cnswcareplan.pdf</a></p>
<b>483</b>	(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters).	<p>There must be evaluation to assure adequate assessment and monitoring of the patient's access and its function.</p> <p>Has there been an evaluation to determine if the optimal type of vascular access for that patient is placed and used? Is the patient's vascular access placed in the optimal location to preserve future vascular access sites? The evaluation may include venous mapping, surgical consult, doppler studies, etc.</p> <p>Few hemodialysis patients should require a central venous catheter as the primary vascular access for over 90 days. If this is the case, ask/review to determine what process is in place to progress to a more permanent vascular access.</p> <p>What vascular access monitoring routine does the facility follow? This may include periodic venous pressure measurements, machine-based procedures, etc. for fistulas and grafts.</p> <p>Is there assessment of the patient's individual vascular access monitoring needs?</p>
<b>484</b>	(9) Evaluation of the patient's ability, interests, preferences, and goals, including level of participation in the dialysis care process, modality and setting, for example, home dialysis, including hemodialysis or peritoneal dialysis; and expectations for care outcomes.	<p>Determine by interview and record review whether the interdisciplinary team has evaluated the patient's interest and capacity for self care. Self care in center may include self cannulation, monitoring of vital signs during treatment, etc.</p> <p>Consider the patient's psychosocial evaluation in this review, as well as functional status.</p>
<b>485</b>	(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis	<p>The regulations for transplant programs require written selection criteria to be developed, and provided upon request to patients and to dialysis facilities. The reason for non-referral must be documented. (482.90 (a)(4))</p> <p>Selection criteria vary among transplant programs; if the facility refers patients</p>

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	for nonreferral must be documented in the patient's medical record.	<p>to multiple transplant programs, selection criteria for each should be available to the patient and the dialysis facility.</p> <p>Does the facility have and use these criteria in determining suitability of patients for transplantation? If the patient is determined as not suitable for referral for transplant, the reason for non-referral must be based on the transplant center's selection/ suitability criteria.</p> <p>This requirement is not dependent on patient interest in transplantation. Each patient should be screened using the selection criteria; the patient's choice of seeking transplantation is addressed under plan of care (482.90 (5))</p>
486	(11) Evaluation of family and other support systems.	<p>Review each patient's medical record for evidence of this evaluation; it may be part of the psychosocial assessment or part of the nursing history. Information should also be obtained from the family, if applicable, about their coping and need for support from the team.</p> <p>If the issue of living donation for kidney transplant emerges, expect staff to facilitate the assessment of that potential donor by a qualified health professional. Refer to the regulations for transplant hospitals at 482.90 and 482.102 for more information regarding assessment and rights of potential living donors.</p>
487	(12) Evaluation of current patient physical activity level.	<p>Review the patient's chart including but not limited to progress notes and care plans for evidence that the nurse or social worker asked the patient about recent and current physical activity, ability to perform activities of daily living with or without help, and/or barriers to independence. Look for evidence that low functioning patients were encouraged to talk with their doctor about safe exercise at home (or in the clinic, if the clinic has an exercise program) and/or referral to physical rehabilitation. Every team assessment must demonstrate this requirement was reviewed.</p> <p><b>Resources:</b> Life Options, <i>Exercise: A Guide for People on Dialysis</i></p>

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		<a href="http://www.lifeoptions.org/catalog/pdfs/booklets/exercise.pdf">www.lifeoptions.org/catalog/pdfs/booklets/exercise.pdf</a> (pages 14, 40-42) Life Options: <i>Exercise for the Dialysis Patient: A Prescribing Guide</i> <a href="http://www.lifeoptions.org/catalog/pdfs/booklets/pro_prescguide.pdf">www.lifeoptions.org/catalog/pdfs/booklets/pro_prescguide.pdf</a> American Nephrology Nurses' Association, <i>Nephrology Nursing Standards of Practice and Guidelines for Care</i> (2005) page 51-53
488	(13) Evaluation of vocational and physical rehabilitation status and potential.	Review the patient's chart for evidence the team evaluated the patient's past work history, current work status, any problems with work due to dialysis, and potential for and barriers to vocational rehabilitation. Every team patient assessment must demonstrate this requirement was reviewed.
489	<b>(b) Standard: Frequency of assessment for new patients.</b> (1) An initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment.	Facility staff members are expected to immediately recognize and address critical medical needs (e.g., severe anemia, severe fluid overload, hyperkalemia), rather than waiting to take action after the comprehensive assessment is completed. Issues identified in pre and post treatment assessments may also need to be addressed prior to completion of the comprehensive assessment.  Input of all team members must be completed within 20 calendar days after the first dialysis treatment in this facility.  If the patient is transferred to this facility, the assessment by this team should be completed within 20 calendar days of admission to this facility. Recognize that the transfer in of a large number of patients at once (e.g., with the opening of a new facility, or in the event of an adverse occurrence or disaster impacting the functionality of the transferring facility) may impact the staff's ability to complete this requirement. Expect to see a written plan to ensure completion of the assessments of these transferred patients promptly.
490	(2) A followup comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90 of this part.	3 months after completion of the initial assessment the team must complete a reassessment of all the areas required at 494.90. The form of the reassessment is not specified, but the record of the patient should clearly demonstrate each section of the assessment outlined above is addressed.
491	<b>(c) Standard: Assessment of treatment</b>	The adequacy of dialysis treatment must be assessed on a routine, on-going



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	<p><b>prescription.</b></p> <p>The adequacy of the patient's dialysis prescription, as described in §494.90(a)(1) of this part, must be assessed on an ongoing basis as follows:</p>	<p>basis.</p>
492	<p>(1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent measure.</p>	<p>At the time of publication of these regulations, the NKF KDOQI Guidelines for Hemodialysis Adequacy (2006) recommended:</p> <p>4.1 Minimally adequate dose: The minimally adequate dose of HD given 3 times per week to patients with <math>K_r</math> less than 2 mL/min/1.73 m<sup>2</sup> should be an spKt/V (excluding RKF) of 1.2 per dialysis. For treatment times less than 5 hours, an alternative minimum dose is a URR of 65%.</p> <p>4.2 Target dose: The target dose for HD given 3 times per week with <math>K_r</math> less than 2 mL/min/1.73 m<sup>2</sup> should be an spKt/V of 1.4 per dialysis not including RKF, or URR of 70%.</p> <p>4.3 In patients with residual urea clearance (<math>K_r</math>) greater than or equal to 2 mL/min/1.73 m<sup>2</sup>, the minimum session spKt/V can be reduced. One method of minimum dose reduction is described in CPR 4.4. In such patients, the target spKt/V should be at least 15% greater than the minimum dose.</p> <p>4.4 Missed and shortened treatments: Efforts should be made to monitor and minimize the occurrence of missed or shortened treatments.</p> <p>In the future, if a scientifically proven equivalent measure becomes available, that measure may be accepted.</p> <p>Recognize that different targets may be applicable for patients having more</p>

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		<p>frequent treatments (e.g. a lower daily dose, or a weekly Kt/V).</p> <p>Assessment of hemodialysis adequacy requires pre and post-dialysis BUN measurement with blood samples being drawn in a particular manner. The KDOQI Guideline for Hemodialysis Adequacy (2006) recommends:</p> <p>3.1 Both samples (predialysis and postdialysis) should be drawn during the same treatment session.</p> <p>3.2 The risk of underestimating predialysis BUN level because of saline dilution or by sampling the blood after treatment has begun should be avoided.</p> <p>3.3 The risk of underestimating the postdialysis BUN level because of access recirculation (AR) should be avoided by first slowing the blood flow through the dialyzer to a rate at which AR is expected to be minimal (100 mL/min) for a period long enough to ensure that unrecirculated blood has advanced to below the sampling port (usually 15 seconds).</p> <p>3.4 An alternative method is to stop the dialysate flow for a period long enough to increase the dialysate outlet BUN level close to that of the blood inlet BUN level (3 minutes) before obtaining the postdialysis sample.</p> <p>Check facility policy for congruence with the KDOQI guidelines.</p> <p>Interview staff members and observe blood sampling procedure if possible to ensure the method used would result in an accurate result, and to ensure all staff members use the same method.</p> <p>Pre and post treatment samples must be drawn during the same dialysis session.</p> <p><b>Resource:</b>  <a href="http://www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/index.htm">www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/index.htm</a></p>

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493	(2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.	<p>At the time of publication of these regulations, the NKF KDOQI guidelines for the peritoneal patient specified a target Kt/V of 1.7 per week measured within the first month after starting dialysis therapy and at least once every 4 months. In the future, if a scientifically proven equivalent measure becomes available, that measure may be accepted.</p> <p>Recognize that obtaining this measure depends on patient cooperation with bringing samples of dialysate effluent and urine specimen if the patient continues to have some function of their native kidneys. If a scheduled sample is not obtained, expect to see some documentation some explanation, which might include reminders and re-education of the patient.</p> <p><b>Resource:</b>  <a href="http://www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/index.htm">www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/index.htm</a></p>
494	<p><b>(d) Standard: Patient reassessment.</b></p> <p>In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted --</p> <p>(1) At least annually for stable patients; and</p>	Expect to see a complete reassessment at least annually for stable patients.
495	<p>(2) At least monthly for unstable patients including, but not limited to, patients with --</p> <p>(i) Extended or frequent hospitalizations;</p> <p>(ii) Marked deterioration in health status;</p> <p>(iii) Significant change in psychosocial needs; or</p> <p>(iv) Poor nutritional status, with unmanaged anemia and inadequate dialysis.</p>	<p>Review facility policy and procedure on how they define “unstable patient.”</p> <p>Examples of “extended or frequent hospitalizations” may include hospitalization longer than 7 days, and more than 3 hospitalizations within 30 days;</p> <p>Examples of “marked deterioration in health status” may include amputations, loss of ~20 pounds in less than 3 months; stroke; severe depression;</p> <p>Examples of “significant change in psychosocial needs” may include death of</p>

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		<p>spouse, divorce, loss of job and health insurance, loss of home;  Examples of “poor nutritional status, with unmanaged anemia and inadequate dialysis” may include patients with simultaneous problems in these three major areas which have significant impact on their morbidity and mortality. For example, if a patient has poor nutritional status, but managed anemia and adequate dialysis, the patient care plan should address nutritional status, and be updated as needed, but a comprehensive reassessment is <u>not</u> required each month.</p>
<b>500</b>	<p><b>§494.90 Condition: Patient plan of care.</b></p> <p>The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient’s needs, as identified by the comprehensive assessment and changes in the patient’s condition, and</p>	<p>The patient plan of care is built on the comprehensive assessment by the interdisciplinary team.</p> <p>All members of the interdisciplinary team must participate in the development and implementation of the plan of care. The facility must recognize the patient as a member of the team and encourage the patient’s participation in care planning. The patient’s needs, wishes, and goals must be considered.</p> <p>Any problem identified in the patient comprehensive assessment must be addressed in the patient plan of care.</p>
<b>501</b>	<p>must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards.</p>	<p>The care plan must include at minimum: problem(s) identified at assessment/reassessment, measurable goals/outcomes, reassessment date.</p> <p>Timelines should be based on reasonable targets for the individual patient and appropriate to the severity of the problem (e.g., acute issues should have shorter timelines). Review of the progress notes of the individual disciplines should show interventions related to the problems and goals identified; progress toward those goals; and identified barriers.</p> <p>Evidence based community accepted standards include the NKF KDOQI and KDIGO guidelines which are used to derive the measurable and expected outcomes.</p> <p><b>Resource:</b></p>

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502	<p>(a) Standard: Development of patient plan of care.</p> <p>The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:</p>	<p>KDOQI and other clinical practice guidelines  <a href="http://www.kidney.org/professionals/kdoqi/guidelines.cfm">www.kidney.org/professionals/kdoqi/guidelines.cfm</a></p> <p>Areas which are not specifically addressed in Standards (a) (1)-(6) of this Condition may be cited at this tag—for example, failure to develop a plan to include uncontrolled hypertension, hypokalemia, and hyperkalemia would be cited here. If, for example, uncontrolled hypertension is identified as a problem, there should be an outcome oriented plan developed and implemented.</p> <p>The facility must demonstrate that the patient has the opportunity to be a participating team member and be able to discuss the plan of care with the entire team. A team conference is necessary to assure the development of a congruent plan. Members, including the patient, may participate in person or via conference call. To facilitate patient participation in the team, care plan conferences should be scheduled at times, dates and places convenient for the patient.</p> <p>If the patient does not attend the patient care plan conference, the patient care plan should reflect any patient comments or input, and the patient care plan should address that input. There should be evidence the patient has consented or committed to any change in behavior or treatment proposed in the plan.</p>
503	<p>(1) Dose of dialysis.</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the prescribed dose of dialysis.</p>	<p>Compare treatment orders and dialysis treatment records. Is the prescribed dose of dialysis being delivered? Does the patient achieve their target weight post treatment?</p> <p>If you identify a trend of unaddressed problems in delivery of the ordered treatment, there should be an outcome oriented plan developed. Use this tag to cite.</p> <p>Cite “dose of dialysis” if there is failure to meet the K/DOQI adequacy measure (or equivalent) for adequacy. Also use “Dose of dialysis” to cite problems with fluid removal or treatment time.</p>

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		<p>If, for example, uncontrolled hypertension is identified as a problem, there should be an outcome oriented plan developed and implemented.</p> <p>Also consider the patient's adherence to the treatment plan. Recognize if the patient shortens treatments, misses treatments, or gains excessive fluid between treatments, the dose of dialysis may not be able to be delivered. Look for interventions from the team (nurse, social worker) to address the issues which may be preventing the patient from adhering to the plan.</p>
504	<p>(2) Nutritional status.</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective nutritional status. A patient's albumin level must be measured at least monthly.</p>	<p>If you identify a trend of unaddressed problems in the patient's nutritional status, there should be an outcome oriented plan developed and implemented. Use this tag to cite.</p> <p>The dietitian, in consultation with the attending physician, is responsible for recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. Cite this tag if the dietitian does not provide these services.</p> <p>Cite "nutritional status" if there is failure to measure the albumin monthly or if there is a lack of an individualized plan to address low albumin levels.</p> <p>Recognize there are two methods of measuring albumin, with different ranges. Review the lab results for the method and normals of the measurement in use. Expect the team to address extremely low albumin levels promptly.</p> <p>Other nutritional markers including but not limited to calcium, phosphorus, potassium and glucose should be routinely monitored.</p> <p>Dialysis patients frequently have calcium and phosphorus imbalances related to their kidney failure which may progress to bone disease and calcifications of tissue. Expect to see the team develop and implement an outcome oriented plan for these problems when identified.</p>



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		<p>Recognize that high parathyroid hormone (PTH) levels are another indicator of mineral bone disorders. Normal range varies with the test in use, from 150-300 pg/ml.</p> <p>If a facility is using a protocol for managing bone disease, recognize that the care for each patient must be individualized.</p>
505	<p>(3) Anemia.</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the expected hemoglobin/hematocrit level.</p>	<p>Compare lab reports, orders for Erythropoietin Stimulating Agents (ESA) and administration records. Are doses being adjusted to achieve and sustain the target level? Are patient lab values monitored and levels higher than the target level addressed?</p> <p>If you identify a trend of unaddressed problems in management of anemia, there should be an outcome oriented plan developed. Use this tag to cite.</p> <p>Cite “anemia” if there is failure to meet the K/DOQI stated range of 11-12 for hemoglobin gm/dL. Also use “anemia” to cite a failure of the facility to take responsibility for the management of anemia (e.g., not providing blood transfusions when indicated).</p> <p>If a facility is using a protocol for managing anemia, recognize that the care for each patient must be individualized.</p>
506	<p>The patient’s hemoglobin/hematocrit must be measured at least monthly.</p>	<p>Expect these values to be measured at least monthly as K/DOQI recommends; many facilities may measure every two weeks.</p>
507	<p>For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoietin and store erythropoietin under refrigeration.</p>	<p>The facility must evaluate the patient/family capacity to safely store and use anemia management drugs (e.g., ESAs, iron). The patient/caregiver should be trained by the facility to administer these medications including aseptic techniques.</p> <p>Interview home patients/ caregivers and review records to evaluate whether the facility meets this requirement.</p> <p>See also 494.100 (a)(3)(ii) under Care at Home.</p>

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508	If a patient has hemoglobin less than 11 gm/dL or hematocrit of less than 33 percent, the dialysis facility must conduct an evaluation to determine whether the patient is an erythropoietin candidate.	<p>Each patient should be evaluated individually; Cite this tag if there is failure to meet the K/DOQI stated range of 11-12 for hemoglobin gm/dL.</p> <p>Some patients' anemia is resistant to ESA therapy. The record should reflect the facility's evaluation of the patient and plan for correction, in accordance with the K/DOQI guidelines.</p>
509	The patient's response to erythropoietin, including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.	<p>The facility must meet the K/DOQI expectations for management of the patient's iron stores. A monthly evaluation of the serum ferritin and transferrin saturation levels should be done initially, then every three months once the patient's anemia is stabilized. The serum ferritin level should be maintained above 200ng/mL for HD patients, and above 100 ng/mL for PD patients. The transferrin saturation should be maintained above 20% for all patients.</p> <p>With increased blood volume, patients' blood pressures may increase. The facility must monitor the trends in patients' blood pressures and act upon significant elevations.</p>
510	<p>(4) Vascular access.</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain vascular access.</p>	Based on the comprehensive assessment, the facility must develop a plan of care to promote each HD patient receiving and maintaining the most optimal vascular access.
511	The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions and other risk factors.	Look for evidence of appropriate referrals for vascular access placement and partnerships with interventional radiology and surgical centers for vascular access care.
512	The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for stenosis.	<p>Review the facility policy for vascular access monitoring. There may be different methods for this: dynamic venous pressure monitoring, dialysis machine-based methods, etc. The documentation of such may be on the dialysis treatment record, or a separate log. Look for evidence that the facility reviewed the VA monitoring documentation for identification of trends.</p> <p>For patients with AVF and AVG, look for evidence of periodic monitoring of</p>

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		the VA for stenosis and signs of impending failure. The plan of care , including VA monitoring, should be individualized.
<b>513</b>	(5) Transplantation status.  When the patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the --	<ul style="list-style-type: none"> <li>• Is there evidence the patient was educated about transplantation, e.g., transplant programs, evaluation process, donor types, risks and benefits, costs, etc.</li> <li>• Is there evidence suitable patients have been referred for evaluation?</li> <li>• Is there documentation from a transplant program of the patient's status, including whether he/she is a candidate for transplant or needs further testing?</li> </ul>
<b>514</b>	(i) Plan for transplantation, if the patient accepts to transplantation referral;	The dialysis facility must develop a plan for transplantation if the patient is interested in being referred for transplant. The plan would include referral of the patient and any potential living donors to the transplant facility.
<b>515</b>	(ii) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or	The dialysis facility must document if a patient has chosen not to be a transplant candidate.
<b>516</b>	(iii) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with §494.80(a)(1) of this part.	<p>Look for documentation of the rationale for nonreferral for transplantation. Remember the facility must use selection criteria developed by the individual transplant programs in determining referral/nonreferral.</p> <p>Recognize patient insurance coverage may dictate which transplant program the patient may access.</p>
<b>517</b>	(6) Rehabilitation status.  The interdisciplinary team must provide the necessary care and services to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years).	<p>The interdisciplinary team provides encouragement, education, referral and facilitates access to rehabilitation activities to enable patients to maintain or return to their desired level of functioning at work, school, home and in their community.</p> <p>Pediatric patient services should address normal growth and development needs as well as education.</p> <p>The social worker may provide direct services, may collaborate with the team to provide services, or may refer the patient to specialist services, such as psychiatry or a state rehabilitation program.</p>

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		<p><b>Resources:</b>            CMS 2744 ESRD Facility Survey -- Vocational Rehabilitation (page 9)  <a href="http://www.cms.hhs.gov/ESRDGeneralInformation/Downloads/facilitysurvey5b3.pdf">www.cms.hhs.gov/ESRDGeneralInformation/Downloads/facilitysurvey5b3.pdf</a>            Life Options, <i>Building Quality of Life: A Practical Guide to Renal Rehabilitation</i>  <a href="http://www.lifeoptions.org/catalog/pdfs/booklets/qualoflife.pdf">www.lifeoptions.org/catalog/pdfs/booklets/qualoflife.pdf</a>            Life Options, <i>A Kidney Patient's Guide to Working and Paying for Treatment</i>  <a href="http://www.lifeoptions.org/catalog/pdfs/booklets/employment.pdf">www.lifeoptions.org/catalog/pdfs/booklets/employment.pdf</a>  <i>Effective Strategies for Improving Employment Outcomes for People with Chronic Kidney Disease</i>  <a href="http://www.rcep6.org/IRI/27iri/IRI27.pdf">www.rcep6.org/IRI/27iri/IRI27.pdf</a>            American Nephrology Nurses' Association, <i>Nephrology Nursing Standards of Practice and Guidelines for Care</i> (2005) page 51-53            National Kidney Foundation brochures on living with kidney disease  <a href="http://www.kidney.org/atoz/atozTopic_br.cfm">www.kidney.org/atoz/atozTopic_br.cfm</a></p>
<b>518</b>	<p>(b) Standard: Implementation of the patient plan of care.</p> <p>(1) The patient's plan of care –</p> <p>(i) Must be completed by the interdisciplinary team;</p>	<p>The interdisciplinary team must include, at a minimum, the patient, the nurse, the social worker, the dietitian and the patient's physician. Look for scheduled conferences of the team to complete the plan of care.</p>
<b>519</b>	<p>(ii) Must be signed by the patient or the patient's designee.</p>	<p>The patient should be involved in the development of the plan. If the patient is not present when the plan is developed, the plan should be reviewed with the patient to ensure his/her understanding. This signature should be obtained prior to plan's implementation.</p> <p>If the patient does not attend the PPC conference, the PPC should reflect any patient comments or input, and the PPC should address that input. There should be evidence the patient has consented or committed to any change in behavior or treatment proposed in the plan.</p>
<b>520</b>	<p>(2) Implementation of the plan of care must</p>	<p>Look for evidence the plan of care was implemented within this timeline. The</p>

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	begin within 10 calendar days after completion (of) the patient assessment as specified in §494.80 of this part.	plan of care should be dated; evidence of implementation should include the date of initial implementation. As example, if the plan of care indicates a referral to physical therapy will be initiated, is there evidence of this referral within this timeline?
521	(3) If the expected outcome is not achieved, the interdisciplinary team, must adjust the patient's plan of care to achieve the specified goals.	<p>If the current plan is not successful in achieving the goals which have been agreed upon by the patient within the identified timetable, the plan must be revised. For example, if the patient continues to have uncontrolled hypertension after implementation of a plan for control, when the timetable for that goal has been reached, the plan must be adjusted.</p> <p>The facility should have and adhere to a timetable for review of outcomes.</p> <p>Cite if the plan of care is not adjusted for persistent problems (e.g., uncontrolled hypertension, hyperkalemia, missed treatments, etc.)</p>
522	(4) The dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically, while the hemodialysis patient is receiving in-facility dialysis.	Expect to see monthly progress notes at a minimum whether the patient is seen in the facility or in the physician's office. If a problem is identified, consider citing the Medical Director at 494.150 (c)(2)(i) (Responsibilities of the Medical Director: Policies and procedures).
523	<p>(c) Standard: Transplantation referral tracking.</p> <p>The interdisciplinary team must track the results of each kidney transplant center referral and must monitor the status of any facility patients who are on the transplant wait list.</p>	<p>Expect to see evidence in the patient record of the status of the patient's transplant referral.</p> <p>The plan of care should address barriers to transplantation. For example, if transplant center requires a patient to lose weight prior to being accepted for transplantation, the patient plan of care should address a plan for weight loss</p>
524	The team must communicate with the transplant center regarding patient transplant status at least quarterly or more frequently, if	Expect to see evidence of communication (phone calls, letters, email) between the dialysis facility and the transplant center regarding patient transplant status.

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	necessary.	
<b>525</b>	<p>(d) Standard: Patient education and training.</p> <p>The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.</p>	<p>A dialysis facility must include sufficient patient education and training to participate in decision-making and to follow their treatment plan.</p> <p>Expect the facility to make attempt to overcome communication barriers in order to provide needed patient education.</p> <p>Review patient records for evidence of patient education.</p>
<b>530</b>	<p><b>§494.100 Condition: Care at home.</b></p> <p>A dialysis facility that is certified to provide services to home patients must ensure, through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients.</p>	<p>This Condition applies to those facilities requesting to provide home dialysis. Home dialysis patients are patients of the ESRD facility. They are entitled to the same rights, services, and efforts to achieve expected patient outcomes as any other patient of the facility.</p> <p>Expect home patients to receive the same quality of care from the interdisciplinary team as in-center patients.</p>
<b>531</b>	<p>(a) Standard: Training.</p> <p>The interdisciplinary team must provide training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in §494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes.</p>	<p>Home dialysis training may only be provided by a dialysis facility certified to provide home dialysis services. A durable medical equipment (DME) company is not qualified to provide home dialysis training. Training must be provided to the patient and/or caregiver before any patient is allowed to do home dialysis. Training must be provided any time there is a change in home dialysis caregiver, treatment modality, or home dialysis equipment.</p> <p>Use the survey tasks of patient interview and clinical record review to determine compliance with this requirement. Patients present in the facility (being trained or for follow-up care) may be interviewed or you may phone selected home patients.</p>
<b>532</b>	<p>The training</p> <p>(1) must be provided by a dialysis facility that is approved to provide home dialysis services;</p>	<p>For a dialysis facility to provide a home dialysis program, the facility must be certified for home dialysis services, both training <i>and</i> support. The facility may choose to apply for certification for peritoneal dialysis (PD) only, home hemodialysis (HHD) only, or both services. These services may be added to an existing facility, a new facility may apply for home dialysis services in addition</p>



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		<p>to in-center services, or a new facility may apply to provide only home dialysis services. The facility application should be directed to the state survey agency A Method II DME cannot provide home training.</p> <p>During your presurvey activities, review the facility file. Is there a CMS-3427 End Stage Renal Disease Application/Notification And Survey And Certification Report indicating that the facility is approved for PD or HHD training and support? If the state requires separate licensure for home therapies, is there a state approval on file?</p>
533	(2) For self-care, must be conducted by a registered nurse who meets the requirements of §494.140(b)(2) of this part; and	<p>The nurse providing home dialysis training must be a registered nurse who meets the practice requirements of the State in which he or she is employed and have at least 12 months experience in providing nursing care plus an additional 3 months of experience working as a nurse in the specific modality (hemodialysis or peritoneal dialysis) for which the nurse will provide self-care training.</p> <p>Use the survey tasks of staff interview and personnel record review to determine compliance.</p>
534	(3) Must be conducted for each home patient and address the specific needs of the patient, in the following areas:	<p>The training must be individualized to the needs of each home training patient. Expect to see each of the areas listed below addressed in the record of the training.</p> <p>Interview patients and staff, observe training (if available) and review clinical records to determine if the training was individualized to the patient.</p>
535	(i) The nature and management of ESRD;	Interview the responsible nurse and the patient regarding the content of the training program. The information provided on this topic should be tailored to the patient, and could be quite complex or relatively simple. At a minimum, the program should address the cause of the patient's kidney failure, the outcomes of that failure, and the steps the patient will need to take to manage his kidney disease.
536	(ii) The full range of techniques associated with treatment modality selected, including	Use the survey tasks of patient and staff interview, observations of training (if available) and clinical record review to determine if the home patients included

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	effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hematocrit level of at least 33 percent or a hemoglobin level of 11 gm/dL;	<p>in your sample received, at a minimum:</p> <ol style="list-style-type: none"> <li>1. Specific (step-by step) instructions on use of the dialysis equipment to be used at home</li> <li>2. Expected procedures to use.</li> <li>3. Instructions in the use of supplies and equipment, to achieve the physician's prescription of Kt/V or URR.</li> <li>4. Training in anemia management. If erythropoietin is administered by the home patient or their caregiver, the training program must include training of these individuals in the storage and administration of erythropoietin</li> </ol> <p>Deficient practices identified here may also impact 494.90(a)(3) Plan of Care.</p>
537	(iii) Implementation of a nutritional care plan;	<p>Expect the qualified dietitian to provide direct service to the home patients. A nutritional assessment must form the basis for the development of a nutritional care plan; the implementation of that plan requires the patient to be informed and to agree to the goals of the plan.</p> <p>Interview the dietitian to determine his/her involvement with home patients; interview home patients regarding the nutritional services they receive, and review clinical records for the documentation of the plan and for updates as the plan is implemented and adjusted to the specific needs of the patient and changes in his/her nutritional status.</p>
538	(iv) How to achieve and maintain emotional and social well-being;	<p>Expect the qualified social worker to provide direct service to the home patients. A psychosocial assessment must form the basis for the development of a teaching plan related to emotional health and social well-being: the implementation of that plan requires the patient to be informed and to agree to the goals of the plan.</p> <p>Use the survey tasks of patient and staff interviews and clinical record review to determine compliance with this regulation.</p>
539	(v) How to detect, report, and manage potential dialysis complications;	The training program must provide information to patients on signs and symptoms of a dialysis complication: how to recognize a potential complication; and when and who to contact if they suspect they may have

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		<p>developed a complication.</p> <p>Complications discussed should be specific to the modality.</p> <p>For PD, physical complications would include peritonitis, catheter dislodgement, hyper or hypotension, hypokalemia, and failure of the dialysate to drain from the peritoneal space. Technical problems could include problems with supplies or equipment.</p> <p>For HHD, physical complications would include bleeding, access problems, hyper/hypotension, etc. Technical problems could include power outages, water supply problems, high chlorine/chloramines, conductivity out of range, or problems with supplies or equipment.</p> <p>Interview staff and patients, and review clinical records to assess compliance.</p>
540	(vi) Availability of support resources and how to access and use resources;	<p>Training must include how to access and use resources. Support resources can include family members/caregivers, machine vendors, water treatment personnel, home training staff, physicians, dietitian, social worker, and other facility personnel.</p> <p>Use the survey tasks of staff and patient interviews to determine compliance.</p>
541	(vii) How to self-monitor health status and record and report health status information;	<p>Interview patients regarding their understanding of self monitoring. Their responses should include awareness of such information as how to use the applicable equipment to monitor blood pressure, temperature, weight, and vascular or peritoneal access.</p> <p>Patients or their caregiver are expected to record treatment and health status information. Review home patient records for the presence of this sort of information, including treatment records.</p> <p>Interview home patients regarding to whom, when, and how they would report health status information.</p>

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542	(viii) How to handle medical and non-medical emergencies;	<p>Interview patients to determine if they have been taught how to handle medical and nonmedical emergencies, including who to contact in an emergency. The facility must provide 24-hour access to medical care. This may be via a call system which can be reached by the patient/family/caregiver by phone, beeper, answering service or similar arrangement.</p> <p>Patients should be taught how to handle situations where there may be no power, water, or a shortage of supplies, etc.</p>
543	(ix) Infection control precautions; and	<p>The appropriate infection control techniques must be included in the home training.</p> <p>The training program for infection control precautions should include, but is not limited to the following areas:</p> <ul style="list-style-type: none"> <li>• Aseptic technique and when this is indicated in the provision of care</li> <li>• When to use protective equipment (e.g. gowns, face shields, gloves)</li> <li>• Hand washing and when hand washing is needed</li> <li>• When and who should wear a face mask</li> <li>• Environment considerations for the room where the PD procedure is performed in the home</li> <li>• Dressing changes</li> <li>• Care of the catheter exit site, catheter, and access site as applicable</li> <li>• Administering medications</li> <li>• Cleaning and disinfecting dialysis equipment</li> <li>• Cleaning and disinfection procedures for spills and splashes of blood or effluent</li> <li>• Proper storage of supplies</li> </ul> <p>Resources: CDC April 27, 2001 and August 9, 2002</p>
544	(x) Proper waste storage and disposal procedures.	<p>Interview home patients (in person or by phone) to determine their level of knowledge and understanding regarding this requirement. The patient's responses should address how to properly dispose of needles, effluents,</p>

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		<p>disposable items, blood tubing and dialyzers in order to minimize risks of infection or injury to self and others and to prevent contamination of the environment. For example, impervious puncture resistant containers are recommended for disposal of sharps. Empty bags and tubing used for the dialysis treatment and contaminated items should be placed in intact plastic bags before discarding.</p> <p>If there are any local laws pertaining to proper waste disposal, the facility must make the patients aware of these.</p>
545	<p>(b) Standard: Home dialysis</p> <p>The dialysis facility must –</p> <p>(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;</p>	<p>The facility must have a method or methods of evaluating the patient and/or caregiver competencies to ensure comprehension of the training provided including demonstrating competency in the performance of procedures and techniques in the provision of dialysis.</p> <p>Review home patient clinical records for evidence of compliance with this requirement.</p>
546	<p>(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and</p>	<p>The facility must keep medical records on all home patients that include self-monitoring data and other information, e.g., treatment flow sheets, medication administration, equipment checks, water treatment system checks.</p> <p>At least every 2 months, the facility is responsible for retrieving and reviewing the medical records generated in the home. Documentation must reflect review of the retrieved information by the appropriate licensed health care professionals. The facility interdisciplinary team is expected to monitor patients' status to determine if patients are following the treatment plan and/or having problems at home.</p> <p>Facility staff must also review the documentation provided by any applicable DME to assess the appropriateness of the delivered supplies relative to the patient dialysis prescription and patient needs.</p> <p>Interview home program staff regarding the provisions to ensure home records</p>

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		are retrieved at least every two months; that these and laboratory test results, etc. are reviewed promptly; and any indicated actions are taken.
547	(3) Maintain this information in the patient's medical record.	<p>The facility must create and maintain a complete, accurate, and accessible record of care for every home dialysis patient.</p> <p>Review home patient records to determine if the record includes documentation showing the patient and/or caregiver received and demonstrated adequate comprehension of the training and the self-monitoring data and other information from the home dialysis patient and/or caregiver has been incorporated and maintained.</p>
548	<p>(c) Standard: Support services</p> <p>(1) A dialysis facility must furnish directly home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company, that include, but are not limited to, the following:</p>	Furnish directly means the facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (e.g., not through "agreements" or "arrangements").
549	(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.	The number, timing and frequency of home visits must be spelled out in the patient's plan of care. Generally, home visits are needed at the initiation of home therapy and whenever a problem, including patient health or equipment, is identified that could be related to treatment at home.
550	(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.	The training and support dialysis facility must identify a specific member of the interdisciplinary team who is responsible for the coordination of each patient's care. This team member must be a licensed health care professional. The duties of the licensed health care professional include: Monitoring the patient's records, monitoring the home environment, ensuring the lab reports are reviewed in a timely manner and acted upon as necessary, coordinating the interdisciplinary team in the care of the patient, serving as the patient's advocate, coordinating clinic visits, ensuring appropriate equipment and supplies are available, ensuring monitoring of the water quality in accordance with the facility's policies and procedures.



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		<p>Ask the home patient what member of the interdisciplinary team functions in this manner? Interview the home training nurse to determine how these assignments are made.</p>
551	<p>(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meet the measurable and expected outcomes as specified in §494.90 of this part.</p>	<p>The individualized comprehensive care plan is expected to meet the same standards as chronic in-patient center patients. See 494.90 Patient plan of care.</p> <p>The standards for treatment access for PD patients are different from hemodialysis patients. The care plan for PD patients should address the catheter exit site care and maintenance of the PD catheter.</p> <p>When patients transfer from a facility based dialysis program to a home dialysis program the interdisciplinary team must develop a new plan of care.</p> <p>If the current plan is not successful in achieving the goals which have been agreed upon by the patient, the plan must be revised.</p> <p>The plan of care must be revised annually or more frequently if the patient needs warrant.</p> <p>Review the home patient's plan of care to determine compliance with this requirement.</p>
552	<p>(iv) Patient consultation with members of the interdisciplinary team, as needed.</p>	<p>Some home dialysis patients may have problems or needs that require consultation with several members of the interdisciplinary team. New dialysis patients, including new home dialysis patients, need a period to adjust and adapt to their treatment. Initially patients may experience anxiety while learning self-care skills, how to perform the dialysis treatment, how to modify their diet, and how to change their behavior. Patients must have access to any member of the interdisciplinary team as needed.</p> <p>Once trained, most home dialysis patients come to a nurse-run clinic monthly where members of the interdisciplinary team can meet with the patient and review records to monitor their care. The frequency of these visits should be</p>

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		<p>adapted to meet the needs of the individual patient. The clinical record must include documentation of these visits.</p> <p>Condition §494.90(b)(4) Patient Plan of Care requires that the facility assure that the physician see all dialysis patients monthly. Since these rules require that home dialysis patients have care that is at least equivalent to the care provided to in-center patients, expect to find documentation that the physician saw his/her patients monthly in the clinic or in his/her office. If the physician sees the patient in a separately located office, the record of that visit may need to be included in the facility record, if there is no other record of the physician's care and oversight. If the facility has offered monthly physician visit services, and the patient refuses this service (perhaps due to long travel distances), the facility's efforts to provide this service must be documented and there must be evidence that the facility provides quality dialysis services within this limitation.</p> <p>The patient must have access to other members of the interdisciplinary team, e.g. the dietitian and social worker, who must be available to provide clinical services as needed by the patient. Simply leaving messages, or sending e-mail or letters does not demonstrate an effective, interactive service is being provided. There must be two-way communication between the patient and the interdisciplinary team.</p> <p>Interview home patients regarding any issues that might benefit from services of the dietitian or social worker. Review clinical records and interview applicable staff to determine if these issues were addressed.</p>
553	(v) Monitoring of the quality of water used by home hemodialysis patients in accordance with the requirements specified in §494.40(a)(1)(i) and (ii) of this part and conducting an onsite evaluation of the water system.	The home training and support facility is responsible for monitoring the quality of the water used by home HD patients. The water treatment systems for home dialysis patients must produce water that meets the AAMI standards and the requirements specified in 494.40(a)(1)(i) and (ii) of this part. Each home water treatment system must include either an RO or a DI treatment component, and a method to remove chlorine/chloramines (see 494.40 (b) and (c)).

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		<p>The facility must have systems established for conducting an on-site evaluation of the water system. The facility should collect and review a water sample from the patient's home prior to selecting a water treatment system for home hemodialysis. The source water should meet the minimum standards of the Safe Drinking Water Act (SDWA) or have an AAMI analysis.</p> <p>The facility should establish what water quality monitoring checks, with acceptable parameters identified, that the patient and/or caregiver needs to complete prior to each dialysis treatment. Chlorine/chloramines levels must be tested prior to the start of each patient treatment in accordance with test method manufacturer's recommendations/instructions.</p> <p>The Medical Director must review all water and dialysate cultures, endotoxin testing, and analysis of chemical contaminants from each home patient system. The facility must maintain documentation of the Medical Director's review, which might be accomplished as part of the QAPI review.</p> <p>Patients or caregivers should be trained in water/dialysate sample collection if either the patient or caregiver is expected to perform the collection in the home. The facility should maintain documentation reflecting the training and the patient and/or caregiver competency in the task.</p> <p>The following are minimum standards that must be followed regarding the PureFlow™ device for in-home water treatment:</p> <ul style="list-style-type: none"> <li>• <b>Chemical Quality of the Source and Treated Water:</b> The chemical quality of the treated water used for dialysis, i.e., the product water, should be analyzed initially and at least once a year at the end of the "Pak" life, or when any modifications are made to the water treatment equipment (other than the replacement of the disposable components), to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded. The</li> </ul>

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		<p>source water should meet the minimum standards of the Safe Drinking Water Act (SDWA) or have an AAMI analysis to determine that the “Pak” water treatment components will remove the contaminants. The following URL contains information on the maximum contaminant levels of the SDWA: <a href="http://www.epa.gov/safewater/contaminants/index.html#mcls">www.epa.gov/safewater/contaminants/index.html#mcls</a>.</p> <ul style="list-style-type: none"> <li>• <b>Microbiological Quality of the Dialysate:</b> The microbiological quality of the dialysate should be analyzed monthly at the end of the “Sak” life using cultures and endotoxin measurements. To obtain meaningful results, a system should be established to ensure proper collection of the samples and their timely submission to the testing laboratory.</li> <li>• <b>Chlorine/Chloramines Testing:</b> An appropriate volume of water should be checked for the presence of chlorine/chloramines after the preparation of each batch of dialysate. If the test shows results above AAMI’s maximum allowable chemical contaminant level, then the user must discard that batch, change the “Pak,” prepare another batch of dialysate and test again.</li> <li>• <b>Training for Water/Dialysate Sampling:</b> The certified dialysis center must have a training and support program which is the responsibility of a registered nurse with at least 18 months experience as an RN; with experience in dialysis for at least 6 of those months and experience in teaching patients with ESRD for at least 3 of those months. As a part of the training program, patients/helpers and staff should be instructed in water/dialysate sample collection that they will be expected to perform in their homes.</li> </ul> <p>Review the records of monitoring of the water treatment systems provided for home patients for compliance with this requirement.</p>
554	The dialysis facility must correct the water quality of the home hemodialysis patient, and if necessary, arrange for backup dialysis until	If analysis of the water quality indicates contamination, then the facility must correct the water to ensure it meets AAMI standards for chemicals and microbiology. If unable to make such corrections in time to allow dialysis

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	<p>the problem is corrected if --</p> <p>(A) Analysis of the water quality indicates contamination; if--</p>	<p>within an acceptable time frame, the dialysis facility must arrange for back up dialysis until the home system is corrected.</p> <p>Interview the responsible staff (e.g., home training nurse, chief technician responsible for the home program) to determine the plan for back up dialysis.</p>
555	<p>(B) The home hemodialysis patient demonstrates clinical symptoms associated with water contamination.</p>	<p>If the patient exhibits clinical symptoms associated with water contamination, the facility must arrange for back up dialysis until the problem is investigated and resolved.</p> <p>Clinical symptoms for water contamination include but are not limited to: pyrogenic reactions (chills, shaking, fever, hypotension, vomiting), septicemia, nausea, headache, dizziness, muscle weakness, skin flushing, itching, diarrhea, hyper/hypotension, hemolysis, abdominal pain, anemia, seizure, cyanosis, mental changes, thirst, and metabolic acidosis.</p> <p>Interview responsible staff members (e.g., home training nurse, chief technician responsible for the home program) regarding their expected actions should a patient exhibit such symptoms. Expect their answers to include that they would immediately arrange for back up dialysis until the cause of the symptoms is identified and any issues with the home water treatment system is resolved.</p>
556	<p>(vi) Purchasing, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.</p>	<p>The dialysis facility is responsible for oversight and overall management. Either the dialysis facility or the durable medical equipment (DME) supplier can be responsible for purchasing, delivering, installing, and maintaining home supplies and equipment. If the patient chooses to use a DME supplier, then there must be a written agreement between the DME supplier and the Medicare certified dialysis facility.</p> <p>If the dialysis facility contracts with a DME/vendor, the facility is still responsible for oversight of the services, should know if there have been any problems, and should take action to protect the patient if serious issues develop.</p> <p>Preventive maintenance needs to be completed in accordance with the</p>

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		<p>manufacturer's recommendations. Either the facility staff or an outside vendor/contracted service could perform the maintenance. The facility should maintain records for the preventive maintenance.</p> <p>The following are minimum standards that must be followed regarding the PureFlow™ device for in-home water treatment:</p> <ul style="list-style-type: none"> <li>• <b>Equipment maintenance:</b> Machine maintenance should include the following: <ul style="list-style-type: none"> <li>○ Exchange/disposal of the “Pak” as indicated by alarms;</li> <li>○ Maintenance of components as directed by the manufacturer;</li> <li>○ An agreement with the manufacturer including a list detailing the work which is done to refurbish the equipment used in exchange. Documentation of work on a specific piece of equipment must be available upon request.</li> </ul> </li> </ul>
557	(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.	<p>The dialysis facility is responsible for identifying a plan and arranging for timely emergency back up dialysis whenever needed by the home patient.</p> <p>The facility should have a plan for actions to take or options offered to the patient in the event dialysis equipment (PD cyclers, hemodialysis machine, water treatment system) is in need of repair and/or service. Possible options include:</p> <ul style="list-style-type: none"> <li>- The patient returns to the facility for the dialysis treatment;</li> <li>-The patient dialyzes in a facility with which the home training facility has an agreement for back-up services;</li> <li>- A back up machine readily delivered; or</li> <li>- Maintenance personnel provide service in time to avoid missed treatments.</li> </ul> <p>Each patient should also have a personal disaster plan to address actions to take in the event of a natural or other disaster affecting their home.</p>
558	(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable	<p>The dialysis facility is responsible for maintaining a record keeping system for the home dialysis patient that supports continuity of care and patient privacy. If applicable, information from the DME supplier must be incorporated.. Home patient records must be maintained at the dialysis facility which provides the</p>



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	<p>medical equipment (DME) suppliers referred to in §414.330(a)(2) of this chapter.</p>	<p>home training and support services.</p> <p>The DME regulations at §414.330(a)(2) require the DME to report to the ESRD facility providing support services, every 30 days, all data for each patient regarding services and items furnished to the patient in accordance with 494.100(c)(2) of this chapter.</p> <p>Use the survey tasks of clinical record review and staff interview to determine compliance with this requirement.</p>
565	<p><b>§494.110 Condition: Quality assessment and performance improvement.</b></p> <p>The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, interdisciplinary quality assessment and performance improvement program.</p>	<p>The facility must have a written plan describing the QAPI program's objectives, organization, responsibilities of all participants, scope and procedures for overseeing the effectiveness of monitoring, assessing and problem-solving activities. Data related to patient outcomes, complaints, adverse events (e.g., clinical variances, occurrences), etc. should be used to identify problems and to improve care. There should be evidence that each member of the interdisciplinary team participates in quality improvement activities. Internal quality improvement activities must evaluate the effectiveness of this program and make changes where indicated.</p>
566	<p>The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors.</p>	<p>All services provided must be included in the QAPI review (e.g. in-center, home hemodialysis, home peritoneal dialysis, reuse, central reprocessing, self-care, care in nursing homes). Clinical indicators must be used to track health outcomes. There must be an organized program to allow identification, prevention and reduction of medical errors.</p>
567	<p>The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.</p>	<p>Expect to see that data collected is processed and analyzed by the interdisciplinary team to include discussion of areas which need improvement and the development and implementation of a plan for such improvement. A stack of laboratory report print-outs does not demonstrate such review. Minutes of QAPI or another method of demonstrating this analysis and action to be taken must be available for review.</p>

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568	<p><b>(a) Standard: Program Scope</b></p> <p>(1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.</p>	<p>Review consists of examining records and interviewing staff to determine the process the facility uses for QAPI.</p> <p>An “ongoing” program looks at indicators as they are available, trends outcomes and develops an improvement plan when indicated. Generally this would require at least monthly review of indicators, since patients are typically evaluated with laboratory results monthly. Facilities should use aggregate data to evaluate the facility patient outcomes; hemodialysis patients and peritoneal dialysis patients may need to be reviewed separately, but both groups of patients should be reviewed on an ongoing basis.</p> <p>Recognize Infection Control tracking and trending must be incorporated into the QAPI program as discussed at 494.30 (c)(1) and (2).</p> <p><b>Resources:</b>  National Coalition on Healthcare  Philip Aspden, Janet M. Corrigan, Julie Wolcott, Shari M. Erickson, Editors, Committee on Data Standards for Patient Safety, <i>Patient Safety: Achieving a New Standard of Care</i> (executive summary) - <a href="http://books.nap.edu/execsumm_pdf/10863.pdf">http://books.nap.edu/execsumm_pdf/10863.pdf</a>  FDA  <a href="http://www.fda.gov/fdac/features/2003/303_meds.html">www.fda.gov/fdac/features/2003/303_meds.html</a></p>
569	<p>(2) The dialysis facility must measure, analyze and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes themselves. The program must include, but not be limited to, the following:</p>	<p>Verify that the facility’s QAPI program monitors systems and processes of care that are used to assure patients achieve the targeted outcomes.</p> <p>The facility is expected to use broadly accepted, community developed standards (e.g., K/DOQI, AAMI,) as performance measures. Where minimum expected values have been determined, facilities are expected to provide care to allow all patients to achieve the minimum expected value.</p> <p>When community developed standards reflect target values, the facility is expected to aim for those targets, and show continuous improvement towards those targets. Expect the facility to be aware of being outside the target range</p>

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570	(i) Adequacy of dialysis	<p>and to demonstrate a response to these findings.</p> <p>For hemodialysis patients, minimum standards are (K/DQOI):</p> <ul style="list-style-type: none"> <li>• Deliver a Kt/V of at least 1.2 (single pool, variable volume) for adult and pediatric patients</li> <li>• Prescribe a Kt/V of at least 1.3 (single pool, variable volume) for adult patients</li> <li>• For treatment schedules other than 3 X a week, deliver a Kt/V of at least 2.0 (single pool, variable volume) <u>per week</u></li> </ul> <p>For peritoneal dialysis, minimum standards are (K/DOQI):</p> <ul style="list-style-type: none"> <li>• Deliver a peritoneal Kt/V<sub>urea</sub> ≥ 1.7 (adults)</li> <li>• Deliver a peritoneal Kt/V<sub>urea</sub> ≥ 1.8 (pediatric)</li> </ul> <p><b>Resource:</b>  NKF KDOQI Adequacy update 2006  <a href="http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm">www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm</a></p>
571	(ii) Nutritional status	<p>Serum albumin is a valid and useful measure of protein-energy nutritional status in maintenance dialysis patients (K/DQOI, Evaluation of Protein-Energy Nutritional Status, Guideline 3). Serum albumin levels are commonly and extensively used to evaluate the nutritional status of ESRD patients; low albumin levels are highly predictive of mortality risk.</p> <p>Target levels: the patient's pre-dialysis albumin should be equal to or greater than the lower limit of the normal range or 4.0 g/dL (BCG testing method).</p> <p><b>Resource:</b>  NKF KDOQI Nutrition Guideline  <a href="http://www.kidney.org/professionals/KDOQI/guidelines_updates/doqi_nut.html">www.kidney.org/professionals/KDOQI/guidelines_updates/doqi_nut.html</a></p>
572	(iii) Anemia management	<p>KDOQI provides a expected range of a hemoglobin 11-12 g/dL or hematocrit of 33-36% in ESA treated patients. A hemoglobin of 11 g/dL is considered a minimum standard.</p>

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		<p>KDOQI provides targets for:  Transferrin saturation (TSAT) &gt;20% (hemodialysis or peritoneal dialysis)  Serum ferritin &gt;200 ng/mL (hemodialysis) or &gt;100 ng/mL (peritoneal dialysis).</p> <p><b>Resource:</b>  NKF KDOQI update 2006 (dialysis)  <a href="http://www.kidney.org/professionals/KDOQI/guidelines_anemia/index.htm">www.kidney.org/professionals/KDOQI/guidelines_anemia/index.htm</a></p>
573	(iv) Vascular access	<p>Fistula First Breakthrough Initiative provides a target of:  ≥ 66% of prevalent dialysis patients have AV fistulas  &lt;10% of dialysis patients have cuffed catheters &gt;3 months without a maturing fistula or graft</p> <p><b>Resources:</b>  NKF KDOQI update 2006  <a href="http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm">www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm</a>  Fistula First Initiative:  <a href="http://www.fistulafirst.org/">www.fistulafirst.org/</a></p>
574	(v) Medical injuries and medical errors identification	<p>Review incident reports and complaint investigations to identify any patient injuries or medication errors. Be aware that falls are not an infrequent occurrence, particularly post dialysis treatment; determine what precautions are in place to prevent falls. Vascular access infiltrations should be reviewed and trended.</p> <p>In reviewing medical records, if you identify a medication error, verify whether or not the facility identified the error and determine what action was taken.</p> <p>Part of the QAPI activity should be to trend any injuries and any medication errors to identify commonalities, causes, and whether the incidents are increasing.</p> <p>Definitions (from Institute of Medicine study):  <b>Error:</b> The failure of a planned action to be completed as intended (error of</p>

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		<p>execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission (IOM, 2004).</p> <p><b>Medication error:</b> Any error occurring in the medication-use process (Bates et al., 1995a). Examples include wrong dosage prescribed, wrong dosage administered for a prescribed medication, or failure to give (by the provider) or take (by the patient) a medication.</p> <p><b>Adverse drug event:</b> Any injury due to medication (Bates et al., 1995b). Examples include a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) or an allergic reaction occurring in a patient not known to be allergic to a given medication.</p>
575	(vi) Hemodialyzer reuse program, if the facility reused hemodialyzers	<p>The KDOQI standard for reprocessing requires discarding a reprocessed dialyzer when the total cell volume is less than 80% of the original volume. This standard requires the original cell volume of each dialyzer be measured.</p> <p>Major problems identified in the Condition of Reuse related to quality assessment and improvement should be referenced here.</p> <p><b>Resource:</b> NKF KDOQI <a href="http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_rec5.htm">www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_rec5.htm</a></p>
576	(vii) Patient satisfaction and grievances.	<p>Facilities must measure patient satisfaction using standardized instruments, analyze the results, and take action as indicated.</p> <p>Facilities must monitor and track patient grievance reports and outcomes as required at 494.180(e)(1)-(3).</p> <p><b>Resources:</b> ESRD Network Decreasing Dialysis Patient Provider Conflict <a href="http://www.esrdnetworks.org/DPPCFinalReport.pdf">www.esrdnetworks.org/DPPCFinalReport.pdf</a> CAHPS (hemodialysis) <a href="http://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp">www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp</a> RAND Dialysis Patient Satisfaction Survey</p>

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		<a href="http://www.rand.org/health/surveys_tools/dpss/index.html">www.rand.org/health/surveys_tools/dpss/index.html</a>
577	<p><b>(b) Standard: Monitoring performance improvement.</b></p> <p>The dialysis facility must continuously monitor its performance, take actions that result in performance improvement, and track performance to ensure that improvements are sustained over time.</p>	<p>“Continuously monitor” requires that outcome data, infections, falls, errors, etc. be monitored as this data is available or these events occur. Expect to see tracking and trending, analysis of root causes, development of improvement plans, implementation of those plans, evaluation of the success of the plan, and revision of the plan as indicated. Once improvement is made, the facility must have a mechanism to ensure that improvement is sustained. This could include practice audits, review of records, or repeat patient satisfaction surveys, etc.</p>
578	<p>Each facility must participate in ESRD network activities and pursue network goals.</p>	<p>Cross reference §494.160 – Relationship with the ESRD Network</p>
579	<p><b>(c) Standard: Prioritizing improvement activities.</b></p> <p>The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety.</p>	<p>The facility must have a system to identify all areas needing improvement and to prioritize these, ranking those which have potential to affect patient health and safety as more urgent than those that do not have such potential. In setting priorities, the prevalence and severity of the identified problems must be considered. Issues that could immediately affect patient health and safety must be immediately addressed.</p>
580	<p>The facility must immediately correct any identified problems that threaten the health and safety of patients.</p>	<p>There must be a plan to identify and quickly correct problems that could adversely affect patient functioning, safety, or health.</p> <p>Life threatening conditions that require instant correction include but are not limited to:</p> <ul style="list-style-type: none"> <li>• contaminants in product water;</li> <li>• unsafe levels of electrolytes in dialysate;</li> <li>• risk of undetected disconnection of blood lines or dislodgment of access device;</li> <li>• defective patient contact equipment;</li> <li>• failure to adequately disinfect reprocessed dialyzers;</li> <li>• failure to reduce residual germicides in reprocessed dialyzers to safe levels;</li> <li>• lack of qualified staff to meet critical patient needs;</li> </ul>



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		<ul style="list-style-type: none"> <li>• identified potential for cross-contamination between infected and non-infected patients; and</li> <li>• failure to use machine provided safety devices (muting machine alarms, bypassing the air bubble detector).</li> </ul>
590	<p><b>§494.120 Condition: Special purpose renal dialysis facilities.</b></p> <p>A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.</p>	<p>This Condition outlines the requirements for dialysis facilities providing care for a limited period of time, either in a vacation camp setting or for patients who could not otherwise receive dialysis in that geographical area.</p> <p>Emergency circumstances could apply in the event of a natural or man-made disaster that prevents the use of established dialysis facilities, or could apply to a patient or group of patients who can not otherwise be served in an area (e.g., for patients with needs for more acute care than is usually available in an outpatient setting, such as patients on respirators or patients who require frequent suctioning.)</p>
591	<p><b>(a) Standard: Approval period.</b></p> <p>The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12 month period.</p>	<p>The maximum period of certification is 8 months. SPDF for vacation camps may be operational for as little as one to two weeks. In the case of a vacation camp SPDF or one for patients with needs for more acute care, the same facility may reapply for certification in the following (or any subsequent) year. The regulation only allows the approval for 8 months in a 12 month period; for a patient with needs for more acute care, it is anticipated the hospital would need to seek permanent placement of that patient during that 8 months.</p>
592	<p><b>(b) Standard: Service limitation.</b></p> <p>Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.</p>	<p>In the case of vacation camps, one purpose of the SPDF is to minimize the time the patient would be away from camp activities. In the case of emergency circumstance facilities, the intent is to temporarily provide service until permanent arrangements are possible. A SPDF established to provide care to patients with needs for more acute care should define the population they expect to serve in their admission criteria.</p>

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593	<p><b>(c) Standard: Scope of requirements.</b></p> <p>(1) Scope of requirements for a vacation camp.</p> <p>A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage –</p> <ul style="list-style-type: none"> <li>(i) Infection control at §494.30 of this part;</li> <li>(ii) Water quality at § 494.40 of this part (except as provided in paragraph (c)(1)(viii) of this section;</li> <li>(iii) Reuse of hemodialyzers at § 494.50 of this part (if reuse is performed);</li> <li>(iv) Patients’ rights and posting of patients’ rights) §§ 494.70(a) and (c) of this part;</li> <li>(v) Laboratory services at § 494.130 of this part;</li> <li>(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and (d) of this part;</li> <li>(vii) Medical records at § 494.170 of this part; and</li> <li>(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to §</li> </ul>	<p>A vacation camp SPDF will have a separate certification number, but must be affiliated with a certified dialysis facility.</p> <p>Because the SPDF for a vacation camp will provide service on a temporary basis, it must meet only these specified portions of the Conditions.</p>

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	494.100(c)(1)(v) (home monitoring of water quality) of this part, in place of § 494.40 (water quality) of this part.	
594	<p>(2) Scope of requirements for an emergency circumstance facility. A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must additionally comply with the following conditions:</p> <p>(i) § 494.20 (compliance with Federal, State, and local laws and regulations).</p> <p>(ii) § 494.60 (physical environment).</p> <p>(iii) § 494.70(a) through (c) (patient rights).</p> <p>(iv) § 494.140 (personnel qualifications).</p> <p>(v) § 494.150 (medical director).</p> <p>(vi) § 494.180 (governance).</p>	<p>An emergency circumstance SPDF will be given a special purpose certification number and must comply with those requirements listed above under 494.20 (c) (1) (i)-(viii), as well as the requirements listed here.</p>
595	<p>(e) Standard: Documentation. All patient care provided in the special purpose facility is documented and forwarded to the patient's dialysis facility within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.</p>	<p>The complete original record of care in the SPDF should be forwarded to the ESRD facility receiving the patient within 30 days of the last treatment in the SPDF. These records should include the location where the treatments occurred.</p>
600	<p><b>§494.130 Condition: Laboratory Services</b></p> <p>The dialysis facility must provide or make available laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient.</p>	<p>Under Clinical Laboratory Improvement Amendments of 1988 (CLIA), laboratory services can only be provided by an appropriately certified laboratory. Arrangements with these providers must be in writing and signed and should specify the types of laboratory tests to be performed and their frequency, methods for collection and delivering results, including a timeline for reporting of “alert” values to a responsible person.</p>

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		<p>Many facilities have agreements with distant laboratories for routine services; there should also be a provision for service from a local laboratory for time sensitive testing.</p>
<b>601</b>	<p>Any laboratory services, including tissue pathology and histocompatibility, must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.</p>	<p>There should be documentation in the patient's record that all laboratory tests prescribed were furnished as ordered. Laboratory reports should include the patient's name and identifier, and the name and address of the laboratory performing the test.</p> <p>The dialysis facility may provide some testing directly. Generally this is limited to CLIA waived tests, such as finger stick blood glucose obtained by glucose monitoring devices cleared by FDA specifically for home use and stool testing for occult blood. Dialysis facilities may also instruct patients in self-monitoring of glucose levels.</p> <p>HLA Laboratories performing Panel Reactive Antibody (PRA) testing for patients on the transplant waitlist must have a "regular" CLIA certificate or certificate of accreditation which allows the laboratory to perform high complexity testing.</p>
<b>Subpart D -- Administration.</b>		
<b>610</b>	<p><b>§494.140 Condition: Personnel qualifications.</b></p> <p>The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions. The dialysis facility's staff must have the</p>	<p>ESRD is an extremely complex disease requiring highly technical and complex treatment, and patients with this disease have special needs that require highly specialized care that can only be provided by qualified personnel. As the demographics of the dialysis population continue to change, producing a more elderly patient population with more co-morbid conditions, direct patient care needs and the skill needed to meet those needs will continue to increase. Also, as we move away from unnecessary process and procedural requirements in the conditions for coverage towards better patient outcomes, it becomes even more important to have qualified, experienced, and well-trained staff to achieve the targeted clinical outcomes for each patient.</p> <p>Facilities may not always be able to directly employ individuals to perform all</p>

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	<p>ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.</p>	<p>required services; and therefore, facilities may furnish services through qualified personnel by arrangement. Any position in a facility, except for the Nurse Manager, may be filled by a contracted employee, but the contracted employees must meet the personnel requirements as well as the demonstrated skills and competencies in §494.140 to ensure that patients receive quality care from all personnel.</p> <p>The expected outcome is the coordinated, comprehensive interdisciplinary delivery of appropriate and effective services provided by skilled professionals. These professionals must meet the requirements in this regulation and adhere to the facility's policies and procedures. The dialysis facility has the flexibility to assign specific duties to each staff member (either employee or contractor) who provides services in the facility, as long as the required outcomes are being met.</p> <p>The dialysis facility's staff (whether employees or contractors) must meet the personnel qualifications and demonstrated competencies necessary to serve the general needs of its patients. The dialysis facility's staff must have the ability to sustain and demonstrate the skills needed to perform the specific duties of their positions.</p> <p>Use the survey tasks of staff interview, observation of care, and review of reuse and water/ dialysate processes to identify any concerns with personnel qualifications. Select personnel files for review based on those concerns, or any specific questions you may have related to staff qualifications (e.g., whether the social worker is Master's prepared). Observe the staff as they perform their tasks. Staff must continuously demonstrate competency to perform assigned duties. If problems in performance are identified, review personnel records for evidence of competency evaluation. If you identify a concern, review applicable policies.</p> <p>If state licensing personnel requirements are more stringent, these must also be met for the Condition to be met.</p>

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<b>611</b>	<p><b>(a) Standard: Medical director.</b></p> <p>(1) The medical director must be a physician who has completed a board approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis.</p>	<p>The facility should maintain verification of nephrology training and experience. Board certification in nephrology is not required, but would serve as evidence of the required training.</p> <p>The medical director of a dialysis unit must have a thorough knowledge and understanding of the complexity of ESRD and its effects on the dialysis patient.</p> <p>If you identify serious concerns with the quality of care or effectiveness of care being delivered, review the medical director's qualifications and interview the medical director to determine compliance with this Standard.</p>
<b>612</b>	<p>(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.</p>	<p>Refer to CMS Regional Offices for approval by the Secretary of DHHS if the facility is using a physician as medical director who does not meet the requirement in paragraph (a)(1) above.</p>
<b>613</b>	<p><b>(b) Standard: Nursing services.</b></p> <p>(1) Nurse manager. The facility must have a nurse manager responsible for nursing services in the facility who must --</p> <p>(i) Be a full-time employee of the facility;</p>	<p>The nurse manager who is responsible for nursing services must be a full-time employee of the facility. The nurse manager of the facility cannot be a contract/agency nurse.</p>
<b>614</b>	<p>(ii) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and</p>	<p>The nurse manager must be a registered nurse who meets state nurse practice acts and other state requirements.</p> <p><b>Resource:</b>  <a href="http://www.nephrologynursing.net/JF2005/Article32031037.pdf">www.nephrologynursing.net/JF2005/Article32031037.pdf</a> (links to nursing qualifications)</p>
<b>615</b>	<p>(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.</p>	<p>The registered nurse functioning as the nurse manager must have at least 18 months of nursing experience, 6 months of which must be as a nurse providing clinical nursing care to patients on maintenance dialysis. Review personnel file for evidence of compliance.</p>
<b>616</b>	<p>(2) Self-care training nurse. The nurse</p>	<p>If a facility offers self-care training, the nurse in charge of self-dialysis training</p>



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	<p>responsible for self-care training must –</p> <p>(i) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and</p>	<p>must be a registered nurse who meets the state requirements, and</p>
<b>617</b>	<p>(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.</p>	<p>The self-care training registered nurse must have a total of at least 15 months of clinical experience. If a home program has both hemodialysis (HD) and peritoneal dialysis (PD), there must be a qualified nurse(s) with at least 3 months experience in providing care in the respective modality in order to train patients/caregivers in that modality. If one nurse is responsible for both the HD and PD programs, the nurse must have at least three months experience in each modality. Review personnel file for evidence of compliance.</p>
<b>618</b>	<p>(3) Charge nurse. The charge nurse responsible for each shift must –</p> <p>(i) Be a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed; and</p>	<p>The charge nurse must be licensed in the state and meet any practice requirements of that state; and</p>
<b>619</b>	<p>(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis.</p>	<p>A charge nurse must have a total of 12 months of nursing experience at minimum, which includes 3 months of specialized experience providing clinical nursing care to patients on maintenance dialysis. Review selected personnel files for compliance.</p>
<b>620</b>	<p>(4) Staff nurse. Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.</p>	<p>Dialysis nurses must be able to demonstrate competency to perform assigned tasks.</p> <p>Observe care delivery and interview staff and patients: if you identify problems or concerns, include the applicable staff nurses on the list of personnel records to review for qualifications and competency.</p>
<b>621</b>	<p><b>(c) Standard: Dietitian.</b></p> <p>The facility must have a dietitian who must –</p>	<p>The Commission on Dietetic Registration is the credentialing agency for American Dietetic Association. Dietitians working in dialysis must be registered with that organization.</p>

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	(1) Be a registered dietitian with the Commission on Dietetic Registration;	<b>Resource:</b> Find a Nutrition Professional: Registered Dietitians and Diet Technicians, Registered <a href="http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/home_4874_ENU_HTML.htm">www.eatright.org/cps/rde/xchg/ada/hs.xsl/home_4874_ENU_HTML.htm</a> (see registered dietitians)
622	(2) Meet the practice requirements in the State in which he or she is employed; and	If your state requires licensure, expect the facility to have evidence the dietitian is currently licensed;
623	(3) Have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.	<p>The dietitian must have one year of professional work experience in clinical nutrition <u>after</u> registration as a dietitian. Generally, the responsibilities of the renal dietitian include: (1) counseling patients on management of protein, sodium, potassium, phosphorus, and fluid controlled diets, translating the chemistry of these limits into meals for patients; (2) monitoring vitamin and mineral supplementation, including iron levels and their effect on erythropoietin; (3) managing glycemic control of diabetic patients by manipulation of diet; and (4) assessing nutritional status by using clinical and biochemical measures.</p> <p>These kinds of activities require a dietitian with specialized experience in clinical nutrition. The specialized training and experience ensure that dialysis facilities have a dietitian knowledgeable about medical nutrition therapy, physiology, and food composition. This specialized knowledge is critical if a dietitian is to effectively manage the complex tasks necessary in treating a dialysis patient, so the patient is able to manage his or her own disease.</p> <p>If the dietitian has been employed less than 1 year, review personnel record for compliance. In all cases, use the survey tasks of patient interview and clinical record review to determine if you need to interview the dietitian or review this personnel file.</p>
624	<b>(d) Standard: Social worker.</b>  The facility must have a social worker who –	Dialysis patients may experience complex emotional and social concerns, including, but not limited to, changes in self-image, loss of independence, changes in financial security, loss of physical integrity, problems with sexual

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	<p>(1) Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education; and</p>	<p>functioning, role changes, anxiety, and discomfort associated with treatment.</p> <p>The social worker must have a masters degree in social work and knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on patients and families. Social workers can provide some of the necessary care and services to help patients achieve and sustain an effective level of vocational, emotional and social well-being. Facility social workers conduct psychosocial evaluations, develop treatment plans based on the patients' current psychosocial needs, provide counseling, long-term behavioral and adaptation therapy, and grief therapy. The social worker can assess and address challenging or disruptive behavior. If patients need services the facility social worker cannot provide, the social worker should refer patients to agencies and/or other professionals for these services.</p> <p>Nonprofessional personnel cannot be employed <u>in place</u> of a fully credentialed MSW, but they can help dialysis patients with services such as transportation and information on Medicare benefits, eligibility for Medicaid, housing, and medications so the MSW can participate fully with the interdisciplinary team to achieve optimal outcomes.</p> <p>The Council on Social Work Education has a directory of accredited masters social work degree programs. Review personnel files to verify compliance.</p> <p><b>Resource:</b> Council on Social Work Education directory of accredited programs: <a href="http://www.cswe.org/CSWE/accreditation/">www.cswe.org/CSWE/accreditation/</a> (see MSW programs)</p>
625	<p>(2) Meets the practice requirements for social work practice in the State in which he or she is employed.</p>	<p>The Association of State Boards of Social Work website has links to State regulations and rules for social work practice in each state.</p> <p>If your state requires social workers to be licensed, expect the facility to have evidence the worker is currently licensed at the required level of licensure. States often require licensure at the specialist level for independent</p>

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		<p>practitioners, but not for social workers employed by an agency or company.</p> <p>Use the survey tasks of patient interview and clinical record review to determine if you need to interview the social worker or review this personnel file.</p> <p><b>Resource:</b>  Association of Social Work Boards (links to statutes and rules by state)  <a href="http://www.aswb.org/members_reglinks.shtml">www.aswb.org/members_reglinks.shtml</a></p>
626	<p><b>(e) Standard: Patient care dialysis technicians.</b></p> <p>Patient care dialysis technicians must –</p> <p>(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and</p>	<p>Use the survey tasks of observation, patient and staff interviews and clinical record reviews to identify patient care technicians whose personnel records you should review to determine if these requirements are met.</p> <p><b>Resource:</b>  <a href="http://www.nant.biz/store/articles.php/tPath/141_143">www.nant.biz/store/articles.php/tPath/141_143</a> (see organizations that certify technicians)</p>
627	<p>(2) Have a high school diploma or equivalency;</p>	<p>Include review for this evidence in the files of selected patient care technicians.</p>
628	<p>(3) Have completed at least 3 months experience, following a training program that is approved by the medical director and governing body. This experience must be under the direct supervision of a registered nurse, and be focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills including patient sensitivity training and care</p>	<p>There must be a training program for patient care technicians approved by the medical director and governing body.</p> <p>A registered nurse must directly supervise the patient care technician for at least 3 months following completion of the training program. “Directly supervise” means the registered nurse must be present in the facility and in the treatment area except for brief break periods whenever technician trainees are working with patients.</p> <p>The person responsible for training must maintain evidence that the patient care</p>

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	of difficult patients.	<p>technician demonstrated competence in the following areas:</p> <ul style="list-style-type: none"> <li>• operation of kidney dialysis equipment and machines</li> <li>• providing direct patient care</li> <li>• communication and interpersonal skills including patient sensitivity training and care of difficult patients</li> </ul>
<b>629</b>	<p><b>(f) Standard: Water treatment system technicians.</b></p> <p>Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.</p>	<p>The training program is expected to follow the AAMI guidelines for water treatment and dialysate preparation. Water treatment system technicians must successfully complete the training program prior to independently performing water treatment system tasks.</p> <p>Interview the water treatment system technicians as part of your review of the water and dialysate systems. If you identify a concern, include the staff member(s) in the list of personnel records to review.</p>
<b>635</b>	<p><b>§494.150 Condition: Responsibilities of the medical director.</b></p> <p>The dialysis facility must have a medical director who meets the qualifications of §494.140(a) of this part to be responsible for the delivery of patient care and outcomes in the facility.</p>	<p>Patient treatment is under the general supervision of a Medical Director who is a physician and meets the qualifications outlined in §494.140 (a) (Personnel qualifications: Medical director). The physician-director is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The medical director may also serve as the chief executive officer of the facility.</p> <p>If you identify major problems (e.g., poor patient outcomes, inadequate dialysis, unsafe practices, staff assigned duties for which they have not been trained), you must consider citing this Condition as not met, as the medical director is responsible for the care and outcomes in the facility.</p>
<b>636</b>	<p>Responsibilities include, but are not limited to, the following:</p> <p>(a) Quality assessment and performance improvement program</p>	<p>The medical director has operational responsibility for the QA/QI program and to ensure that program data is used to develop actions to improve quality of care. The medical director must ensure that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. The medical director must ensure that the facility achieves community accepted outcomes in the areas that include but not limited to: adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries and medical errors identification, hemodialysis reuse program, patient satisfaction</p>

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		<p>and grievance.</p> <p>The medical director must ensure that all clinical staff in the facility, including attending physicians, “buy-in” and actively participate in achieving the performance goals and objectives specified in the facility's QAPI program. The medical director is expected to educate and encourage facility staff, including attending physician and nonphysician staff, who have not actively participated in the facility’s QAPI program. In those rare instances when in-house or attending physician or nonphysician staff will not actively participate in the facility’s QAPI program, we would expect the medical director to refer those individuals to the facility’s governing body through its CEO or administrator.</p> <p>Expect that the facility's medical director seeks and uses comparative data with other facilities (when available), and uses the facility's historical data to demonstrate internal improvements in outcomes over time. This standard underscores the medical director's ongoing responsibility to ensure that each patient treated in the facility achieves the best possible outcomes of care.</p> <p>Review the materials documenting the QAPI program for active participation by the medical director. If there is evidence one or more of the physicians on staff is not participating in the quality improvement efforts, what action has been taken to address this?</p>
637	(b) Staff education, training, and performance	<p>The medical director is responsible for ensuring that facility staff members receive the appropriate education and training to competently perform their job responsibilities.</p> <p>“Performance” refers to the responsibility of the medical director for assuring that the staff adequately monitors the patient and the dialysis process; that the staff members responsible for operation of the water treatment system have the necessary education, training and experience; that staff members responsible for hemodialyzer reuse have the necessary education, training and experience.</p>



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638	<p>(c) Policies and procedures.</p> <p>The medical director must</p> <p>(1) Participate in the development, periodic review and approval of a “patient care policies and procedures manual” for the facility; and</p>	<p>Consider citing this tag if you identify problems in staff education, training or performance of assigned responsibilities.</p> <p>The policies and procedures manual provides an opportunity for the medical director to incorporate improved treatment methodologies and current medical practices into day-to-day patient care within the facility in order to ensure better outcomes of care. The medical director must participate in the development, periodic review, and approval of the patient care policies and procedures manual.</p> <p>You should expect the patient care policies and procedures to address such areas as:</p> <ul style="list-style-type: none"> <li>• the types of dialysis offered by the facility</li> <li>• expectations of attending physicians, consultants, and staff providing care in the facility or for patients doing self-care or home dialysis</li> <li>• delivery and monitoring of dialysis</li> <li>• infection control</li> <li>• patient and staff safety</li> <li>• disaster preparedness plan</li> <li>• patient participation in care</li> <li>• appropriateness of patient teaching materials for self-care training if home or self-dialysis training is offered</li> </ul> <p>Corporate owned facilities may use a standard “Policy and Procedure Manual” developed by the corporation. Expect a mechanism for the facility medical director to have input into the manual, to have some leeway in “personalizing” policies for unique local situations, and to be required to review and approve the manual.</p> <p>If you identify problems during the survey, review applicable policies. If you then identify inadequate, inaccurate, or out-of-date policies, consider citing this tag.</p>
639	(2) Ensure that:	The medical director is responsible for assuring that attending physicians

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	(i) All policies and procedures relative to patient care and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and	<p>comply with facility policies and procedures (e.g., monthly progress note, responding to pages, active participation in QAPI).</p> <p>In those instances when facility staff or attending physicians or nonphysicians have not, or will not, follow the facility's written patient care policies and procedures, expect the medical director to educate and encourage those individuals to remedy their actions. In those rare instances when the medical director has been unsuccessful in achieving compliance, expect the medical director to refer the matter to the facility's governing body (see § 494.180) for action.</p> <p>If you identify evidence that staff or physicians do not follow the facility policies and procedures, consider citing this tag.</p>
640	(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in §494.180(f) of this part.	<p>The facility must have and follow written policies and procedures for involuntary discharge and transfer. There are four reasons for which a facility can involuntarily discharge or transfer a patient as listed in 494.110(f)(1)-(4).</p> <p>The medical director must ensure that the interdisciplinary team follows the facility's patient discharge and transfer policies and procedures (that are consistent with those described in § 494.180(f). The medical director must monitor and review each involuntary patient discharge to ensure that the patient's interdisciplinary team has performed the tasks required in § 494.180(f).</p> <p>The medical director <u>and attending physician</u> need to sign an order if any patient is being involuntarily discharged or transferred under 494.110(f)(4).</p> <p>Ask the nurse manager or administrator if there have been any involuntary discharges; review these for compliance with this requirement.</p> <p><b>Resource:</b> Decreasing Dialysis Patient Provider Conflict (DPC) - <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a></p>

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<b>641</b>	<p><b>§494.160 Condition: Relationship with the ESRD Network</b></p> <p>The dialysis facility must cooperate with the ESRD network designated for its geographic area,</p>	<p>For an initial survey, there should be a signed agreement between the facility and the applicable Network</p> <p>In general the Network monitors ESRD facilities for compliance with patient focused goals and activities which may vary from Network to Network. Each Network is required to post their annual report which includes these goals and activities on their website. Remember to contact the Network prior to each visit of an ESRD facility to determine if the Network staff has knowledge of any issues or complaints.</p>
<b>642</b>	<p>in fulfilling the terms of the Network's current statement of work.</p>	<p>Facilities must comply with form submission timeliness and accuracy and requests for corrective action plans.</p>
<b>650</b>	<p><b>§494.170 Condition: Medical records.</b></p> <p>The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p>	<p>The facility must create and maintain a complete and accurate record of care for every individual evaluated or treated.</p> <p>In ESRD, the term "medical records" includes written documents, computerized electronic information, laboratory reports, dialyzer reuse records, and other forms of information regarding the condition and care of the patient. Hemodialysis machine maintenance records and water treatment logs are also considered medical records.</p> <p>Refer to 494.100 (c)(2) for guidance related to records of home patients</p>
<b>651</b>	<p><b>(a) Standard: Protection of the patient's record.</b></p> <p>The dialysis facility must –</p> <p>(1) Safeguard patient records against loss, destruction, or unauthorized use.</p>	<p>The medical record system must protect the security of all medical record entries and ensure that records are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.</p> <p>Electronic medical records systems must be designed to prevent accidental loss or destruction of medical record information, and have safeguards to prevent alteration of entries without notation of the alteration (e.g., a late entry must be indicated as such).</p>

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		<p>For electronic records, the system must limit access to medical records to only authorized persons, and ensure that records are not released to unauthorized individuals.</p> <p>In the event of loss of medical records due to unavoidable circumstances, (e.g., natural or man-made disaster) there should be evidence in the QAPI of the event, what records were lost/destroyed, and what steps were taken to prevent similar losses in the future.</p>
652	<p>(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:</p> <ul style="list-style-type: none"> <li>(i) The transfer of the patient to another facility.</li> <li>(ii) Certain exceptions provided for in the law.</li> <li>(iii) Provisions allowed under third party payment contracts.</li> <li>(iv) Approval by the patient.</li> <li>(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.</li> </ul>	<p>Facilities must follow the HIPAA requirements.</p> <p>494.170(a)(2)(v) gives state surveyors and ESRD Networks rights to access and review patient records.</p> <p><b>Resource:</b> Health Insurance Portability and Accountability Act (HIPAA) <a href="http://www.hhs.gov/ocr/hipaa/">www.hhs.gov/ocr/hipaa/</a></p>
653	<p>(3) Obtain written authorization from the patient or legal representative before releasing information that is not authorized by law.</p>	<p>As required by HIPAA</p> <p><b>Resource:</b> <a href="http://www.hhs.gov/ocr/hipaa/">www.hhs.gov/ocr/hipaa/</a></p>
654	<p><b>(b) Standard: Completion of patient records and centralization of clinical information.</b></p> <p>(1) Current medical records and those of discharged patients must be completed</p>	<p>Entries in the medical record system must be signed to be complete. The ESRD must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes</p>

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	promptly.	<p>responsibility for accuracy of the entry. The identification may include written signature, initials, computer key, or other code. If initials or computer codes are used as signatures, a list to identify the user must be maintained.</p> <p>When rubber stamps are authorized to be used as a signature, only the individual whose signature the stamp represents may use the stamp.</p> <p>The records of discharged patients must be completed promptly and include the disposition of the patient.</p>
655	(2) All clinical information pertaining to a patient must be centralized in the patient's record. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.	<p>Documentation must be maintained current to ensure the record provides an up-to-date evaluation of the status of the patient at all times. It is essential that each clinical event be documented as soon as possible after its occurrence.</p> <p>Every medical record must be complete with documentation of orders, diagnosis, evaluations, treatments, test results, consents, care provided and the patient's response to that care.</p> <p>Dialysis treatment records are the primary means of documenting the daily care of hemodialysis patients. These treatment summaries should include such information as patient assessments pre and post treatment, vital signs, vascular access in use, weight, laboratory test results, medications given, and other treatment related parameters, such as target weight, blood and dialysate flow rates, and documentation of testing for machine safety such as pH and conductivity. If part of the record is maintained electronically, all staff members must know how to access the electronic as well as the hard copy portions of the chart.</p>
656	(3) The dialysis facility must complete, maintain, and monitor home care patients records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.	<p>The facility should have a system to review records kept by home patients concerning the dialysis process and to incorporate those records into the patient's permanent record. These records could include electronic transfer of information maintained on a memory card by the treatment device (e.g., peritoneal dialysis cycler). Refer to 494.100 (c) (2) for guidance related to records of home patients.</p>

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657	<p><b>(c) Standard: record retention and preservation.</b></p> <p>Patient records must be retained for a period of time not less than that required by State law or, in the absence of State law –</p> <p>(1) Adults. 5 years from the date of the patient’s discharge, transfer, or death; or</p> <p>(2) Minors. 3 years or until the patient reaches legal age under State law, whichever is longer, from the date of the patient’s discharge, transfer, or death.</p>	<p>The accumulation of records for a patient treated several times a week for years can become voluminous. The current working chart may contain only most recent treatment records, and perhaps a year of progress notes, orders, lab reports, etc. Older records may be stored in a convenient secure location, but must be readily accessible. Verify the lack of additional records if you are unable to locate specific documents in the current working chart.</p> <p>Electronic storage of records is permissible if a means to protect the integrity of the record is provided.</p> <p>Note that the retention requirements begin after the patient is no longer on census at this facility; these requirements also apply to the records of machine maintenance, reuse, water treatment and dialysate preparation as each of these records is part of the medical record for the patients on service at the time those records were completed.</p> <p>State requirements for record retention vary; be aware of the requirements in your state.</p>
658	<p><b>(d) Standard: Transfer of patient record information.</b></p> <p>When a dialysis patient is transferred, the dialysis facility releasing the patient must send the patient’s medical record and other information necessary in the patient’s care or treatment to the receiving facility within 1 working day of the transfer.</p>	<p>The facility is responsible for prompt transfer of medical information to the receiving facility. The intent is to maintain continuity of care whenever patients have to leave the community temporarily (e.g., vacation, business, hospitalization), or transfer permanently to a new facility.</p>
660	<p><b>§494.180 Condition: Governance.</b></p> <p>The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and</p>	<p>Identifiable- means there must be evidence in writing that identifies the individual or individuals that are responsible for the conduct of the facility operations.</p> <p>There are several types of facility ownership, including:</p>



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	<p>responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the ESRD network.</p>	<ul style="list-style-type: none"> <li>- <b>Hospital-based</b> - The facility must be owned by and located in a hospital to be hospital-based. A facility can be physically located inside a hospital and NOT be a hospital-based facility.</li> <li>- <b>Satellite facility</b> - Owned by a hospital but located away from the hospital campus. A satellite facility is surveyed separately and has its own certification number.</li> <li>- <b>Corporate entity</b> – Owned by a group, individual or company; generally these are part of a multi-facility group of several to hundreds.</li> <li>- <b>Physician-owned</b> – May a limited liability company or a corporation, could own one or several facilities.</li> </ul> <p>Before going to the facility (pre-survey), you should review the facility file for the following forms (as available) to determine facility ownership:</p> <ul style="list-style-type: none"> <li>--CMS 855 form (i.e., Medicare Federal Health Care Provider/Supplier Enrollment Application - CMS 855 A (Provider) and CMS 855 B (Supplier))</li> <li>--Certificate of Need (CON) documents, if required by your state</li> <li>--State license if required by your state</li> </ul> <p>If you have questions, once in the facility, ask to see the Governing Body by-laws, which should clearly state who is the owner. Sometimes there is a difference between who "owns" a facility and who "operates and manages" the facility.</p> <p>When facilities are part of a large dialysis organization (LDO) the corporation should appoint a local Governing Body to guide the day to day operation of the facility. Generally, the local Governing Body will include the medical director, the facility administrator or nurse manager and a regional administrator for the LDO. Determine who is named as responsible in the facility.</p> <p>If the owner has changed without your state agency being notified, you should consider citing the facility at 494.180 (i).</p>
<b>661</b>	<b>(a) Standard: Designating a chief</b>	The administrator or chief executive officer (CEO) may have an administrative

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	<p><b>executive officer or administrator.</b></p> <p>The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to –</p>	<p>background or could be one of the qualified interdisciplinary team. If the state requires ESRD licensing that includes more stringent personnel requirements, those must be met for this standard to be met.</p> <p>There should written evidence of the appointment of an administrator/ CEO. This individual must have the authority and demonstrate responsibility for the day-to-day management and oversight of the facility physical plant and operations.</p>
662	(1) Staff appointments;	<p>The Governing Body, through the administrator, is responsible for the appointment of medical staff and ancillary personnel (e.g. nurse practitioners, physician assistants, etc.) and for the employment of professional and technical personnel. Consider citing this tag if an employee is hired who is not qualified for the position (e.g. a non-MSW as the social worker).</p>
663	(2) Fiscal operations;	<p>The Governing Body, through the administrator, is responsible for maintaining sound fiscal operations. Consider citing this tag if you discover missed doses of medications, broken equipment, or deterioration of the physical plant attributable to fiscal mismanagement.</p>
664	(3) The relationship with the ESRD networks; and	<p>The ESRD Networks are a CMS contractor assigned responsibilities via a Statement of Work to:</p> <ul style="list-style-type: none"> <li>• Collect data including the information that allows patients to be enrolled into the ESRD Medicare benefit program</li> <li>• Provide education and oversight to improve the quality of care delivered to dialysis and kidney transplant patients</li> <li>• Respond to complaints and grievances</li> </ul> <p>There are 18 ESRD Networks; each covers a specified geographic area. For an initial survey, there should be a signed agreement between the facility and the applicable Network. Each Network is required to post their annual report on their websites; these include the individual Network's goals and activities.</p>

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		<p>Remember to contact the Network prior to each visit of an ESRD facility to determine if the Network staff has knowledge of any issues or complaints.</p> <p><b>Resource:</b> Forum of ESRD Networks – <a href="http://www.esrdnetworks.org">www.esrdnetworks.org</a> (map with link to your Network’s latest published annual report, includes information by state)</p>
665	(4) Allocation of necessary staff and other resources for the facility’s quality assessment and performance improvement program described in §494.110 of this part.	<p>The Governing Body, through the administrator, is responsible to allocate sufficient staff, time and resources to support the effective function of facility’s QAPI program.</p> <p>Consider citing this tag if the staff report they are unable to conduct QAPI activities due to requirements for clinical staffing, or demands to provide care in multiple units.</p>
666	<p><b>(b) Standard: Adequate number of qualified and trained staff.</b></p> <p>The governing body or designated person responsible must ensure that –</p> <p>(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients;</p>	<p>There must be enough qualified staff on duty to meet the needs of the patients. Acuity and care needs of patients and experience level of staff must be considered in evaluating the adequacy of staffing. Some facilities define a patient/staff ratio in their policies and procedures. Compare the staffing records with this policy if you identify a problem in this area.</p> <p>Observe care delivery. Expect sufficient numbers of staff to be present in the treatment area to be able to visualize every patient during treatment. Are patient requests and alarms responded to appropriately and promptly? Observe the number of staff on the treatment floor at various times during the day (e.g., during lunch breaks, shift change over, etc.).</p> <p>Review records for evidence that qualified staff perform assessments and respond to patient emergencies.</p> <p>If State law requires a registered nurse or physician to perform certain tasks (e.g. administer emergency intravenous medications), then such a person must be present during dialysis treatments.</p>

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		Be aware of any state laws that include specific staff-to-patient ratios; failure to comply with those laws may be cited at this tag.
667	(2) A registered nurse is present in the facility at all times that patients are being treated;	<p>There must be a qualified registered nurse on duty and available at all times when patients are being treated. Short personal breaks away from the treatment floor are expected and acceptable; if only one RN is on duty, that RN is expected to spend the majority of time on the treatment floor.</p> <p>Be aware that recent data in the nursing literature demonstrates an evidence-based positive correlation between the availability of professional nursing service and patient outcomes.</p> <p>Use the survey tasks of observation, patient and staff interview and review of records (e.g., timesheets or timecards) to assess compliance.</p>
668	(3) All employees have appropriate orientation to the facility and their work responsibilities upon employment;	<p>The dialysis facility must provide an orientation appropriate to the job duties assigned.</p> <p>Review selected personnel records for evidence of orientation.</p>
669	(4) All employees have an opportunity for continuing education and related development activities; and	<p>What continuing educational programs are offered to staff? Expect that staff may attend professional meetings as well as internal programs. How are learning needs identified? Is QA/QI data used to develop continuing education programs?</p> <p>Some in-services may be considered mandatory: infection control, fire safety, disaster preparedness, hazardous materials, etc. See also 494.30 (a)(1).</p> <p>Use staff interviews, personnel file review and review of records (e.g., educational programs) to verify compliance.</p>
670	<p>(5) There is an approved written training program specific to dialysis technicians that includes:</p> <p>(i) Principles of dialysis</p>	<p>The dialysis facility must provide a training program for dialysis technicians that includes these required elements and that is approved by the medical director and governing body.</p> <p>Some states have more stringent requirements for technician training. If that is</p>

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	<p>(ii) Care of patients with kidney failure, including interpersonal skills;</p> <p>(iii) Dialysis procedures and documentation, including the initiation, monitoring, and termination of dialysis;</p> <p>(iv) Possible complications of dialysis;</p> <p>(v) Water treatment;</p> <p>(vi) Infection control; and</p> <p>(vii) Safety; and</p> <p>(viii) Dialyzer reprocessing, if applicable.</p> <p>(6) When State requirement meet or exceed §494.180(b)(5) the State requirements must be met.</p>	<p>the case in your state and the training program does not meet your state requirements cite that deficient practice at this tag.</p> <p>Use the survey tasks of staff interview: interview one or more dialysis technicians during your observations of care. If you identify concerns, review the written training program for inclusion of the required content.</p>
671	<p><b>(c) Standard: Medical staff appointments.</b></p> <p>The governing body --</p> <p>(1) Is responsible for all medical staff appointments and credentialing, including attending physicians, physician assistants, and nurse practitioners; and</p>	<p>Privileges are granted by the facility's Governing Body based on that individual practitioner's qualifications and performance.</p> <p>Review documentation for verification appointees to the medical staff are licensed as required by the state and are working within the scope of the privileges granted by the Governing Body.</p> <p>Be aware that some states have ESRD licensure requirements in this area. What does your state require? Cite deficient practices in this area at this tag.</p>
672	<p>(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in §494.110 of this part. (text in parentheses was omitted)</p>	<p>If you identify a problem involving the medical staff (e.g., not documenting monthly progress notes as required by facility policy), use interviews to determine if the medical staff member is not informed vs. not compliant. Cite "not informed" at this tag, cite "not compliant" at 494.150 (c)(2)(i).</p> <p>Is every member of the medical staff informed of the facility's QAPI program? If you identify a problem in QAPI, ask the facility if they review practitioner specific outcomes. What processes are in place to ensure that all members of the medical staff are aware of the performance of the unit related to patient outcomes?</p>

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673	<p><b>(d) Standard: Furnishing Services</b></p> <p>The governing is responsible for ensuring that the dialysis facility furnishes directly (see §494.10 of this part) services on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under §494.100 of this part). (This standard was omitted.)</p>	<p>To define “furnishes directly” per 494.10: the ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility. This is not meant to preclude the use of agency or traveling staff.</p> <p>Each physical location for dialysis services must be certified separately, and all approved services for that facility must be provided on the premises of that location. Hospital based facilities may be located on the same campus of the hospital, with various services (e.g., home training vs. in center dialysis) being provided in different rooms but sharing the same address on that campus.</p> <p>Home dialysis services will be provided at the patient’s home, by patients themselves or caregivers. Training and support for home dialysis will generally be provided at the certified facility, although training may be provided in the patient’s home to meet the needs of the patient and helper (if applicable).</p> <p>All services provided by each facility must be under the direction of the same professional staff and Governing Body.</p>
674	<p><b>(e) Standard: Internal grievance process.</b></p> <p>The facility’s internal grievance process must be implemented so that the patient may file a grievance with the facility without reprisal or denial of services.</p>	<p>The facility’s policies and procedures should describe grievance procedures available to the patient. There should be evidence that the facility informed the patient and/or the patient’s representative of their internal grievance process, and that the facility has implemented this process in accordance with 494.180 (e)(1)-(3).</p> <p>Explain to facility administration that it is expected for facilities to have grievances. Having grievances indicates that patients feel comfortable filing a grievance without fearing retribution.</p> <p>Review evidence of any grievances submitted and determine if the facility implemented a process to ensure the patient would not fear or experience reprisal or denial of services.</p>



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		Expect the facility to be aware of the resources available in the “Decreasing Dialysis Patient Provider Conflict” (DPC) materials which were distributed by the Networks to every facility and are available on some of the Network’s web sites.
675	The grievance process must include— (1) A clearly explained procedure for the submission of grievances;	Each facility must have an established process for patients to file a grievance which is explained to all patients or his/her legal representative.
676	(2) Timeframes for reviewing the grievance;	The facility grievance policy must have clearly defined timeframes for a grievance to be acknowledged, investigated and addressed. Timeframes should be sufficient to conduct an investigation yet ensure that the grievance is addressed in a timely manner. If there is a prolonged investigation, the patient (or legal representative) should be informed of the progress periodically. The facility’s grievance process should assure those grievances involving situations or practices that place patients or staff members in immediate danger are resolved immediately.
677	(3) A description of how the patient or the patient’s designated representative will be informed of steps taken to resolve the grievance.	Interview the responsible staff (e.g., nurse manager, administrator) regarding how the patient or his/her representative, including those who have limited education, are hearing/visually impaired, and/or those with limited (or no) English proficiency are informed about the grievance policy.
678	<p><b>(f) Standard: Discharge and transfer policies and procedures.</b></p> <p>The governing body must ensure that all staff follow the facility’s patient discharge and transfer policies and procedures.</p>	<p>Review this standard if any patient has been involuntarily discharged or transferred since the last survey. Involuntary discharge or transfer indicates a failure to resolve patient/facility issues and should be preceded by demonstrated effort on the part of the interdisciplinary team to address the problem in a more mutually beneficial way. The facility must have and follow written policies and procedures for involuntary discharge and transfer. There are four reasons for which a facility can involuntarily discharge or transfer a patient as listed in 494.110(f)(1)-(4).</p> <p>If patients have been involuntarily discharged or transferred review a sample of those medical records to ensure compliance with these regulations and facility policy. See also requirements under 494.70(b).</p>

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		<b>Resource:</b> Decreasing Dialysis Patient Provider Conflict (DPC) - <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a>
679	<p>The medical director ensures that no patient is discharged or transferred from the facility unless –</p> <p>(1) The patient or payer no longer reimburses the facility for the ordered services;</p> <p>(2) The facility ceases to operate;</p> <p>(3) The transfer is necessary for the patient’s welfare because the facility can no longer meet the patient’s documented medical needs; or</p> <p>(4) The facility has reassessed the patient and determined that the patient’s behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient’s interdisciplinary team--</p>	<p>The medical director must be informed that a patient is being involuntarily discharged or transferred. The medical director needs to ensure that the reasons for this action are consistent with this regulation.</p> <p>A facility has the right to involuntarily discharge or transfer a patient for nonpayment of fees. Expect to see evidence that the facility staff (e.g., social worker, financial counselor, nurse) had made attempts to help the patient resolve nonpayment issues.</p> <p>In this case, facility staff members would likely assist patients to obtain dialysis in other facilities.</p> <p>There should be documented evidence of the medical need and reasons why the facility can no longer meet that need.  Are the reasons and steps taken documented in the record?  Refer to 494.70(b).</p> <p>There should be documented evidence of the reasons for involuntary discharge or transfer and the reassessment of the patient prior to discharge or transfer</p>
680	(i) documents the reassessments, ongoing problems(s) and enters this documentation into the patient’s medical record;	Expect to see a comprehensive reassessment by the interdisciplinary team
681	(ii) Obtains a written physician’s order that	There must be a written order signed by the medical director and the attending

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	must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;	physician for involuntary discharge or transfer.
682	(iii) Attempts to place the patient in another facility and documents that effort; and	Facility staff members are expected to directly contact other nephrologists and dialysis facilities to obtain alternate care.
683	(iv) Notifies the State survey agency and the ESRD Network that services the area (where the facility is located) of the involuntary transfer or discharge.	<p>Expect to see evidence of notification of the State Agency and ESRD Network prior to involuntary discharge or transfer.</p> <p>The following is excerpted from the recommendations of the Decreasing Dialysis Patient Provider Conflict materials:</p> <ul style="list-style-type: none"> <li>• When discussions regarding discharging a patient arise, the interdisciplinary care team should consider the ethical, legal, and regulatory obligations toward the patient who requires life-sustaining treatment.</li> <li>• Treatment should continue without bias or discrimination towards patients whose behaviors place only them at risk.</li> <li>• In the rare event a decision is made to terminate the physician/provider-patient relationship for behaviors which put the facility or others at risk, multidisciplinary renal care team good faith attempts at intensive interventions should have occurred over a reasonable period of time prior to the decision. Treatment should be continued until the patient-provider relationship has been legally and appropriately terminated. This includes advance notice and directly contacting other nephrologists and dialysis facilities to obtain alternate care. It is recommended that transfer within provider groups be facilitated if required to ensure continued treatment.</li> <li>• In addition to the provision of a list of other nephrologists and dialysis facilities the discharging facility has an ethical responsibility to the patient with a life threatening condition to actively participate in a well documented good faith effort to obtain dialysis placement to ensure continuity of care. This involves: <ul style="list-style-type: none"> <li>○ Active involvement of the patient's nephrologists</li> <li>○ Provision of accurate medical records and information to prospective</li> </ul> </li> </ul>

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		<p>providers in accordance with HIPAA and/ or the Federal Privacy Act including the reason for discharge</p> <ul style="list-style-type: none"> <li>○ Informing the patient of his/her rights under HIPAA to: <ul style="list-style-type: none"> <li>▪ Review records for transfer AND</li> <li>▪ Submit a statement in a reasonable time prior to the transfer for inclusion in medical record if not in agreement with the record</li> </ul> </li> <li>○ Prospective providers have an ethical obligation to earnestly consider accepting patients who have been discharged by other providers. This may require: <ul style="list-style-type: none"> <li>▪ A face to face meeting with the potential provider, patient and family</li> <li>▪ Use of treatment trials and behavior contracts</li> </ul> </li> <li>● When chronic placement is not obtained, the discharging physician and facility should work with area providers to ensure continued treatment. Are the reasons and steps taken prior to discharge documented in the record? Refer to 494.70(b).</li> </ul> <p><b>Resource:</b> Decreasing Dialysis Patient Provider Conflict (DPC) - <a href="http://www.esrdnetworks.org/dpc.htm">www.esrdnetworks.org/dpc.htm</a></p>
684	<p><b>(g) Standard: Emergency coverage.</b></p> <p>(1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.</p>	<p>The facility must provide information to all patients regarding who to call and how to obtain emergency medical care. Simply calling 911 is not a sufficient plan for emergent dialysis-related medical care because of the specialized requirements of dialysis patients to maintain their dialysis access, to manage their precarious electrolyte status and anemia. The patient needs to be able to reach an on call dialysis physician or extender for dialysis-related emergencies. All staff should be knowledgeable and trained in their respective roles in emergency situations.</p>
685	<p>(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called , and</p>	<p>There must always be available a listing of physicians names and contact numbers. There must be a plan for coverage for that physician for illness/holidays.</p>

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	how they can be reached.	
<b>686</b>	<p>(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must --</p> <p>(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.</p> <p>(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.</p>	<p>Inpatient care must include the capacity to provide acute dialysis services.</p> <p>Review the agreement with a local hospital that can provide dialysis services. This hospital does not have to be certified as an ESRD provider, but must be able to provide acute dialysis treatment as well as emergency and inpatient treatment, and other hospital services.</p>
<b>687</b>	<p><b>(h) Standard: Furnishing data and information for ESRD program administration.</b></p> <p>The dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment.</p>	<p>All dialysis facilities must electronically submit data to allow patient enrollment in and disenrollment from the ESRD benefit program, assessment of clinical outcomes, and claims processing.</p>
<b>688</b>	<p>The data and information must --</p> <p>(1) Be submitted at the intervals specified by the Secretary.</p>	<p>Cite this tag if the Network reports the facility is not submitting required information at the specified intervals.</p>
<b>689</b>	<p>(2) Be submitted electronically in the format specified by the Secretary;</p>	<p>Cite this tag if the Network reports the facility is not submitting data electronically.</p>
<b>690</b>	<p>(3) Include, but not be limited to:</p> <p>(i) Cost reports</p>	<p>Cite this tag if the RO reports the facility is not electronically submitting cost report data.</p>

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691	(ii) ESRD administrative forms	Cite this tag if the Network reports the facility is not electronically submitting ESRD administrative forms (e.g. the annual facility survey).
692	(iii) Patient survival information, and	Cite this tag if the facility is not electronically submitting patient survival information.
693	(iv) Existing ESRD clinical performance measures and any future clinical performance standards developed in accordance with the National Technology Transfer and Advancement Act process adopted by the Secretary.	Facilities are expected to submit clinical performance data on 100% of their patients at the frequency determined by the Secretary. The specific clinical measures to be submitted will be determined by the Secretary.
694	<p><b>(i) Standard: Disclosure of ownership.</b></p> <p>In accordance with §§420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.</p>	<p>The ESRD facility must supply full and complete information regarding ownership to the State survey agency.</p> <p>Review facility file as part of the presurvey activities to determine previous ownership. Ask the facility administrator if any changes in ownership have occurred since the previous survey? Did they report these changes to the State survey agency? Cite this tag if changes in ownership were not reported.</p>