

State Operations Manual

Appendix H - Guidance to Surveyors: End-Stage Renal Disease Facilities

Table of Contents (Rev., 200, 02-21-20)

Transmittals for Appendix H

Part I - Regulation & Interpretive Guidance

Subpart A - General Provisions

§ 494.1 Basis and scope

§ 494.10 Definitions

§ 494.20 Condition: Compliance with Federal, State, and local laws and regulations

Subpart B - Patient Safety

§ 494.30 Condition: Infection control

§ 494.40 Condition: Water and dialysate quality

§ 494.50 Condition: Reuse of hemodialyzers and bloodlines

§ 494.60 Condition: Physical environment

§ 494.62 Condition: Emergency Preparedness

Subpart C - Patient Care

§ 494.70 Condition: Patients' rights

§ 494.80 Condition: Patient assessment

§ 494.90 Condition: Patient plan of care

§ 494.100 Condition: Care at home

§ 494.110 Condition: Quality assessment and performance improvement

§ 494.120 Condition: Special purpose renal dialysis facilities

§ 494.130 Condition: Laboratory services

Subpart D - Administration

§ 494.140 Condition: Personnel qualifications

§ 494.150 Condition: Responsibilities of the medical director

§ 494.160 [Reserved]

§ 494.170 Condition: Medical records

§ 494.180 Condition: Governance

Part II - ESRD Core Survey Process

***NOTE:** Publication of the ESRD Facility survey process is pending and will be updated in a future release.*

Part I - Regulation & Interpretive Guidance

Subpart A - General Provisions

§ 494.10 Basis and Scope

(a) Statutory basis. This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) 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.

(3) 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 support services, and institutional dialysis services and supplies, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B)), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1881(b)(14) to an individual with acute kidney injury (as defined in section 1834(r)(2)).

(4) Section 1862(a) of the Act, which specifies exclusions from coverage.

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(7) Section 1861(s)(2)(F) of the Act, which authorizes coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI.

(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.

§ 494.10 Definitions

Dialysis facility means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in §413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.

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.

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.

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.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

V100

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.20 - Condition: Compliance with Federal, State, and local laws and regulations

Interpretive Guidelines §494.20

Guidance is pending and will be updated in future release.

V101

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.20 – Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

Interpretive Guidelines §494.20

Guidance is pending and will be updated in future release.

Subpart B—Patient Safety

V110

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30 - Condition: Infection control.

Interpretive Guidance §494.30

Guidance is pending and will be updated in future release.

V111

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30 - 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.

Interpretive Guidance §494.30

Guidance is pending and will be updated in future release.

V112

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(a) - Standard: Procedures for infection control.

The facility must demonstrate that it follows standard infection control precautions by implementing—

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,” developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this

*material at NARA, call 202-741-6030, or go to:
http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.
The recommendation found under section header “HBV-Infected Patients”, found on pages 27 and 28 of RR05 (“Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients”), concerning isolation rooms, must be complied with by February 9, 2009.*

Interpretive Guidelines § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V113

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Wear disposable gloves when caring for the patient or touching the patient’s equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V114

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V115

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

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). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V116

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Items taken into the dialysis station should 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.

- Non-disposable 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.***
- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) 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.***

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V117

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

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 that where used equipment or blood samples are handled.

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.

Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V118

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V119

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

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.

Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V120

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.

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.

Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V121

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(a)(4) – [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—
(i) Handling, storage and disposal of potentially infectious waste; and

Interpretive Guidance § 494.30(a)(4)(i)

Guidance is pending and will be updated in future release.

V122

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.130(a)(4) – [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] [Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—](ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

Interpretive Guidance § 494.30(a)(4)(ii)

Guidance is pending and will be updated in future release.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(a)(3) [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] Patient isolation procedures to minimize the spread of infectious agents and communicable diseases;

Interpretive Guidance § 494.30(a)(3)

Guidance is pending and will be updated in future release.

V124

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Routine Testing for Hepatitis B

The HBV serological status (i.e. HBsAg, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit.

Routinely test all patients [as required by the referenced schedule for routine testing for Hepatitis B Virus].

Promptly review results, and ensure that patients are managed appropriately based on their testing results.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V125

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Routine Testing for Hepatitis B

When a seroconversion occurs, review all patients' routine laboratory test results to identify additional cases. 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.

V126

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Hepatitis B Vaccination

Vaccinate all susceptible patients and staff members against hepatitis B.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V127

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Hepatitis B Screening: Patients and Staff

Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose.

-- If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs.

-- If anti-HBs are ≥10 mIU/mL, consider immune, and retest patients annually.

-- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V128

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Isolation of HBV+ Patients

To isolate HBsAg positive patients, designate a separate room for their treatment.

For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activity.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V129

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(a)(1)(ii) - When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

Interpretive Guidance § 494.30(a)(1)(ii)

Guidance is pending and will be updated in future release.

V130

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Isolation of HBV+ Patients

To isolate HBsAg positive patients... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V131

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Isolation of HBV+ Patients

Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V132

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Infection Control Training and Education

Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.

END CDC RR-05 REQUIREMENTS

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V142

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

***§494.30(b) Standard: Oversight. The facility must—
(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;***

Interpretive Guidance § 494.30(b)(1)

Guidance is pending and will be updated in future release.

V143

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(b)(2) – [Standard: Oversight. The facility must -] Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

Interpretive Guidance § 494.130(b)(2)

Guidance is pending and will be updated in future release.

V144

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(b)(3) – [Standard: Oversight. The facility must -] Require all clinical staff to report infection control issues to the dialysis facility’s medical director (see §494.150 of this part) and the quality improvement committee.

Interpretive Guidance § 494.30(b)(3)

Guidance is pending and will be updated in future release.

V145

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.30(c) - Standard: Reporting. The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

Interpretive Guidance § 494.30(c)

Guidance is pending and will be updated in future release.

V146

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

*§494.30(a) – [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—]
(2) The “Guidelines for the Prevention of Intravascular Catheter-Related Infections” entitled “Recommendations for Placement of Intravascular Catheters in Adults and Children” parts I – IV; and “Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients,” Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to:*

http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html

Interpretive Guidance § 494.30(a)(2)

Guidance is pending and will be updated in future release.

V147

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-10 Requirements, as Adopted by Reference 42 CFR 494.30 (a)(2):

Recommendations for Placement of Intravascular Catheters in Adults and Children

I. Health care worker education and training

A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections.

B. Assess knowledge of and adherence to guidelines periodically for all persons who ... manage intravascular catheters.

II. Surveillance

A. Monitor the catheter sites visually or by palpation ... of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.

VI. Catheter and catheter-site care

Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI (catheter related blood stream infections).

Interpretive Guidance § 494.30(a)(2)

Guidance is pending and will be updated in future release.

V148

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From CDC RR-10 Requirements, as Adopted by Reference 42 CFR 494.30(a)(2):

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.

I. Surveillance

A. Conduct surveillance ... to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection-control practices.

B. Express ... data as the number of catheter-associated BSIs per 1,000 catheter-days for both adults and children ... to facilitate comparisons with national data in comparable patient populations and health-care settings.

C. Investigate events leading to unexpected life- threatening or fatal outcomes. This includes any process variation for which a recurrence would likely present an adverse outcome.

END CDC RR-10 REQUIREMENTS

Interpretive Guidance § 494.30(a)(2)

Guidance is pending and will be updated in future release.

V175

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.40 – Condition: Water and dialysate quality.

Interpretive Guidance § 494.40

Guidance is pending and will be updated in future release.

V176

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.40 - The facility must be able to demonstrate the following—

(a) Standard: Water purity. Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, “Dialysate for hemodialysis,” ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552 (a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V177

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4 Fluid quality

4.1 Water

4.1.1 Maximum level of chemical contaminants in water

Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall not contain chemical contaminants at concentrations in excess of those listed in ANSI/AAMI RD62 ... which is reproduced in Table 1 below.

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 uses (Reproduced from ANSI/AAMI RD62:2001)

Contaminant	Maximum concentration (mg/L)
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	0.008
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free Chlorine	0.50
Copper	0.10
Fluoride	0.20
Nitrate (as N)	2.0
Sulfate	100
Thallium	0.002
Zinc	0.10

NOTE—American National Standards are revised every three to five years. Users should consult the most recent edition of ANSI/AAMI RD62 to ensure that the levels listed in this table are still valid.

The manufacturer or supplier of a complete water treatment system should recommend a system that is capable of meeting the requirements of this clause at the time of installation given the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality.

Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this standard.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V178

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.1.2 Bacteriology of water: Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower 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 those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V179

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.1.2 Bacteriology of water

The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation

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.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V180

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.3.2.1 Bacteriology of conventional dialysate

Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL.

The action level for the total viable microbial count in conventional dialysate should be 50 CFU/mL and the action level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V181

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.3.2.2 Bacteriology of ultrapure dialysate: Ultrapure dialysate should contain a total viable microbial count lower than 0.1 CFU/mL and an endotoxin concentration lower than 0.03 EU/mL. If those limits are exceeded in ultrapure dialysate, corrective measures should be taken to reduce the levels into an acceptable range. The user is responsible for monitoring the dialysate bacteriology of the system following installation. It is incumbent on the user to establish a regular monitoring routine.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V182

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5 Equipment

5.1 General:

A dialysis facility should develop contingency plans to cover the failure of its water purification and distribution system or a critical component of that system. Such contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility's municipal water supply

or electrical service following a natural disaster or water main break. Other plans should address how to deal with sudden changes in municipal water quality, as well as with failure of a critical component of the water purification and distribution system.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2 Water purification systems

5.2.1 General

Water purification systems consist of three basic sections: a pretreatment section that conditions the water supplied to the primary purification device, which may be followed by other devices that polish final water quality. The pre-treatment section commonly includes a sediment filter, cartridge filters capable of retaining particles of various sizes, a softener, and carbon adsorption beds. The primary purification process most commonly used is reverse osmosis, which may be followed by deionization and ultrafiltration for polishing the product water from the reverse osmosis system.

Whether a particular device is included in an individual water purification system will be dictated by local conditions.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V184

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment

The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimize the length and complexity of the distribution system. Access to the

purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V185

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment (access to ports and meters)

The layout of the water purification system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V186

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment (alarms in the treatment area)

Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, should be configured to sound in the patient treatment area, as well as in the water treatment room.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V187

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment (schematic diagrams and labels)

Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.

Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.

If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V188

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.2 Sediment filters (equipment configuration)

6.2.2 Sediment filters (monitoring)

5.2.2 Sediment filters:

Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet.

6.2.2 Sediment filters:

Sediment filters should be monitored on a periodic basis... [for a] pressure drop (ΔP) across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used to remove particulate matter from the sediment filter. The frequency of backwashing should follow the manufacturer's recommendations.

Sediment filter monitoring should include daily verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.

[Refer to RD62:2001, 4.3.8 Sediment filters:] Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V189

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

5.2.3 Cartridge filters (equipment configuration)

6.2.3 Cartridge filters (monitoring)

5.2.3 Cartridge filters

The cartridge is contained within an opaque filter housing with seals to separate the feed and product water streams.

When the maximum [pressure drop] ΔP recommended by the filter manufacturer is reached, the cartridge should be replaced according to the manufacturer's instructions.

6.2.3 Cartridge filters

Cartridge filters should be monitored on a periodic.... basis for a [pressure drop] ΔP across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A marked decrease in ΔP without a corresponding decrease in flow rate may indicate a loss of filter integrity. Follow the manufacturer's recommendations concerning when to replace cartridge filters.

Replacement of the cartridge will usually be indicated by an increase in ΔP to some specified value. A log sheet should be developed to record the pressure drop measurements.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V190

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.4 Softeners: (auto regen/timers/salt/salt level)

6.2.4 Softeners (monitoring)

Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as “regeneration,” which involves exposure of the resin bed to a saturated sodium chloride solution.

5.2.4 Softeners (Refer to RD62:2001, 4.3.10)

Automatically regenerated water softeners: 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.

The face of the timers used to control the regeneration cycle should be visible to the user.

6.2.4 Softeners

Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.

The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V191

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

6.2.4 Softeners: (Testing hardness/log)

Users should ensure that test accuracy and sensitivity are sufficient to satisfy the total hardness monitoring requirements of the reverse osmosis machine manufacturer. Total hardness of the water exiting the water softener should be measured at the end of each treatment day.

Water hardness test results should be recorded in a water softener log.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V192

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption

Two carbon beds shall be installed in series with a sample port following the first bed. A sample port shall also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed.

Refer to RD62:2001, 4.3.9 Carbon adsorption media: 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.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V193

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

5.2.5 Carbon adsorption: (banks of tanks)

Carbon beds are sometimes arranged as series-connected pairs of beds so that they need not be overly large. The beds within each pair are of equal size and water flows

through them are parallel. In this situation, each pair of beds should have a minimum empty bed contact time of 5 minutes at the maximum flow rate through the bed. When series connected pairs of beds are used, the piping should be designed to minimize differences in the resistance to flow from inlet and outlet between each parallel series of beds to ensure that an equal volume of water flows through all beds.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V194

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption: (Iodine #900/replacement)

When granular activated carbon is used as the media, it shall have a minimum iodine number of 900. Other forms of carbon should not be used unless there is 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 for hemodialysis applications.

Refer to RD62:2001, 4.3.9 Carbon adsorption media: Exhausted carbon adsorption media shall be discarded and replaced with new media according to a replacement schedule determined by regular monitoring.

Interpretive Guidelines §494.40(a)

Guidance is pending and will be updated in future release.

V195

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption: (10 minute EBCT)

Refer to RD62:2001, 4.3.9 Carbon adsorption media: When granulated activated carbon is used as the adsorption medium... 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).

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V196

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.2.5 Carbon adsorption (monitoring and testing frequency)

Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.

Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.

Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].

Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

Interpretive Guidelines § 494.40(a)

Guidance is pending and will be updated in future release.

V197

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption: (positive sample of chlorine or chloramine)

When samples from the first sampling port are positive for chlorine or chloramine, operation may be continued for a short time (up to 72 hours) until a replacement bed is installed, provided that samples from the second sampling port remain negative. The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds should be replaced.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V198

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

5.2.6 Chemical injection systems

6.2.6 Chemical injection systems

5.2.6 Chemical injection systems

Chemical injection systems consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber located in the main water line. Chemical injection systems also include some means of regulating the metering pump to control the addition of a chemical. This system should be designed to tightly control the addition of the chemical. The control system should ensure that a chemical is added only when water is flowing through the pretreatment cascade and that it is added in fixed proportion to the water flow or based on some continuously monitored parameter, such as pH, using an automated control system. If an automated control system is used to inject the chemical, the controlling parameter should be independently monitored. There should also be a means of verifying that the concentrations of any residuals arising from the chemical added to the water are reduced to a safe level before the water reaches its point of use.

When acid is added to adjust pH, a mineral acid should be used.

6.2.6 Chemical injection systems

Systems for chemical injection should be monitored according to the manufacturer's instructions. If a facility designs its own system, procedures should be developed to ensure proper preparation of the chemical, adequate mixing of the injected chemical with the water flowing through the pretreatment cascade, and reduction to a safe level of the concentration of any chemical residuals before the point of water use. The facility should also verify that the injected chemical does not degrade the performance

of downstream devices, including the primary purification process. The adequacy of these procedures must be verified using an independent laboratory. Verification can be accomplished by testing samples from the chemical reservoir and the water line after the point of injection for at least three batches of chemical.

When the chemical to be injected is prepared at a facility from powder or by dilution of a liquid concentrate, the chemical injection reservoir must be labeled with the name of the chemical and its concentration, the date the solution was prepared, and the name of the person who mixed the solution.

Each batch of chemical should be tested for correct formulation before use. A batch of chemical must not be used or transferred to the injection system reservoir until all tests are completed. The test results—and verification that they meet all applicable criteria—should be recorded and signed by the individual performing the tests.

Protective clothing and an appropriate environment, including ventilation adequate to meet applicable OSHA environmental exposure limits, should be provided when chemicals for injection are prepared in a dialysis facility.

Interpretive Guidelines § 494.40(a)

Guidance is pending and will be updated in future release.

V199

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.7 Reverse osmosis (configuration)

6.2.7 Reverse osmosis (monitoring)

Refer to RD62:2001, 4.3.7 Reverse osmosis: 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] 5.2.2.

5.2.7 Reverse osmosis

Users should carefully follow the manufacturer's instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters.

6.2.7 Reverse osmosis

All results of measurements of RO performance should be recorded daily in an operating log that permits trending and historical review.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V200

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.7 Reverse osmosis: (alarms)

6.2.7 Reverse osmosis (monitoring)

Refer to RD62:2001, 4.3.7 Reverse osmosis: 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.

5.2.7 Reverse osmosis:

Refer to RD62:2001, 4.3.7 Reverse osmosis: When a reverse osmosis system is the last chemical purification process in the water treatment system, it [should] include 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.

6.2.7 Reverse osmosis:

Reverse osmosis systems should be monitored daily using continuous-reading monitors that measure product water conductivity (or total dissolved solids (TDS)).

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V201

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.2.7 Reverse osmosis: (Chemical analysis: frequency)

Chemical analysis for the contaminants listed in 4.1.1 (Table 1) should be done when the RO system is installed, when membranes are replaced, and at not less than annual intervals thereafter to ensure that the limits specified in 4.1.1 are met (see Table 1). Chemical analyses should be done when seasonal variations in source water suggest worsening quality or when rejection rates fall below 90%.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V202

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.8 Deionization: (continuous monitor resistivity)

6.2.8 Deionization (monitoring)

Refer to RD62:2001, 4.3.6 Deionization: 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.

5.2.8 Deionization

Deionization may be used to polish product water from a reverse osmosis system or may be used as a standby if the reverse osmosis system fails.

6.2.8 Deionization

Deionizers shall be monitored continuously using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms. Resistivity monitors shall have a minimum sensitivity of 1.0 megohm-cm. Patients shall not be dialyzed on deionized water with resistivity less than 1.0 megohm-cm measured at the output of the deionizer

Resistivity monitor readings should be recorded on a log sheet twice each treatment day.

Interpretive Guidelines § 494.40(a)

Guidance is pending and will be updated in future release.

V203

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.8 Deionization (alarms/divert to drain)

Refer to RD62:2001, 4.3.6 Deionization:

An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use, for example by being diverted to drain. The alarm must be audible in the patient care area.

The resistivity monitor following the final deionizer bed shall be connected to an audible and visible alarm in the dialysis treatment area, and the DI system shall divert product water to drain or otherwise prevent product water from entering the distribution system should an alarm condition occur. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V204

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.8 Deionization (carbon adsorption and ultrafilter)

Systems that include deionizers as a component shall also contain carbon adsorption upstream of the deionizer to avoid formation of carcinogenic nitrosamines.

In all instances, deionizers shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device to remove microbiological contaminants that may originate in the deionizer resin bed.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V205

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.8 Deionization (utilization as polisher or backup)

The usual application for a deionizer is as a polisher following reverse osmosis or as a standby process if the reverse osmosis system fails. Use of deionization as the primary means of purification in an outpatient facility is not recommended because of the inability of deionization and ultrafiltration to remove certain low-molecular-weight toxic bacterial products, such as microcystins.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V206

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.2.8 Deionization (chemical analysis: frequency)

When deionization is employed as the primary method for removing inorganic contaminants (reverse osmosis is not employed), or when deionization is necessary to polish RO-treated water, chemical analyses to ensure that the requirements of AAMI 4.1.1 (Table 1) are met should be performed when the system is installed and at annual intervals thereafter.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V207

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.9 Ultrafiltration (effective/opaque housing)

6.2.9 Ultrafiltration (monitoring)

Refer to RD62:2001, 4.3.12 Ultrafilters: 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.

5.2.9 Ultrafiltration

Refer to RD62:2001, 4.3.12 Ultrafilters: Ultrafilters [should] have an opaque housing or that other means be used to inhibit proliferation of algae.

Ultrafilters should be included in routine disinfection procedures to prevent uncontrolled proliferation of bacteria in the feed water compartment of the filter.

6.2.9 Ultrafiltration

The pressure drop across the ultrafilter (ΔP) should be measured using simple inlet and outlet pressure gauges. Ultrafilters operated in the cross-flow mode should also be monitored in terms of the flow rate of water being directed to drain (concentrate).

Results of pressure measurements and bacteria and endotoxin levels should be recorded in a log.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V208

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3 Water storage and distribution

5.3.1 General: Design

A water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V209

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.2 Water storage: tank shape/configuration

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 µm air filter. The filter should be changed on a regular schedule according to the manufacturer's instructions. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

7.1 General strategies for bacterial control [in storage tanks]:

An ultrafilter, distal to the storage tank, or some other form of bacterial control device is recommended.

Storage tanks are therefore not recommended for use in dialysis systems unless they are frequently drained and adequately disinfected.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V210

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.3 Water storage and distribution

6.3.2 Water storage (monitoring)

Routine monitoring of water storage tanks for bacteria and endotoxin levels is generally accomplished indirectly by monitoring the water at the first outlet to the distribution loop (see 6.3.3). If direct monitoring of a water storage tank is performed as part of a troubleshooting process, bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3). All bacteria and endotoxin results should be recorded on a log sheet.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V211

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.3 Water distribution systems (continuous flow rates)

7 Strategies for bacterial control

7.1 General

5.3.3 Water distribution systems

Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation. A centrifugal pump made of inert materials is necessary to distribute the purified water and aid in effective disinfection.

7 Strategies for bacterial control

7.1 General

To minimize biofilm formation, there should always be flow in a piping system. A minimum velocity of 3 ft/sec in the distal portion of the loop of an indirect feed system and a minimum velocity of 1.5 ft/s in the distal portion of a direct feed system are recommended when the system is operating under conditions of peak demand.

Dead-end pipes and unused branches and taps that can trap fluid must be eliminated because they act as reservoirs of bacteria and are capable of continuously inoculating the entire volume of the system. These measures also minimize the possibility that pockets of residual disinfectant could remain in the piping system after disinfection.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V212

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.3 Water distribution systems (no added burden)

Product water distribution systems shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc, or bacterial contaminants to the purified water.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V213

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.3.3 Water distribution systems (bacteria and endotoxin testing)

Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL)]

Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits.

Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken.

Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3).

All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V214

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4 Bacterial control devices

5.3.4.1 Ultraviolet irradiators

Refer to RD62:2001, 4.3.13 Ultraviolet irradiators: 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/cm², [except in the case described below]. The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions.

5.3.4.1 Ultraviolet irradiators

If the irradiator includes a meter as described above, the minimum dose of radiant energy should be at least 16 milliwatt-sec/cm².

To prevent the use of sublethal doses of radiation that may lead to the development of resistant strains of bacteria, UV irradiators shall be equipped with a calibrated ultraviolet intensity meter ...or with an on-line monitor of radiant energy output that activates a visible alarm, which indicates that the lamp should be replaced.

Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output.

6.3.4 Bacterial control devices

6.3.4.1 Ultraviolet irradiators

Ultraviolet irradiators intended for use as a direct means of bacterial control shall be monitored for radiant energy output. UV irradiators should be monitored at the frequency recommended by the manufacturer. A log sheet should be used to indicate that monitoring has been performed.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V215

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4.1 Ultraviolet irradiators (filter)

UV irradiators [shall] be followed by a means of reducing endotoxin concentrations, such as an ultrafilter in the purified water distribution system or reverse osmosis in the pretreatment cascade.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V216

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4.2 Ozone generators: system requirements/monitoring

6.3.4 Bacterial control devices

Ozone can be used for bacterial control only in systems constructed from ozone-resistant materials (see AAMI 5.3.3 for suitable piping materials).

5.3.4.2 Ozone generators

Refer to RD62:2001, 4.3.15 Ozone disinfection systems: 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.

6.3.4 Bacterial control devices

6.3.4.2 Ozone generators

Ozone generators should be monitored for ozone output at a level specified by the manufacturer. The output of the ozone generator should be measured by the ozone concentration in the water. A test based on indigo trisulfonate chemistry, or the equivalent, should be used to measure the ozone concentration ...each time disinfection is performed. An ozone-in-ambient-air test should be conducted on a periodic basis, as recommended by the manufacturer, to ensure compliance with the OSHA permissible exposure limit of 0.1 ppm. A log sheet should be used to indicate that monitoring has been performed.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V217

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4.3 Hot water disinfection systems

Refer to RD62:2001, 4.3.14 Hot water disinfection systems: 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 delivering hot water at the temperature and for the exposure time specified by the manufacturer.

5.3.4.3 Hot water disinfection systems

Hot water disinfection systems can be used only in systems constructed from heat-resistant materials, such as cross-linked polyethylene, polypropylene, and stainless steel (see [AAMI] 5.3.3).

The manufacturer's instructions for using hot water disinfection systems should be followed. If no manufacturer's instructions are available, the effectiveness of the system can be demonstrated by verifying that the system maintains a specified temperature for a specified time and by performing ongoing surveillance with bacterial cultures and endotoxin testing.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V218

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.3.4 Bacterial control devices

6.3.4.3 Hot water disinfection systems: monitoring

Hot water disinfection systems should be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Also, hot water disinfection should be performed at least as often as recommended by the manufacturer. The temperature of the water should be recorded at a point farthest from the water heater—

that is, where the lowest water temperature is likely to occur...and measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting temperature and time requirements specified by the equipment manufacturer.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V219

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7 Strategies for bacterial control

7.1 General (disinfection and frequency)

Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but disinfection must be performed at least monthly.

A mechanism should be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V220

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7 Strategies for bacterial control

7.1 General (disinfection of machine supply line)

Users should establish a procedure for regular disinfection of [the line between the outlet from the water distribution system and the back of the dialysis machine].

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4 Concentrate preparation

5.4.1 General

Dialysate is customarily prepared from two concentrates: the bicarbonate concentrate, which contains sodium bicarbonate (and sometimes additional sodium chloride), and the acid concentrate, which contains all remaining ions, acetic acid, and sometimes glucose.

Acid concentrate can be supplied by the manufacturer in bulk (usually 55 gallon containers) or in gallon containers.

There are systems available that allow a user at a dialysis facility to prepare acid concentrate from packaged powder and purified water using a mixer. Acid concentrate prepared at the dialysis facility from powder and water is the responsibility of the user.

Bicarbonate concentrate can be supplied by the manufacturer in one of three ways:

- 1. In gallon containers,***
- 2. As packaged powder that is mixed with purified water at the dialysis facility, and***
- 3. In powder cartridges that are used to prepare concentrate on-line at the time of dialysis.***

Interpretive Guidance § 494.40(a)

This is an informational tag outlining the methods used for bicarbonate and acid concentrate delivery.

V222

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4 Concentrate preparation

5.4.3 Bulk storage tanks (acid concentrate)

Procedures should be in place to control the transfer of the acid concentrate from the delivery container to the storage tank to prevent the inadvertent mixing of different concentrate formulations. If possible, the tank and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The storage tanks and inlet and outlet connections, if remote from the tank, should be secure and labeled clearly.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V223

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4 Concentrate preparation

5.4.2 Materials compatibility

All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides or germicidal procedure used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited.

V224

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems

Concentrate mixing systems require a purified water source, a suitable drain, and a ground fault protected electrical outlet.

V225

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems: (safe environment/PPE)

Protective measures should be used to ensure a safe work environment.

Operators should at all times use appropriate personal protective equipment, such as face shields, masks, gloves, gowns, and shoe protectors, as recommended by the manufacturer.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V226

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems

6.4.1 Mixing systems (monitoring)

5.4.4.1 Mixing systems

If a concentrate mixing system is used, the preparer should follow the manufacturer's instructions for mixing the powder with the correct amount of water.

If a concentrate mixing system is used, the number of bags or the weight of powder added should be determined and recorded.

Manufacturer's recommendations should be followed regarding any preventive maintenance and sanitization procedures. Records should be maintained indicating the date, time, person performing the procedure, and results (if applicable).

6.4.1 Mixing systems

Systems for preparing either bicarbonate or acid concentrate from powder should be monitored according to the manufacturer's instructions.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V227

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.4.1 Mixing systems (self-designed)

If a facility designs its own system, procedures should be developed and demonstrated to ensure proper mixing of the concentrate, including establishment of acceptable limits for tests of proper concentration. The adequacy of those procedures must be verified using an independent laboratory that is capable of meeting the requirements of ANSI/AAMI RD61:2000 (see 2.4). Verification can be accomplished by testing a sample from each batch prepared over a 3-day period.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V228

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems (labeling)

Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.

Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.

Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.

Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V229

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems (permanent records)

6.4.1 Mixing systems (verification testing)

5.4.4.1 Mixing systems

In addition to container labeling, there should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date (if applicable).

6.4.1 Mixing systems

Acid and bicarbonate concentrates may be tested by using conductivity or by using a hydrometer.

Concentrates should not be used or transferred to holding tanks or distribution systems until all tests are completed. The test results and verification that they meet all applicable criteria should be recorded and signed by the individuals performing the tests.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V230

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.4.1 Mixing systems (cleaning)

Concentrate mixing equipment should be either: (1) completely emptied, cleaned, and disinfected according to the manufacturer's instructions; or (2) cleaned and disinfected

using a procedure demonstrated by the facility to be effective in routinely producing concentrate meeting [these regulations related to allowable bacterial and endotoxin levels].

The disinfection data should be recorded for each ... disinfection cycle using a dedicated log.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V231

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.2 Acid concentrate mixing systems: empty completely/prevent corrosion

Acid concentrate mixing tanks should be designed to allow the inside of the tank to be completely emptied and rinsed according to the manufacturer's instructions when concentrate formulas are changed.

Acid concentrate mixing tanks should be emptied completely before mixing another batch of concentrate.

Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V232

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.3 Bicarbonate concentrate mixing systems: empty/ disinfect/prevent corrosion

Bicarbonate concentrate mixing tanks should be designed to drain completely.

Mixing tanks should have a tight-fitting lid and should be designed to allow all internal surfaces to be disinfected and rinsed.

Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V233

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.3 Bicarbonate concentrate mixing systems

7 Strategies for bacterial control

7.1 General

5.4.4.3 Bicarbonate concentrate mixing systems

Once mixed, bicarbonate concentrate should be used within the time specified by the manufacturer of the concentrate.

7 Strategies for bacterial control

7.1 General

Storage times for bicarbonate concentrate should be minimized, as well as the mixing of fresh bicarbonate concentrate with unused portions of concentrate from a previous batch. The manufacturer's instructions should be followed if they are available.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V234

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.3 Bicarbonate concentrate mixing systems

Over-agitating or over-mixing of bicarbonate concentrate should be avoided, as this can cause CO2 loss and can increase PH.

ANSI/AAMI RD52:2004

5.4.4.3 Bicarbonate concentrate mixing systems

Systems designed for mixing dry acid concentrates may use methods that are too vigorous for dissolving dry bicarbonate.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V235

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.5 Additives: mixing spikes

Concentrate additives should be mixed with liquid acid concentrates according to the manufacturer's instructions, taking care to ensure that the additive is formulated for use in concentrates of the appropriate dilution ratio. When liquid additives are used, the volume contributed by the additive should be considered when calculating the effect of dilution on the concentration of the other components in the resulting concentrate. When powder additives are used, care should be taken to ensure that the additive is completely dissolved and mixed before the concentrate is used.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V236

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.5 Additives (labeling)

5.4.4.1 Concentrate jugs

If a chemical spike is added to an individual container to increase the concentration of an electrolyte, the label should show the added electrolyte, the date and time added, and the name of the person making the addition.

Containers should be labeled to indicate the final concentration of the added electrolyte...This information should also be recorded in a permanent record. Labels should be affixed to the containers when the mixing process begins.

6.4.2 Additives

When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate should be labeled with the name of the patient, the final concentration of the added electrolyte, the date on which the prescribed concentrate was made, and the name of the person who mixed the additive.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V237

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5 Concentrate distribution:

5.5.1 Materials compatibility

All components used in concentrate distribution systems (including concentrate jugs, storage tanks, and piping) that contact the fluid shall be fabricated from nonreactive materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited.

V238

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.2 System configurations: elevated tanks

Elevated tanks for bicarbonate concentrate distribution should be equipped with conical or bowl-shaped bottoms, tight-fitting lids, a spray mechanism, and high- and low-level alarms. Any air vents should have 0.2 µm hydrophobic vent filters.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V239

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems: weekly disinfection/dwell times/conc

Bicarbonate concentrate delivery systems should be disinfected on a regular basis to ensure that the dialysate routinely achieves the level of bacteriological purity [required by these regulations].

For piped distribution systems, the entire system, including patient station ports, should be purged of bicarbonate concentrate before disinfection. Each patient station port should be opened and flushed with disinfectant and then rinsed; otherwise, it would be a “dead leg” in the system.

Appropriate dwell times and concentrations should be used as recommended by the manufacturer of the concentrate system. If this information is not available, bleach may be used at a dilution of 1:100 and proprietary disinfectants at the concentration recommended by the manufacturer for disinfecting piping systems.

6.5 Concentrate distribution:

The interval between disinfection should not exceed 1 week. If the manufacturer does not supply disinfection procedures, the user must develop and validate a disinfection protocol.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V240

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (Ultraviolet Irradiation)

UV irradiation devices that are used to control bacteria proliferation in the pipes of bicarbonate concentrate distribution systems should 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/cm². The device should be sized for the maximum anticipated flow rate according to the manufacturer's instructions and be equipped with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp should be replaced.

Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output. Disinfection of the bicarbonate concentrate distribution system should continue to be performed routinely.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V241

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (Ozone Disinfection)

When used to disinfect the pipes of a bicarbonate concentrate delivery system, an ozone generator should be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer.

When ozone disinfection systems are used, ambient air should be monitored for ozone as required by the U.S. Occupational Safety and Health Administration (OSHA).

V242

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.5 Concentrate distribution (Initial Bicarbonate Monitoring)

Once a bicarbonate distribution system has been activated, dialysate should be monitored weekly until sufficient data has been obtained to demonstrate consistent compliance with acceptable levels of contamination. The frequency of monitoring may then be reduced, but monitoring should be performed at least monthly. If elevated bacteria or endotoxin levels are found in the dialysate, all systems involved in dialysate preparation, including the bicarbonate concentrate distribution system should be evaluated and appropriate action, such as disinfection, should be taken. The frequency of monitoring should then be increased until it can be demonstrated that the problem has been resolved.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V243

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.5 Concentrate distribution (Bicarbonate Jugs – Rinsing)

Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V244

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (disinfection of bicarbonate jugs)

6.5 Concentrate distribution

7 Strategies for bacterial control

7.1 General

5.5.4 Bicarbonate concentrate distribution systems (disinfection of bicarbonate jugs)
When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be rinsed free of residual concentrate before disinfection.

6.5 Concentrate distribution

When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be disinfected at least weekly.

7 Strategies for bacterial control

7.1 General

Following disinfection, jugs should be drained, rinsed, and inverted to dry.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V245

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.3 Acid concentrate distribution systems (labeling)

Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection).

All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary.

More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V246

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (color-coded)

Bicarbonate concentrate delivery piping should be color-coded blue at the point of use (at the jug filling station or dialysis machine connection). All joints should be sealed to prevent leakage of concentrate.

V247

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.5 Concentrate outlets (designated outlets and labeling)

6.5 Concentrate distribution

5.5.5 Concentrate outlets: separate/labeled/connection safety

To prevent mix-ups with delivery of two or more types of acid concentrate, each concentrate should have its own outlet. Concentrate outlets should be compatible with the dialysis machine and have a means of minimizing the risk that the wrong concentrate will be connected to an outlet. The dispensing outlets should be labeled with the appropriate symbol (see AAMI Table 3) indicating the proportioning ratio for the dialysis machine and should be color-coded blue for bicarbonate, red for acid.

6.5 Concentrate distribution

A daily check to ensure that the appropriate acid and bicarbonate concentrate is connected to the corresponding concentrate delivery line is recommended if the storage tank is not permanently connected to its distribution piping.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V248

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.6 Dialysate proportioning

The acid and bicarbonate concentrates [must] be matched with respect to the proportioning ratio and with the model and setup configuration of the dialysis machine.

Several types of three-stream concentrates are available, with different ratios of acid concentrate to bicarbonate concentrate to water (see Table 3). The different proportioning types are not compatible with one another.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V249

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.6 Dialysate proportioning (dialysis machine recalibration)

6.6 Dialysate proportioning

5.6 Dialysate proportioning (dialysis machine recalibration)

Changing from one proportioning ratio to another requires recalibration for some models of dialysis machines. For those machines, the type of concentrate should be labeled on the machine or clearly indicated by the machine display. It is strongly recommended that facilities configure every machine to use only one type of concentrate.

6.6 Dialysate proportioning

Dialysate proportioning should be monitored following the procedures specified by the equipment manufacturer. The user should maintain a record of critical parameters such as conductivity and approximate pH. When the user has specific requirements for monitoring dialysate proportioning, such as when dialysis machine settings are changed to allow the use of concentrates with a different proportioning ratio, the user should develop procedures for routine monitoring of dialysate electrolyte values.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V250

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.6 Dialysate proportioning (dialysate conductivity and pH measurement)

It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6 Monitoring

6.1 General

Quality control and quality assurance procedures should be established to ensure ongoing conformance to policies and procedures regarding dialysate quality. This clause defines some of the monitoring activities to be conducted at the dialysis facility as part of the quality assurance process. The test methods described in [AAMI] 6.2 do not represent the only acceptable methods available, but are intended to provide examples of acceptable methods. The frequency of monitoring is generally recommended by the equipment manufacturer. Table 4 can be used as a guideline for setting up a quality assurance monitoring program in the absence of a manufacturer's recommendations or to supplement those recommendations.

Interpretive Guidance §494.40(a)

This is an informational tag. Expected monitoring is listed under each water system and dialysate component; there may be some variation from this Table based on specific equipment in use.

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6 Monitoring

6.1 General

Table 4—Monitoring guidelines for water purification equipment and distribution systems and dialysate

NOTE—Refer to footnote for an explanation of the use of Xs in the Specification column.

<i>Item to monitor</i>	<i>What to monitor</i>	<i>Special interval</i>	<i>Normal interval</i>	<i>Specification</i>
<i>Sediment filter</i>	<i>Pressure drop across the filter</i>	<i>NA</i>	<i>Daily</i>	<i>Pressure drop less than XXXX</i>
<i>Sediment filter backwashing cycle</i>	<i>Backwash cycle timer setting</i>	<i>NA</i>	<i>Daily—beginning of the day</i>	<i>Backwash clock set to XX:XX</i>
<i>Cartridge filter</i>	<i>Pressure drop across the filter</i>	<i>NA</i>	<i>Daily</i>	<i>Pressure drop less than XXXX</i>
<i>Water softener</i>	<i>Product water softness</i>	<i>NA</i>	<i>Daily—end of the day</i>	<i>Hardness as calcium carbonate less than 1 grain/gal, unless otherwise specified by the manufacturer of the reverse osmosis equipment</i>
<i>Water softener brine tank</i>	<i>Level of undissolved salt in tank</i>	<i>NA</i>	<i>Daily—end of the day</i>	<i>Salt level at XXX</i>
<i>Water softener regeneration cycle</i>	<i>Regeneration cycle timer setting</i>	<i>NA</i>	<i>Daily—beginning of the day</i>	<i>Softener timer set to XX:XX</i>
<i>Carbon adsorption beds</i>	<i>Product water free chlorine and/or total chlorine between the beds</i>	<i>NA</i>	<i>Prior to beginning each patient shift</i>	<i>< 0.1 mg/L of total chlorine</i>
<i>Chemical injection system</i>	<i>Level of chemical in the reservoir, injector function, value of the controlling parameter (e.g., pH)</i>	<i>NA</i>	<i>Daily</i>	<i>Chemical level in reservoir \geq XXX; controlling parameter in range XX–XX</i>
<i>Reverse osmosis</i>	<i>Product water conductivity, total dissolved solids (TDS), or resistivity and calculated rejection</i>	<i>NA</i>	<i>According to the manufacturer's recommendations (continuous monitors)</i>	<i>Rejection \geq XX%</i>
<i>Reverse osmosis</i>	<i>Product and reject flow rates, and calculated recovery</i>	<i>NA</i>	<i>Daily (continuous monitors)</i>	<i>Product water flow rate > X.X gpm; recovery in the range XX–XX %</i>
<i>Deionizers</i>	<i>Product water resistivity</i>	<i>NA</i>	<i>Continuous</i>	<i>Resistivity > 1 megohm-cm</i>
<i>Ultrafilters</i>	<i>Pressure drop across the filter</i>	<i>NA</i>	<i>Daily</i>	<i>Pressure drop less than XXXX</i>
<i>Water storage tanks</i>	<i>Bacterial growth and pyrogens</i>	<i>Weekly, until a pattern of consistent compliance with limits can be demonstrated</i>	<i>NA</i>	<i>Bacterial count \leq 50 CFU/mL; endotoxin \leq 1 EU/mL</i>
<i>Water distribution piping system</i>	<i>Bacterial growth and pyrogens</i>	<i>Weekly, until a pattern of consistent</i>	<i>Monthly</i>	<i>Bacterial count \leq 50 CFU/mL; endotoxin \leq 1 EU/mL</i>

<i>Item to monitor</i>	<i>What to monitor</i>	<i>Special interval</i>	<i>Normal interval</i>	<i>Specification</i>
		<i>compliance with limits can be demonstrated</i>		
<i>UV light sources</i>	<i>Energy output</i>	<i>NA</i>	<i>Monthly</i>	<i>Light output > XXX</i>
<i>Ozone generators</i>	<i>Concentration in the water</i>	<i>NA</i>	<i>During each disinfection</i>	<i>Ozone concentration > XXX</i>
<i>Hot water disinfection systems</i>	<i>Temperature and time of exposure of the system to hot water</i>	<i>NA</i>	<i>During each disinfection</i>	<i>Temperature not less than XX °C; minimum exposure time at temperature ≥ XX minutes</i>
<i>Dialysate</i>	<i>Bacterial growth and endotoxin in the dialysate</i>	<i>NA</i>	<i>Monthly, rotated among machines so that at least two machines are tested each month and so that each machine is tested at least once per year</i>	<i>Bacterial growth ≤50 CFU/mL; endotoxin ≤ 1 EU/mL</i>
<i>Dialysate</i>	<i>Conductivity and pH</i>	<i>NA</i>	<i>Each treatment</i>	<i>Conductivity within ± 5% of the nominal machine value; pH in the range 6.9–7.6</i>

NOTE: It is not possible to specify universally acceptable operating ranges for each device listed in the table, since some of these values will be system-specific. In those cases (denoted by Xs in the Specification column of the table), the facility should define an acceptable operating range based on manufacturer's instructions or measurements of system performance.

V252

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General

7.2.2 Sample collection

7.2.1 General

Culture water ...weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.

Monitoring can be accomplished by direct plate counts, in conjunction with the measurement of bacterial endotoxin.

7.2.2 Sample collection

Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin-free container. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected. Sample taps should not be disinfected.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V253

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General: Dialysate (dialysate sampling frequency)

Culture ... dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.

Samples of water should be collected from several places to give an indication of the microbial quality of 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.

Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. 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.

7.2.2 Sample collection

Dialysate samples should be collected from a dialysate port of the dialyzer... [or] dialysate sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V254

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General

Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V255

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General (repeat cultures)

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.

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 detected before collecting samples.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V256

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2.3 Heterotrophic plate count (dip samplers)

Dip samplers may be used for bacterial surveillance... in conjunction with a quality assurance program designed to ensure their appropriate use. Elements of the quality assurance program should include staff training in areas such as the correct methods of inoculation, incubation, and interpretation, and verification involving duplicate samples sent to a certified laboratory on at least an annual basis. Plates shall be incubated at 35 °C for 48 hours.

Colonies should be counted using a magnifying device.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V257

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2.3 Heterotrophic plate count

Samples that cannot be cultured within 1 to 2 hours can be refrigerated for up to 24 hours.

Use of a calibrated loop to apply the sample to the agar plate is not permitted.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V258

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2.4 Bacterial endotoxin test

At a minimum, two tubes should be run each time the assay is performed. The first tube contains LAL reagent and the sample to be tested. The second tube contains LAL reagent, a known amount of endotoxin, and the sample to be tested. The second tube acts as a positive control to confirm the absence of any interference that might lead to a false negative result.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V259

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

9 Personnel (policies and procedures)

Policies and procedures that are understandable and accessible are mandatory.

V260

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

9 Personnel (components of the training program)

A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.

Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer.

The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs).

Periodic audits of the operators' compliance with procedures should be performed.

The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

End of ANSI/AAMI RD52:2004 Requirements

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(b) - Standard: chlorine/chloramines.

(1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal.

(2)(i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested;

Interpretive Guidance § 494.40(b)(1) and (2)(i)

Guidance is pending and will be updated in future release.

V270

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

Interpretive Guidance § 494.40(b)(2)(ii)(A)

Guidance is pending and will be updated in future release.

V271

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and

Interpretive Guidance § 494.40(b)(2)(ii)(B)

Guidance is pending and will be updated in future release.

V272

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(C) Immediately notify the medical director; and

Interpretive Guidance § 494.40(b)(2)(ii)(C)

Guidance is pending and will be updated in future release.

V273

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.

Interpretive Guidance § 494.40(b)(2)(ii)(D)

Guidance is pending and will be updated in future release.

V274

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(c) - Corrective action plan. 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.

Interpretive Guidance § 494.40(c)

Guidance is pending and will be updated in future release.

V275

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(d) - Adverse events. 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—

- (1) Obtain blood and dialysate cultures and endotoxin levels;*
- (2) Evaluate the water purification system; and*
- (3) Take corrective action.*

Interpretive Guidance § 494.40(d)

Guidance is pending and will be updated in future release.

V276

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(e) – Standard: In-center use of preconfigured hemodialysis systems. When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system’s FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality...

Interpretive Guidance § 494.40(e)

Guidance is pending and will be updated in future release.

V277

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(e) - Standard: In-center use of preconfigured hemodialysis systems.... The facility must meet all AAMI RD52:2004 requirements for water and dialysate....

Interpretive Guidance § 494.40(e)

Guidance is pending and will be updated in future release.

V278

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.40(e) - Standard: In-center use of preconfigured hemodialysis systems.... Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

Interpretive Guidance § 494.40(e)

Guidance is pending and will be updated in future release.

V300

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50 - Condition: Reuse of hemodialyzers and bloodlines.

Interpretive Guidance § 494.50

Guidance is pending and will be updated in future release.

V301

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(a) – Standard: General requirements for the reuse of hemodialyzers and bloodlines: Certain hemodialyzers and bloodlines–

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

Interpretive Guidance § 494.50(a)(1)

Guidance is pending and will be updated in future release.

No tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(a)(2) [Certain hemodialyzers and bloodlines --] Must be reused only for the same patient; and

Interpretive Guidance § 494.50(a)(2)

This tag is informational. This requirement is addressed in the ANSI/AAMI RD: 47 guideline at V327 and should be cited there.

V303

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(a)(3) - [Certain hemodialyzers and bloodlines --] Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

Interpretive Guidance § 494.50(a)(3)

Guidance is pending and will be updated in future release.

V304

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(b) - Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines: A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in “Reuse of Hemodialyzers,” third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201- 4598.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V305

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

4 Records

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 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V306

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

4.1 Dialyzer reprocessing manual

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 the dialyzer reprocessing manual. The dialyzer manufacturer's labeling should be consulted to determine if a specific dialyzer requires special considerations.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V307

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

5 Personnel qualifications and training

5.1 Qualifications

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. Education shall be geared to meet the needs of this wide range of personnel.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V308

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

5.2 Training

5.2.1 Curriculum

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:

- a. the facility's specific reprocessing procedure, including a rationale for each step;*
- b. basic documentation requirements of the program;*
- c. the operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components;*
- d. microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infectious hazards;*
- e. the risks and hazards of multiple use of hemodialyzers;*
- f. the consequences of not performing tasks properly;*

- 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;*
- h. the use and location of protective eyewear, respirators, masks, and special clothing;*
- i. emergency procedures as required by the facility; and*
- j. the principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on these characteristics.*

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V309

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

5.2.2 Documentation

Each person performing procedures for the multiple use of dialyzers shall have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area covered by his or her training. Successful completion of training shall 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V310

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 (b)(1):

4 Records

4.4 Personnel health monitoring records

A file must be kept of the results of medical examinations of personnel that are required by OSHA or other regulatory agencies.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V311

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 (b)(1):

6 Patient considerations

6.1 Medical issues

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. 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 have shown sensitivity to materials used in the reprocessing of hemodialyzers.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V312

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

6.2 Informed consent

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V313

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7 Equipment

Each piece of equipment used for reprocessing shall be appropriately designed, constructed, and tested to perform its intended task. 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V314

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.1 Water systems

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 these regulations].

Water bacteriology monitoring shall be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.

11.4 Germicide

11.4.1.5 Water quality monitoring

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 these

regulations] 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 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 required levels.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V315

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2 Reprocessing systems

7.2.1 Utility requirements

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 for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V316

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2.3 Maintenance (written procedures for maintenance)

4 Records

4.3 Equipment maintenance record

7.2.3 Maintenance

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.

4 Records

4.3 Equipment maintenance record

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.

4 Records

A place should be provided for the signature or other unique mark of identification of the person...performing preventative maintenance procedures.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V317

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2.4 Repairs

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 equipment and, if appropriate, after repairs of manual equipment before either the dialyzer is reprocessed or the reprocessed dialyzer is used for clinical dialysis.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V318

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 (b)(1):

8 Physical plant and environmental safety considerations

8.1 Reprocessing area and ventilation

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 [AAMI] 8.5).

Table 1—OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated

<i>Substance/material</i>	<i>Limits (PEL)^a</i>
<i>Acetic acid</i>	<i>10 ppm TWA^b</i>
<i>Chlorine dioxide (syn: chlorine oxide)</i>	<i>0.1 ppm TWA</i>
<i>Citric acid</i>	<i>None developed</i>
<i>Formaldehyde</i>	<i>0.75 ppm TWA 2 ppm STEL^c (15 min) 0.5 ppm action level</i>
<i>Glutaraldehyde</i>	<i>0.2 ppm ceiling NIOSH/OSHA</i>
<i>Hydrogen peroxide</i>	<i>1 ppm TWA</i>
<i>Peracetic acid</i>	<i>None developed</i>
<i>Phenol</i>	<i>5 ppm TWA</i>

ppm = parts per million

^a) PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs.

^b) TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period.

^c) STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V319

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

8.5 Environmental safety

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 [NIOSH]/OSHA, 1980; Sax, 1979; material safety data sheets [MSDS]).

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V320

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

8.4 Personnel protection: gear

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V321

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

8.2 Storage area

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V322

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

9 *Reprocessing supplies*

9.1 *Specifications and testing*

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.

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V323

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

9.2 *Inventory control*

Reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V324

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 b)(1):

7.2.2 Process control testing: methods established

7.2.2.1 Dialyzer test methods

Dialyzer test methods ([AAMI] 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V325

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2.2 Process control testing: concentration of germicide

7.2.2.2

The test for the concentration of germicide or chemical shall be established before clinical use of the reprocessed dialyzers ([AAMI] 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. If

chemicals are used to enhance heat disinfection, both a presence test and a verification of time and temperature shall be performed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V326

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

4 Records

4.2 Reprocessing record: complete/available to patient

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V327

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10 Hemodialyzer labeling

Each reprocessed hemodialyzer shall be used for only one patient. 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V328

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10.1 Time of labeling

Each hemodialyzer shall be labeled before or at the first use of the device, and the label shall be updated after each use (see AAMI 10.3).

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V329

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10.2 Label composition

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V330

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10.3 Information recorded on label/similar name warning

The dialyzer shall be labeled with the 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 [AAMI] 4.2) 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V331

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11 Reprocessing

11.1 Transportation and handling

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 described in this recommended practice shall be validated and documented by the responsible party.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V332

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.2 Rinsing/cleaning

11.2.1

When pre-cleaning is done, it is part of the reprocessing procedures.

All applicable requirements for design and maintenance of equipment included in this document should be adhered to for pre-cleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should be adhered to.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V333

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.2 Rinsing/cleaning

11.2.3

Pre-cleaning the dialyzer (rinsing and cleaning) shall be done with a fluid or fluids made with water that meets the requirements of these regulations related to allowable bacterial and endotoxin levels.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V334

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1.2 Dialyzer header cleaning and disinfection

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.

If the header cap is removed to clean the header space, cleaning shall be done with water meeting the requirements of these regulations related to allowable bacterial and endotoxin levels.

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. If any cracking of the header occurs, the process should be evaluated.

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 these regulations.

If automated equipment is used, the manufacturer's instruction for use shall be followed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V335

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

*11.2 Rinsing/cleaning: chemicals used/rinse after each
11.2.4*

Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid, 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.

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V336

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.3 Performance measurements

11.3.1 Performance test after each use

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V337

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.3.3 Blood path integrity test

A membrane integrity test such as an air pressure leak test shall be done between uses.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V338

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4 Germicide

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V339

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1 Interior (blood/dialysate compartment)

11.4.1.1 Germicidal process

Chemical germicides or other procedures used for disinfecting of hemodialyzers have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms.

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 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.

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 AAMI 12.4). To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite and formaldehyde.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V340

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1.4 Chemical germicidal procedure

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V341

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1.6 Chemical germicide concentration

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 ... the solution [should] be thoroughly mixed.

Interpretive Guidance 494.50(b)(1)

Guidance is pending and will be updated in future release.

V342

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.2 Exterior: low-level disinfection

The outside of the dialyzer should be soaked or wiped clean of visible blood and other foreign material. For chemically disinfected dialyzers, a low-level germicide that is

compatible with the dialyzer's materials of construction should be used for this purpose.

Interpretive Guidance 494.50(b)(1)

Guidance is pending and will be updated in future release.

V343

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.5 Inspection: after reprocessing

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.

11.5.1

The dialyzer jacket should be free of visible blood or other foreign material.

11.5.2

There shall be no leaks or cracks in the dialyzer jacket or the blood or dialysate ports.

11.5.3

No more than a few dark, clotted fibers should be evident on inspection of the exterior of the hollow fibers.

11.5.4

The headers of hollow-fiber dialyzers should be free of all but small peripheral clots or other deposits.

11.5.5

Blood and dialysate ports shall be capped without evidence of leakage.

11.5.6

The label shall be properly filled out and legible.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V344

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.6 Disposition of rejected dialyzers

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 [AAMI] 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V345

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.7 Storage

Reprocessed dialyzers that meet the performance and inspection criteria for multiple use should be stored according to the provisions of [AAMI] 8.2. Prolonged storage (greater than 1 month) should be documented to be safe and effective.

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V346

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues

A written procedure that has been shown to be effective shall be followed.

12.5 Written procedure for tests for germicide or other residues

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V347

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.1 Visual inspection (dialyzer inspection prior to use)

The dialyzer should be inspected before it is prepared for use. Completion of this inspection should be recorded in the reprocessing record (see [AAMI] 4.2), along with the signature or other unique means of identifying the person completing the inspection. The inspection should include the following:

- a. The reprocessed dialyzer shall be legibly labeled with the information recommended in [AAMI] 10.3.*
- b. There should be no indication of structural damage or tampering with the dialyzer.*
- c. The ports of the dialyzer should be properly capped.*
- 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.*
- e. The duration and conditions of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer; and*

f. The cosmetic appearance of the dialyzer should be aesthetically acceptable to the staff and the patient.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V348

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.2 Verification of patient identification

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.

NOTE—This step may be done later in the procedure but shall precede initiation of dialysis.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V349

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.3 Verification of germicidal contact

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V350

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.3.1 Presence test of each hemodialyzer

Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V351

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.3.2 Process control and sampling (testing for presence of germicide)

[If a germicide manufacturer does not require testing each hemodialyzer for the presence of germicide], the presence of germicide may be ensured by [either] a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide.

12.3.2.1 Process control

- a. Use hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process; or*
- b. Use an indicator substance (e.g., FD&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.*

12.3.2.2 Sampling for process validation

- 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 should be taken immediately after the dialyzers have been reprocessed.***
- 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.***
- c. Sampling and testing are to be accomplished before patients use any hemodialyzers processed on this shift.***

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V352

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.4 Priming the dialyzer and rinsing the germicide

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V353

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.4.1 Testing for residual germicide

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. 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. The priming, removal, and residual testing process should be reinstated 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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V354

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13 Monitoring

13.1 Dialysis

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. Applicable home dialysis patients and their assistants should be instructed in the appropriate observation, recording requirements, and reporting procedures.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V355

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.2 Symptoms

13.2.1 Fever and chills

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 100° F, taken orally, or chills should be reported to the physician, [advanced practice registered nurse or physician assistant]. Any patient with an unexplained fever and/or chills should be evaluated for the possibility of a pre-existing infection (e.g., [at an] 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.

13.2.2 Other symptoms

Other unexplained symptoms such as pain in the blood- access arm at the onset of dialysis should be evaluated by the physician, [advanced practice registered nurse or physician assistant] 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 treatment equipment.

Suspected reactions to the residual germicide should prompt reevaluation of the rinsing procedure and a test for residual germicide (see [AAMI] 12.4.1).

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V356

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.2.3 Recording

Any significant events such as the occurrence of symptoms listed in [AAMI] 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 [AAMI] 4.5).

4 Records

4.5 Complaint investigation record

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 shall be reviewed periodically for trends of adverse reactions. Compliance with the FDA's Medical Device User Reporting procedures shall be demonstrated.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release

V357

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.3 Dialyzer failures (blood leaks)

Dialyzer blood leaks should be recorded in a log kept in the complaint investigation record file (see [AAMI] 4.5). If there is excessive deviation from the expected performance, testing should be repeated (see [AAMI] 11.3.1) and appropriate adjustments made in the reprocessing procedure.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V358

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.4 Clinical results (monitoring patient results; Kt/V)

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release

V359

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11 Reprocessing

11.3.2 Ultrafiltration

If the expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release

V360

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14 Quality assurance (internal standards and clinical outcomes)

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 practices including reuse. Final oversight is the responsibility of the medical director. See Table 2 for a summary of the audit schedule.

14.1 Records

A record of review, comments, trend analysis, and conclusions arising from QA practices serve as a foundation for future review and as documentation to external evaluation.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V361

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.2 Schedule of quality assurance activities

Problems in a particular aspect of operations should be reviewed and tracked until a solution is in place and demonstrated to be effective. The medical director is responsible for scheduling review, endorsing findings, and, when appropriate, implementing changes.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V362

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.3 Patient considerations

Personnel should audit at least annually compliance with the facility's policy to inform patients of the facility's reuse practices.

V363

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.4 Equipment Manuals and Procedures

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V364

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.5 Physical plant and environmental safety considerations (audit frequency)

Designated staff members should audit the provisions of [AAMI] 8.1, [Reprocessing area and ventilation], at least annually. The provisions of [AAMI] 8.2, [Storage area], and [AAMI] 8.4, [Personnel protection] should be audited quarterly.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V365

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.6 Reprocessing supplies (audit frequency)

Designated staff members should audit the provisions of [AAMI] section 9[: Reprocessing supplies: Specifications and testing, and inventory control] at least semiannually.

V366

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.7 Hemodialyzer labeling (audit frequency)

Designated staff members should audit the provisions of [AAMI] section 10.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V367

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.8 Reprocessing (audit frequency)

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.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V368

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.9 Preparation for dialysis (audit frequency)

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.

End ANSI/AAMI RD:47:2002/A1:2003 Requirements

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V378

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(b) Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines. A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(2) Reprocess hemodialyzers and bloodlines –

(i) By following manufacturer’s recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

Interpretive Guidance § 494.50(b)(2)

Guidance is pending and will be updated in future release.

V379

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(b) Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines. A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.

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:

(1) Monitor patient reactions during and following dialysis.

Interpretive Guidance § 494.50(c)(1)

This tag is informational, as this requirement is addressed in the ANSI/AAMI RD:47:2002, section 13, at tags V354 and V355.

V381

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.

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:

(2) When clinically indicated (for example, after adverse patient reactions), the facility must –

(i) Obtain blood and dialysate cultures and endotoxin levels; and

Interpretive Guidance § 494.50(c)(2)(i)

Guidance is pending and will be updated in future release.

V382

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(c)(2) When clinically indicated (for example, after adverse patient reactions), the facility must –

(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.

Interpretive Guidance § 494.50(c)(2)(ii)

Guidance is pending and will be updated in future release.

V383

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.50(c)(2) When clinically indicated (for example, after adverse patient reactions), the facility must –

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

Interpretive Guidance § 494.50(c)(2)(iii)

Guidance is pending and will be updated in future release.

V400

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.60 Condition: Physical environment

Interpretive Guidance §494.60

Guidance is pending and will be updated in future release.

V401

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.60 Condition: Physical environment.

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.

Interpretive Guidance §494.60

Guidance is pending and will be updated in future release.

V402

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.60 (a) Standard: Building. 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.

Interpretive Guidance §494.60(a)

Guidance is pending and will be updated in future release.

V403

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.60(b) Standard: Equipment maintenance. 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.

Interpretive Guidance §494.60(b)

Guidance is pending and will be updated in future release.

V404

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60 (c) Standard: Patient care environment.

(1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

Interpretive Guidance §494.60(c)(1)

Guidance is pending and will be updated in future release.

V405

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(c)(2) - The dialysis facility must:

(i) Maintain a comfortable temperature within the facility; and

(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

Interpretive Guidance §494.60(c)(2)

Guidance is pending and will be updated in future release.

V406

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(c)(3) - The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

Interpretive Guidance § 494.60(c)(3)

Guidance is pending and will be updated in future release.

V407

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(c)(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).

Interpretive Guidance §494.60(c)(4)

Guidance is pending and will be updated in future release.

V417

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(d) - Standard: Fire safety. (1) Except as provided in paragraph (d)(2) of this section, dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level, must comply with provisions of the Life Safety Code (NFPA 101 and its Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4) applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

Interpretive Guidance § 494.60(d)(1)

Guidance is pending and will be updated in future release.

V418

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(d)(2) - Notwithstanding paragraph (d)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), III(200), or V(000), as defined in the Life Safety Code, section 21.1.6.1, which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.

Interpretive Guidance §494.60(d)(2)

Guidance is pending and will be updated in future release.

V419

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(d)(3) - If CMS finds that a fire and safety code imposed by the facility's State law 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.

Interpretive Guidance § 494.60(d)(3)

Guidance is pending and will be updated in future release.

V420

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§494.60(d)(4) – In consideration of a recommendation by the State survey agency or at the discretion of the Secretary, the Secretary may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ESRD facility, but only if the waiver will not adversely affect the health and safety of the patients.

Interpretive Guidance § 494.60(d)(4)

Guidance is pending and will be updated in future release.

V421

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(d)(5) – No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in sections 20.1.3.7 and 21.1.3.7 of the Health Care Facilities Code (NFPA 99 and its Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6).

Interpretive Guidance § 494.60(d)(5)

Guidance is pending and will be updated in future release.

V422

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(e) - Standard: Building Safety. (1) Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must meet the applicable provisions of the Health Care Facilities Code, regardless of the number of patients served.

Interpretive Guidance §494.60(e)

Guidance is pending and will be updated in future release.

No tag

§ 494.60(e)(2) – Chapters 7,8,12, and 13 of the Health Care Facilities Code do not apply to a dialysis facility.

V423

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60(e)(3) – If application of the Health Care Facilities Code would result in unreasonable hardship for the dialysis facility, CMS may waive specific provisions of the Health Care Facilities Code for such facility, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidance §494.60(e)(3)

Guidance is pending and will be updated in future release.

V424

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.60 (f): Incorporation by reference. – The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: www.archives.gov/federal_register/cfr/ibr-locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1-617-770-3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

Interpretive Guidance §494.60(f)

Guidance is pending and will be updated in future release.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Refer to all applicable E-Tags

§ 494.62 Condition of participation: Emergency preparedness.

Interpretive Guidance § 494.62

For all applicable requirements under Emergency Preparedness, please refer to Appendix Z of the State Operations Manual. ESRD Facilities must also comply with the requirements outlined in Appendix Z.

Subpart C – Patient Care

V450

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70 Condition: Patients' rights.

Interpretive Guidance §494.70

Guidance is pending and will be updated in future release.

V451

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70 - 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.

Interpretive Guidance § 494.70

Guidance is pending and will be updated in future release.

V452

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

*§ 494.70(a) - Standard: Patients' rights. The patient has the right to— (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;
Interpretive Guidance §494.70(a)(1)*

Guidance is pending and will be updated in future release.

V453

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(2) - Receive all information in a way that he or she can understand;

Interpretive Guidance §494.70(a)(2)

Guidance is pending and will be updated in future release.

V454

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(3) - Privacy and confidentiality in all aspects of treatment;

Interpretive Guidance §494.70(a)(3)

Guidance is pending and will be updated in future release.

V455

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(4) - Privacy and confidentiality in personal medical records;

Interpretive Guidance §494.70(a)(4)

Guidance is pending and will be updated in future release.

V456

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(5) - Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

Interpretive Guidance §494.70(a)(5)

Guidance is pending and will be updated in future release.

V457

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(6) - Be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives;

Interpretive Guidance §494.70(a)(6)

Guidance is pending and will be updated in future release.

V458

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(7) - 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. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;

Interpretive Guidance §494.70(a)(7)

Guidance is pending and will be updated in future release.

V459

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(8) - Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

Interpretive Guidance §494.70(a)(8)

Guidance is pending and will be updated in future release.

V460

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(9) - Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

Interpretive Guidance §494.70(a)(9)

Guidance is pending and will be updated in future release.

V461

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(10) - Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

Interpretive Guidance §494.70(a)(10)

Guidance is pending and will be updated in future release.

V462

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(11) - Be informed of services available in the facility and charges for services not covered under Medicare;

Interpretive Guidance §494.70 (a)(11)

Guidance is pending and will be updated in future release.

V463

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(12) - Receive the necessary services outlined in the patient plan of care described in § 494.90;

Interpretive Guidance §494.70 (a)(12)

Guidance is pending and will be updated in future release.

V464

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(13) - Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

Interpretive Guidance §494.70 (a)(13)

Guidance is pending and will be updated in future release.

V465

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(14) - Be informed of the facility's internal grievance process;

Interpretive Guidance §494.70 (a)(14)

Guidance is pending and will be updated in future release.

V466

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(15) - Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

Interpretive Guidance §494.70 (a)(15)

Guidance is pending and will be updated in future release.

V467

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.70(a)(16) - Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and (17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

Interpretive Guidance §494.70 (a)(16) and (17)

Guidance is pending and will be updated in future release.

V468

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

***§ 494.70(b) - Standard: Right to be informed regarding the facility's discharge and transfer policies. The patient has the right to –
(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and***

Interpretive Guidance §494.70(b)(1)

Guidance is pending and will be updated in future release.

V469

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in § 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.

Interpretive Guidance §494.70(b)(2)

Guidance is pending and will be updated in future release.

V470

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Posting of rights. The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

Interpretive Guidance §494.70(c)

Guidance is pending and will be updated in future release.

V500

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.80 Condition: Patient assessment.

Interpretive Guidance § 494.80

Guidance is pending and will be updated in future release.

V501

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The facility's interdisciplinary team, consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team 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.

Interpretive Guidance §494.80

Guidance is pending and will be updated in future release.

V502

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions.

Interpretive Guidance §494.80 (a)(1)

Guidance is pending and will be updated in future release.

V503

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Evaluation of the appropriateness of the dialysis prescription,

Interpretive Guidance §494.80 (a)(2)

Guidance is pending and will be updated in future release.

V504

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Blood pressure, and fluid management needs.

Interpretive Guidance §494.80

Guidance is pending and will be updated in future release.

V505

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) Laboratory profile,

Interpretive Guidance §494.80(a)(3)

Guidance is pending and will be updated in future release.

V506

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Immunization history, and medication history.

Interpretive Guidance §494.80

Guidance is pending and will be updated in future release.

V507

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).

Interpretive Guidance §494.80 (a)(4)

Guidance is pending and will be updated in future release.

V508

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(5) Evaluation of factors associated with renal bone disease.

Interpretive Guidance §494.80(a)(5)

Guidance is pending and will be updated in future release.

V509

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(6) Evaluation of nutritional status by a dietitian.

Interpretive Guidance §494.80 (a)(6):

Guidance is pending and will be updated in future release.

V510

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(7) Evaluation of psychosocial needs by a social worker.

Interpretive Guidance §494.80(a)(7):

Guidance is pending and will be updated in future release.

V511

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters).

Interpretive Guidance §494.80(a)(8)

Guidance is pending and will be updated in future release.

V512

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes.

Interpretive Guidance §494.80(a)(9)

Guidance is pending and will be updated in future release.

V513

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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 for non-referral must be documented in the patient's medical record.

Interpretive Guidance §494.80(a)(10)

Guidance is pending and will be updated in future release.

V514

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(11) Evaluation of family and other support systems.

Interpretive Guidance §494.80(a)(11)

Guidance is pending and will be updated in future release.

V515

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(12) Evaluation of current patient physical activity level.
(13) Evaluation for referral to vocational and physical rehabilitation services.

Interpretive Guidance §494.80(a)(12)(13)

Guidance is pending and will be updated in future release.

V516

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Frequency of assessment for patients admitted to the dialysis facility. (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.

Interpretive Guidance §494.80(b)(1)

Guidance is pending and will be updated in future release.

V517

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) A follow up 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.

Interpretive Guidance §494.80(b)(2)

Guidance is pending and will be updated in future release.

V518

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Assessment of treatment prescription. The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1), must be assessed on an ongoing basis as follows:

(1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

Interpretive Guidance §494.80(c)(1)(2)

Guidance is pending and will be updated in future release.

V519

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(d) Standard: Patient reassessment. 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— (1) At least annually for stable patients; and

Interpretive Guidance §494.80(d)

Guidance is pending and will be updated in future release.

V520

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.

Interpretive Guidance §494.80(d)(2)(i)(ii)(iii)(iv)

Guidance is pending and will be updated in future release.

V540

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.90 Condition: Patient plan of care.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V541

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The interdisciplinary team as defined at § 494.80 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 must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence based professionally-accepted clinical practice standards.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V542

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient.

Interpretive Guidance § 494.90(a)

Guidance is pending and will be updated in future release.

V543

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and

Interpretive Guidance § 494.90 (a)(1)

Guidance is pending and will be updated in future release.

V544

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V545

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Nutritional status. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

Interpretive Guidance § 494.90(a)(2)

Guidance is pending and will be updated in future release.

V546

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

Interpretive Guidance § 494.90(a)(3)

Guidance is pending and will be updated in future release.

V547

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.

Interpretive Guidance § 494.90(a)(4)

Guidance is pending and will be updated in future release.

V548

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V549

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V550

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(5) Vascular access. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type,

taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.

Interpretive Guidance § 494.90 (a) (5)

Guidance is pending and will be updated in future release.

V551

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V552

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

Interpretive Guidance § 494.90 (a)(6):

Guidance is pending and will be updated in future release.

V553

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

Interpretive Guidance § 494.90 (a)(7)(i):

Guidance is pending and will be updated in future release.

V554

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the–
(A) Plan for transplantation, if the patient accepts the transplantation referral;
(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or
(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10).

Interpretive Guidance § 494.90 (a)(7)(ii)

Guidance is pending and will be updated in future release.

V555

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.

Interpretive Guidance § 494.90 (a)(8):

Guidance is pending and will be updated in future release.

V556

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Implementation of the patient plan of care.

(1) The patient's plan of care must–

(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and

(ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.

Interpretive Guidance § 494.90 (b)(1)(i)(ii)

Guidance is pending and will be updated in future release.

V557

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

Interpretive Guidance § 494.90 (b)(2)

Guidance is pending and will be updated in future release.

V558

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).

Interpretive Guidance § 494.90:

Guidance is pending and will be updated in future release.

V559

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must—

(i) Adjust the plan of care to reflect the patient's current condition;

(ii) Document in the record the reasons why the patient was unable to achieve the goals; and

(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

Interpretive Guidance § 494.90 (b)(3)(i)(ii)(iii)

Guidance is pending and will be updated in future release.

V560

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing 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.

Interpretive Guidance § 494.90 (b)(4):

Guidance is pending and will be updated in future release.

V561

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Transplantation referral tracking. The interdisciplinary team must—
(1) Track the results of each kidney transplant center referral;
(2) Monitor the status of any facility patients who are on the transplant wait list; and
(3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.

Interpretive Guidance § 494.90 (c)(1)(2)(3)

Guidance is pending and will be updated in future release.

V562

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(d) Standard: Patient education and training. 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, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

Interpretive Guidance § 494.90 (d)

Guidance is pending and will be updated in future release.

V580

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.100 Condition: Care at home.

Interpretive Guidance § 494.100:

Guidance is pending and will be updated in future release.

V581

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

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 and meet all applicable conditions of this part.

Interpretive Guidance § 494.100:

Guidance is pending and will be updated in future release.

V582

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Training. The interdisciplinary team must oversee training of 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) and when the home dialysis caregiver or home dialysis modality changes.

Interpretive Guidance § 494.100 (a):

Guidance is pending and will be updated in future release.

V583

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The training must— (1) Be provided by a dialysis facility that is approved to provide home dialysis services;

Interpretive Guidance §494.100 (a)(1):

Guidance is pending and will be updated in future release.

V584

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and

Interpretive Guidance § 494.100 (a)(2):

Guidance is pending and will be updated in future release.

V585

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD.

(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of

erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.

(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.

(iv) Availability of support resources and how to access and use resources.

(v) How to self-monitor health status and record and report health status information.

(vi) How to handle medical and non-medical emergencies.

(vii) Infection control precautions.

(viii) Proper waste storage and disposal procedures.

Interpretive Guidance § 494.100 (a)(3)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii):

Guidance is pending and will be updated in future release.

V586

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Home dialysis monitoring. The dialysis facility must – (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

Interpretive Guidance § 494.100 (b)(1):

Guidance is pending and will be updated in future release.

V587

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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

(3) Maintain this information in the patient's medical record.

Interpretive Guidance § 494.100 (b)(2)(3):

Guidance is pending and will be updated in future release.

V588

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Support services. (1) A home dialysis training facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company.

Interpretive Guidance § 494.100 (c)(1):

Guidance is pending and will be updated in future release.

V589

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Services include, but are not limited to, the following: (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.

Interpretive Guidance § 494.100 (c)(1)(i):

Guidance is pending and will be updated in future release.

V590

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

Interpretive Guidance § 494.100 (c)(1)(ii):

Guidance is pending and will be updated in future release.

V591

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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 meets the measurable and expected outcomes as specified in § 494.90 of this part.

Interpretive Guidance § 494.100 (c)(1)(iii):

Guidance is pending and will be updated in future release.

V592

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(iv) Patient consultation with members of the interdisciplinary team, as needed.

Interpretive Guidance § 494.100 (c)(1)(iv):

Guidance is pending and will be updated in future release.

V593

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and

Interpretive Guidance § 494.100 (c)(1)(v):

Guidance is pending and will be updated in future release.

V594

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

testing of the water and dialysate system in accordance with—

*(A) The recommendations specified in the manufacturers' instructions; and
(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate.*

Interpretive Guidance § 494.100 (c)(1)(v)(A)(B):

Guidance is pending and will be updated in future release.

V595

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

Interpretive Guidance § 494.100 (c)(1)(v)(B):

Guidance is pending and will be updated in future release.

V596

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

*(1) Analysis of the water and dialysate quality indicates contamination; or
(2) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.*

Interpretive Guidance § 494.100 (c)(1)(v)(C)(1)(2):

Guidance is pending and will be updated in future release.

V597

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

Interpretive Guidance § 494.100 (c)(1)(vi):

Guidance is pending and will be updated in future release.

V598

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

Interpretive Guidance § 494.100 (c)(1)(vii):

Guidance is pending and will be updated in future release.

V599

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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 medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

Interpretive Guidance § 494.100 (c)(1)(vii)(2):

Guidance is pending and will be updated in future release.

V625

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.110 Condition: Quality assessment and performance improvement.

Interpretive Guidance § 494.110:

Guidance is pending and will be updated in future release.

V626

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. 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. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.
Interpretive Guidance § 494.110:

Guidance is pending and will be updated in future release.

V627

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Program scope.

(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.

Interpretive Guidance § 494.110 (a)(1):

Guidance is pending and will be updated in future release.

V628

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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 or be the outcomes themselves. The program must include, but not be limited to, the following:

Interpretive Guidance § 494.110 (a)(2):

Guidance is pending and will be updated in future release.

V629

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(i) Adequacy of dialysis.

Interpretive Guidance § 494.110 (a)(2)(i):

Guidance is pending and will be updated in future release.

V630

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(ii) Nutritional status.

Interpretive Guidance § 494.110 (a)(2)(ii):

Guidance is pending and will be updated in future release.

V631

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(iii) Mineral metabolism and renal bone disease.

Interpretive Guidance § 494.110 (a)(2)(iii):

Guidance is pending and will be updated in future release.

V632

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(iv) Anemia management.

Interpretive Guidance § 494.110 (a)(2)(iv):

Guidance is pending and will be updated in future release.

V633

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(v) Vascular access.

Interpretive Guidance § 494.110 (a)(2)(v):

Guidance is pending and will be updated in future release.

V634

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(vi) Medical injuries and medical errors identification.

Interpretive Guidance § 494.110 (a)(2)(vi):

Guidance is pending and will be updated in future release.

V635

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

Interpretive Guidance § 494.110 (a)(2)(vii):

Guidance is pending and will be updated in future release.

V636

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(viii) Patient satisfaction and grievances.

Interpretive Guidance § 494.110 (a)(2)(viii):

Guidance is pending and will be updated in future release.

V637

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(ix) Infection control; with respect to this component the facility must—
(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;
(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and
(C) Take actions to reduce future incidents.

Interpretive Guidance § 494.110 (a)(2)(ix)(A)(B)(C):

Guidance is pending and will be updated in future release.

V638

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Monitoring performance improvement. The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

Interpretive Guidance § 494.110 (b):

Guidance is pending and will be updated in future release.

V639

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Prioritizing improvement activities. 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.

Interpretive Guidance § 494.110 (c):

Guidance is pending and will be updated in future release.

V640

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The facility must immediately correct any identified problems that threaten the health and safety of patients.

Interpretive Guidance § 494.110 (c):

Guidance is pending and will be updated in future release.

V660

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.120 Condition: Special purpose renal dialysis facilities.

Interpretive Guidance § 494.120:

Guidance is pending and will be updated in future release.

V661

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

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.

Interpretive Guidance § 494.120:

Guidance is pending and will be updated in future release.

V662

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Approval period. The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12- month period.

Interpretive Guidance § 494.120 (a):

Guidance is pending and will be updated in future release.

V663

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Service limitation. 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.

Interpretive Guidance § 494.120 (b):

Guidance is pending and will be updated in future release.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Scope of requirements.

(1) Scope of requirements for a vacation camp. 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–

(i) Infection control at § 494.30;

(ii) Water and dialysate quality at § 494.40 (except as provided in paragraph (c)(1)(viii) of this section);

(iii) Reuse of hemodialyzers at § 494.50 (if reuse is performed);

(iv) Patients' rights and posting of patients' rights § 494.70(a) and § 494.70 (c);

(v) Laboratory services at § 494.130;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and (d);

(vii) Medical records at § 494.170; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100 (c)(1)(v) (home monitoring of water quality) in place of § 494.40 (water quality).

Interpretive Guidance § 494.120 (c)(1):

Guidance is pending and will be updated in future release.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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 comply with (c)(1) of this section and in addition to complying with the following conditions:

- (i) Section 494.20 (compliance with Federal, State, and local laws and regulations).**
- (ii) Section 494.60 (physical environment).**
- (iii) Section 494.70(a) through section 494.70(c) (patient rights).**
- (iv) Section 494.140 (personnel qualifications).**
- (v) Section 494.150 (medical director).**
- (vi) Section 494.180 (governance).**

Interpretive Guidance § 494.120 (c)(2):

This is an informational tag. Sections of the regulations listed here are to be used to survey an emergency circumstance SPRDF. If deficient practices are identified, the appropriate tags under the referenced regulations should be used.

An SPRDF set up for an emergency circumstance will be issued a unique CCN. These facilities may only provide care to those patients who would otherwise be unable to obtain treatment in that geographic area, and are limited to an 8-month period of operation.

V666

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(d) Standard: Physician contact. The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90).

Interpretive Guidance § 494.120 (d):

Guidance is pending and will be updated in future release.

V667

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(e) Standard: Documentation. All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

Interpretive Guidance § 494.120 (e):

Guidance is pending and will be updated in future release.

V675

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.130 Condition: Laboratory services.

Interpretive Guidance § 494.130:

Guidance is pending and will be updated in future release.

V676

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. 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.

Interpretive Guidance § 494.130

Guidance is pending and will be updated in future release.

Subpart D- Administration

V680

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.140 Condition: Personnel qualifications.

Interpretive Guidance § 494.140:

Guidance is pending and will be updated in future release.

V681

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. 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.

Interpretive Guidance § 494.130:

Guidance is pending and will be updated in future release.

V682

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Medical director. (1) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12- months of experience providing care to patients receiving dialysis.

Interpretive Guidance § 494.140 (a)(1):

Guidance is pending and will be updated in future release.

V683

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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.

Interpretive Guidance § 494.140 (a)(2):

Guidance is pending and will be updated in future release.

V684

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Nursing services. (1) Nurse manager. The facility must have a nurse manager responsible for nursing services in the facility who must—
(i) Be a full time employee of the facility;
(ii) Be a registered nurse; and
(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.

Interpretive Guidance § 494.140 (b)(1)(i)(ii)(iii):

Guidance is pending and will be updated in future release.

V685

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Self-care and home dialysis training nurse. The nurse responsible for self-care and/or home care training must—

(i) Be a registered nurse; and

(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.

Interpretive Guidance § 494.140 (b)(2)(i)(ii):

Guidance is pending and will be updated in future release.

V686

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) Charge nurse. The charge nurse responsible for each shift must—

(i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

(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; and

Interpretive Guidance § 494.140 (b)(3)(i)(ii):

Guidance is pending and will be updated in future release.

V687

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

Interpretive Guidance § 494.140 (b)(3)(iii):

Guidance is pending and will be updated in future release.

V688

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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.

Interpretive Guidance § 494.140 (b)(4):

Guidance is pending and will be updated in future release.

V689

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Dietitian. The facility must have a dietitian who must— (1) Be a registered dietitian with the Commission on Dietetic Registration; and

Interpretive Guidance § 494.140 (c)(1):

Guidance is pending and will be updated in future release.

V690

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian;

Interpretive Guidance § 494.140 (c)(2):

Guidance is pending and will be updated in future release.

V691

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

*(d) Standard: Social worker. The facility must have a social worker who—
(1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or
(2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140 (d)(1).*

Interpretive Guidance § 494.140 (d)(1)(2):

Guidance is pending and will be updated in future release.

V692

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(e) Standard: Patient care dialysis technicians. Patient care dialysis technicians must—
(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
(2) Have a high school diploma or equivalency;

Interpretive Guidance § 494.140 (e)(1)(2):

Guidance is pending and will be updated in future release.

V693

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, 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 of difficult patients.

Interpretive Guidance § 494.140 (e)(3):

Guidance is pending and will be updated in future release.

V694

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The training program must include the following subjects:

- (i) Principles of dialysis.***
- (ii) Care of patients with kidney failure, including interpersonal skills.***
- (iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.***
- (iv) Possible complications of dialysis.***
- (v) Water treatment and dialysate preparation.***
- (vi) Infection control.***
- (vii) Safety.***
- (viii) Dialyzer reprocessing, if applicable***

Interpretive Guidance § 494.140 (e)(3)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii):

Guidance is pending and will be updated in future release.

V695

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

- (4) Be certified under a State certification program or a national commercially available certification program, as follows—*
- (i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or*
 - (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.*

Interpretive Guidance § 494.140 (e)(4)(i)(ii):

Guidance is pending and will be updated in future release.

V696

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(f) Standard: Water treatment system technicians. 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.

Interpretive Guidance § 494.140 (f):

Guidance is pending and will be updated in future release.

V710

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.150 Condition: Responsibilities of the medical director.

Interpretive Guidance § 494.150:

Guidance is pending and will be updated in future release.

V711

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients.

Interpretive Guidance § 494.150:

Guidance is pending and will be updated in future release.

V712

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.

Interpretive Guidance § 494.150 (a):

Guidance is pending and will be updated in future release.

V713

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Staff education, training, and performance.

Interpretive Guidance § 494.150 (b):

Guidance is pending and will be updated in future release.

V714

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Policies and procedures. The medical director must— (1) Participate in the development, periodic review and approval of a “patient care policies and procedures manual” for the facility; and

Interpretive Guidance § 494.150 (c)(1):

Guidance is pending and will be updated in future release.

V715

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Ensure that— (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

Interpretive Guidance § 494.150 (c)(2)(i):

Guidance is pending and will be updated in future release.

V716

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f).

Interpretive Guidance § 494.150 (c)(2)(ii):

Guidance is pending and will be updated in future release.

V725

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.170 Condition: Medical records.

Interpretive Guidance § 494.170

Guidance is pending and will be updated in future release.

V726

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

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.

Interpretive Guidance § 494.170

Guidance is pending and will be updated in future release.

V727

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Protection of the patient's record. The dialysis facility must—
(1) Safeguard patient records against loss, destruction, or unauthorized use; and
(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:
(i) The transfer of the patient to another facility.
(ii) Certain exceptions provided for in the law.
(iii) Provisions allowed under third party payment contracts.
(iv) Approval by the patient.
(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

Interpretive Guidance § 494.170 (a)(1)(2)(i)(ii)(iii)(iv)(v)

Guidance is pending and will be updated in future release.

V728

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.

Interpretive Guidance § 494.170 (a)(3)

Guidance is pending and will be updated in future release.

V729

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Completion of patient records and centralization of clinical information.

(1) Current medical records and those of discharged patients must be completed promptly.

Interpretive Guidance § 494.170 (b)(1):

Guidance is pending and will be updated in future release.

V730

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. 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.

Interpretive Guidance § 494.170 (b)(2)

Guidance is pending and will be updated in future release.

V731

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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.

Interpretive Guidance § 494.170 (b)(3)

Guidance is pending and will be updated in future release.

V732

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: record retention and preservation. In accordance with 45 CFR § 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer or death.

Interpretive Guidance § 494.170 (c)

Guidance is pending and will be updated in future release.

V733

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(d) Standard: Transfer of patient record information. When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

Interpretive Guidance § 494.170 (d):

Guidance is pending and will be updated in future release.

V750

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 494.180 Condition: Governance.

Interpretive Guidance § 494.180

Guidance is pending and will be updated in future release.

V751

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and 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.

Interpretive Guidance § 494.180:

Guidance is pending and will be updated in future release.

V752

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to–

Interpretive Guidance § 494.180 (a)

Guidance is pending and will be updated in future release.

V753

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(1) Staff appointments;

Interpretive Guidance § 494.180 (a)(1)

Guidance is pending and will be updated in future release.

V754

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) Fiscal operations;

Interpretive Guidance § 494.180 (a)(2)

Guidance is pending and will be updated in future release.

V755

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) The relationship with the ESRD networks; and

Interpretive Guidance § 494.180 (a)(3)

Guidance is pending and will be updated in future release.

V756

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in § 494.110.

Interpretive Guidance § 494.180 (a)(4):

Guidance is pending and will be updated in future release.

V757

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(b) Standard: Adequate number of qualified and trained staff. The governing body or designated person responsible must ensure that— (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; and
Interpretive Guidance § 494.180 (b)(1):

Guidance is pending and will be updated in future release.

V758

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

The registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

Interpretive Guidance § 494.180 (b)(1):

Guidance is pending and will be updated in future release.

V759

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

Interpretive Guidance § 494.180 (b)(2):

Guidance is pending and will be updated in future release.

V760

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and

Interpretive Guidance § 494.180 (b)(3):

Guidance is pending and will be updated in future release.

V761

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) All employees have an opportunity for continuing education and related development activities;

Interpretive Guidance § 494.180 (b)(4):

Guidance is pending and will be updated in future release.

V762

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(c) Standard: Medical staff appointments. The governing body— (1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners and clinical nurse specialists; and

Interpretive Guidance § 494.180 (c)(1):

Guidance is pending and will be updated in future release.

V763

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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.

(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients

Interpretive Guidance § 494.180 (c)(2)(3):

Guidance is pending and will be updated in future release.

V764

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(d) Standard: Furnishing services. The governing body is responsible for ensuring that the dialysis facility furnishes services directly 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).

Interpretive Guidance § 494.180(d)

Guidance is pending and will be updated in future release.

V765

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(e) Standard: Internal grievance process. The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include—

- (1) A clearly explained procedure for the submission of grievances.*
- (2) Timeframes for reviewing the grievance.*
- (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.*

Interpretive Guidance § 494.180(e)(1)(2)(3)

Guidance is pending and will be updated in future release.

V766

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

- (f) Standard: Involuntary discharge and transfer policies and procedures. The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless –*
- (1) The patient or payer no longer reimburses the facility for the ordered services;*
 - (2) The facility ceases to operate;*
 - (3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or*

Interpretive Guidance § 494.180 (f)(1)(2)(3)

Guidance is pending and will be updated in future release.

V767

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

- (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—*
- (i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;*
 - (ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;*
 - (iii) Obtains a written physician's order that 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;*
 - (iv) Contacts another facility, attempts to place the patient there, and documents that effort; and*
 - (v) Notifies the State survey agency of the involuntary transfer or discharge.*
- (5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.*

Interpretive Guidance § 494.180 (f)(4)(i)(ii)(iii)(iv)(v)(5)

Guidance is pending and will be updated in future release.

V768

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(g) Standard: Emergency coverage. (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

Interpretive Guidance § 494.180 (g)(1):

Guidance is pending and will be updated in future release.

V769

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(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 how they can be reached.

Interpretive Guidance § 494.180 (g)(2):

Guidance is pending and will be updated in future release.

V770

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

- (i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.***
- (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.***

Interpretive Guidance § 494.180 (g)(3)(i)(ii):

Guidance is pending and will be updated in future release.

V771

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(h) Standard: Furnishing data and information for ESRD program administration. Effective February 1, 2009, 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. The data and information must—

- (1) Be submitted at the intervals specified by the Secretary;*
- (2) Be submitted electronically in the format specified by the Secretary;*
- (3) Include, but not be limited to—*
 - (i) Cost reports;*
 - (ii) ESRD administrative forms;*
 - (iii) Patient survival information; and*
 - (iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.*

Interpretive Guidance § 494.180 (h)(1)(2)(3)(i)(ii)(iii)(iv):

Guidance is pending and will be updated in future release.

V772

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(i) Standard: Relationship with the ESRD network. The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

Interpretive Guidance § 494.180 (i):

Guidance is pending and will be updated in future release.

V773

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(j) Standard: Disclosure of ownership. 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.

Interpretive Guidance § 494.180 (j):

Guidance is pending and will be updated in future release.

Part II - ESRD Core Survey Process

NOTE: Publication of the ESRD Facility survey process is pending and will be updated in a future release.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R200SOMA</u>	02/21/2000	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X-Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2000	N/A
<u>R01SOM</u>	05/21/2004	Initial Release of Pub 100-07	N/A	N/A