§ 494.50 Condition: Reuse of hemodialyzers and bloodlines.

(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;
(2) Must be reused only for the same patient; and
(3) 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.

(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:


Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4596.

(2) Reprocess hemodialyzers and bloodlines—
(1) By following the manufacturer’s recommendations; or
(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a 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.

(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.
(2) When clinically indicated (for example, after adverse patient reactions), the facility must—
(i) Obtain blood and dialysate cultures and endotoxin levels; and
(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.
(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 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.

(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.

(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.

(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.

(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.

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

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

(d) Standard: Emergency preparedness. The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility’s geographic area.

(1) Emergency preparedness of staff. The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:
(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—
(A) What to do:
(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;
(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a