

➡ **Dialyzer Reprocessing/Reuse Review:** ▲

Purpose - To validate that dialyzer reprocessing and the clinical use of reprocessed dialyzers are conducted safely, and facility QA oversight of the reuse program assures ongoing patient protection

Observe the following high risk components of dialyzer reprocessing, and interview the reuse technician:

- **Transportation of used/dirty dialyzers** to the reprocessing area – *how promptly they are reprocessed or, if refrigerated, ask about procedures for refrigeration and maximum refrigeration time.*
- **Pre-cleaning procedures** - *if manual pre-cleaning, header removal/cleaning and/or reverse ultrafiltration are conducted, observe these processes for 1-2 dialyzers and interview about the procedures, the water source for pre-cleaning and the maximum allowable water pressures at the pre-rinse sink.*

Focused interview with reuse technician *about germicide mixing, storage and spill management; dialyzer labeling/similar names warnings; reprocessing procedures; and dialyzer refrigeration and storage.*

Review the documentation of facility oversight of dialyzer reprocessing/reuse program in the following areas:

- **QA audits - Review 12 months of facility documentation of the following reuse observational audits.** *For clarification, you may need to interview a technical administrative person, instead of the reuse technician:*
 - Observations of reprocessing procedures -each reuse technician observed at least semi-annually
 - Observations of preparation of dialysis machines with reprocessed dialyzers, i.e., germicide tests, priming, 2 persons identification of patient/dialyzer quarterly
 - Dialyzer labeling, including similar names labeling quarterly
- **Reprocessing equipment preventative maintenance** - *Briefly look at 12 months of documentation, to verify adherence to manufacturer's directions for daily calibration of automated equipment (this may be located on a daily "start-up" log) and routine maintenance procedures.*
- **Reuse adverse events/dialyzer "complaint" log** - *Look at 12 months for actions taken in response to occurrences possibly related to reprocessing.*

Triggers for citation or more investigation of concerns:

- Improperly performed dialyzer pre-cleaning, header removal/cleaning (V334)
- Water used for pre-cleaning dialyzers not purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)
- Germicide not stored, mixed or handled per manufacturer's DFU (V321)
- Knowledge deficit of reuse tech in key patient safety areas per interview guide (V309, 319, 320, 328, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)
- QA audits listed above not done or incomplete - **Extend** to review all of the required QA audits for reuse (V362-368)

- Noticeable strong germicide odors and/or patient or staff complaints regarding germicide odors-*review the last 12 months of ambient air vapor testing for the germicide* (V318)
- Serious adverse events possibly related to dialyzer reprocessing/reuse, **e.g., dialyzing patient on another patient's dialyzer**, without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)-**Extend** to include reuse as a focus area for QAPI Review.

Extending the facility-based reprocessing/reuse review may include: *Observing the complete dialyzer reprocessing procedures, i.e., pre-rinse, automated cleaning, testing, germicide instillation, and labeling for at least 2-3 dialyzers* (V327-345); and additional interviews with reuse technicians and/or technical supervisory personnel.

Note: *If centralized dialyzer reprocessing is conducted with the dialyzers transported to an off-site location for reprocessing, refer to the current CMS Survey and Certification guidance in the State Operations Manual.*