Form Approved
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Reprocessing Observation Checklist

(Adapted from AAMI Dialysis Standards, 2012 Edition)

Reprocessing Documentation Review	Yes/No
Is there a written reuse policy identifying:	
staff in charge of reprocessing program and training	
procedures specific to reuse method in use;	
Quality control and monitoring	
Are all operating logs complete (daily reprocessing records, water treatment records, etc.)?	
Are required chemical and microbiological analyses current and properly documented?	
Are repair and service logs complete?	
Is a written complaint and incident file established and maintained?	
Is training documented for staff members who operate and monitor the reprocessing system?	
Observation of reprocessing process	
Steps of the process	
Header cleaning/precleaning	
Header cleaning manual or machine (name of machine)	
Reprocessing machine (name)	
Documentation of completion for all steps	
Operator manual available for all machines	
Monitoring log available (for the machines)	
How often are preventive maintenance procedures performed? Most recent (date)	
Water system	
Designed and installed appropriately	
Monitored appropriately (review log?)	
Most recent water testing result (?) within limit (cultures, endotoxin testing, and chemical analysis)	
Dialyzer is tested for concentration of germicide before use	
Method used	
Log of test results is available	
Result is within limit for a randomly-picked dialyzer	
Reprocessing area	
Is the processing area clean and sanitary	
Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage	
Are new, used, and reprocessed dialyzers clearly segregated?	
Are reprocessed dialyzers protected from casual access	

Do reprocessing personnel wear appropriate personal protective equipment when performing reprocessing steps	
Are appropriate washing facilities, eyewash stations, respirators and other personnel safety devices in place?	
Supplies	
Are supplies used for reprocessing certified or labeled by the supplier for dialyzer reprocessing	
Are there written specifications or are the supplies labeled by the supplier for dialyzer reprocessing?	
Does the policy call for first-in, first-out inventory control?	
Are all supplies within the dates specified for use? (check one or two items)	
Hemodialyzer labeling	
Are all reprocessed dialyzers in use during treatment labeled for the patient	
Does the labeling uniquely identify the patient who is using the dialyzer?	
Are dialyzers being labeled before their first use in a treatment?	
Are the labels updated after each use?	
Does the reuse label obscure pertinent information on the manufacturer's label	
Is the blood path visible	
Do dialyzer labels contain the patient's name, number of reuses and date of last reprocessing?	
What method is used to alert the staff of patients with the same or similar last names?	
Are the dialyzers checked before use to ensure that an appropriate amount of time has passed since reprocessing the dialyzer?	
Observe reprocessing process	
Note set up and take down of reprocessed dialyzers on the treatment floor. Are dialyzers handled and transported in a clean and sanitary manner?	
How soon after the end of treatment is a dialyzer to be reprocessed?	
What is the policy and procedure when a dialyzer is not reprocessed within the recommended 2 hours?	
If dialyzers are refrigerated, check the temperature and time logs to verify that they match the policy	
Watch the precleaning process to confirm that maximum pressures or other limits for the dialyzer set by the dialyzer manufacturer are adhered to.	
What chemicals are used in the reprocessing of dialyzers?	
If more than one chemical is used to clean and disinfect a dialyzer is there information that validates that each chemical is reduced to safe levels before introduction of the next chemical and has no adverse effect on the dialyzer performance and integrity?	
Is there a maximum storage temperature for the germicide in use, and if so, how is compliance documented?	
How is the expiration of diluted chemicals documented?	
What steps are taken to assure that expired germicide is not used?	
Header cleaning	
Do you remove header caps?	
Do you remove O-ring?	
What safeguard is in place to ensure the original O-ring and header caps are kept with their respective dialyzer?	
Are instruments or other material used in header cleaning, and if so, are	

they new or cleaned and disinfected between uses and has the user determined that the instrument or material does not damage the end of the dialyzer?	
Are properly disinfected port caps used?	
Is the outside of reprocessed dialyzers cleaned with a low-level germicide?	
Examine a number of randomly selected reprocessed dialyzers to ensure that external surfaces are clean, the dialyzer has not been damaged, the dialyzer has been satisfactorily rinsed of blood, and the appearance is aesthetically acceptable and properly labeled.	
What do you do with failed dialyzers?	
What is the maximum storage time for reprocessed dialyzers?	
What happens to a dialyzer that exceeds maximum storage time?	
Preparation and testing before use	
What is the contact time for the chemical germicide used?	
How is the presence of chemical germicide verified and documented	
Residual germicide measured by an appropriate test (name of test)	
What is the maximum allowable time between rinsing and testing the dialyzer and beginning dialysis?	
Are reprocessing records complete, legible, signed, and secure	