



Dialyzer Reprocessing Manual Checklist

The AAMI/ANSI Standard for Reuse of Hemodialyzers (RD47 2002, 2008) states in section 4.1 that the dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures. It should also include samples of forms and labels in use in your reprocessing program.

- A. ___ Dialyzer manufacturer's specifications for each dialyzer model reprocessed.
- B. ___ Specifications of water pressure, flow rate, temperature, maximum contaminants, bacteria and endotoxin for the water used to reprocess dialyzers.
- C. ___ Germicide and cleaning agent specifications on handling, storage, dilution, mixing, validation for efficacy, and safety data including a Material Safety Data Sheet (MSDS) from the manufacturer.
- D. ___ Specifications for all environmental control and safety equipment such as vent hoods, eye wash stations and drain requirements.
- E. ___ Specifications for all materials used in the reprocessing procedure such as test strips & reagents, port caps, and spill control materials. All chemical agents and solutions used should have Material Safety Data Sheets.
- F. ___ Dialysis centers reprocessing policy including the form used to advise patients of the centers reprocessing practices and the institutional consent for hemodialysis treatment form.
- G. ___ All training procedures and training materials excluding test questions and answers.
- H. ___ All operational procedures and/or Instruction Manuals including manufacturers manuals for automated equipment and germicides, and process protocols for manual systems.
- I. ___ All maintenance and calibration procedures for manual or automatic reprocessing equipment.
- J. ___ Test procedures and water quality test schedule.
- K. ___ Procedures for inspection of environmental conditions.
- L. ___ Samples of all forms, labels, records and logs used in the dialyzer reprocessing program. The samples should be properly filled out with example information and signed by the authorized reprocessing manager.
- M. ___ Copies of any disks/CDs/DVDs containing software used for recording or managing the reprocessing program. Disks should be labeled with their contents and date or revision code and must match with all copies in use.
- N. ___ Procedure for review and periodic update of the dialyzer reprocessing manual: to include contact of equipment and germicide manufacturers on a periodic basis to obtain the latest revision of all instruction manuals.

Note: Specifications required and stated in B, C, D, I above may be listed as a part of manufacturer's installation/use manual.