

## **75203 Water Quality**

### **(a)**

All water used in the reprocessing of dialyzers including solution makeup water shall be first passed through a reverse osmosis (RO) membrane unit.

### **(b)**

Water shall not exceed 200 colony forming units (CFU) as tested using a standard plate count method.

### **(c)**

Bacterial testing of the water shall be done monthly and the results documented in the Equipment Record.

### **(d)**

The water treatment system shall be regularly maintained and verification of maintenance so noted according to the schedule in the Equipment Record.

### **(e)**

Dialysis facilities may store water according to written water storage procedures.

(1) Water storage shall be validated for the maximum time of water storage at the 200 CFU standard and for pyrogens using either the USP Rabbit Test for Pyrogens or the Limulus Amebocyte Lysate (LAL) test. (2) Water stored for more than eight (8) hours shall not be used in reprocessing and shall be drained from the storage tank unless stored water is continuously recirculated through a reverse osmosis membrane or other filter having a maximum pore size of 0.45  $\mu$ m.

All filter systems shall be maintained to provide effective removal of micro-organisms and to prevent microbiological accumulation on or within the filter. (3) Bacterial testing of the stored water shall be done monthly at the maximum time of water storage and the results documented in the Equipment Record. A count of greater than 200 CFU shall require the facility to revalidate the water storage procedures for pyrogens and bacterial growth. (4) A consistent rise in patient post-dialysis treatment temperatures to greater than or equal to 100 degrees F and/or symptoms of chills and/or fever traced to water storage shall require the facility to revalidate the water storage procedures for pyrogens and bacterial growth.

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