



“Getting More Information”

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

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FDA SAFETY ALERT:
CHLORAMINE CONTAMINATION
OF HEMODIALYSIS WATER SUPPLIES

To hemodialysis personnel:

This is to alert you to a potentially hazardous chloramine contamination problem which can occur when the water system in a dialysis facility is altered without making needed adjustments in filtration capacity, and to provide guidance on how such problems can be avoided. **Please share this alert with those in your organization who are responsible for the quality and maintenance of the dialysis water supply.**

In a recent incident at a large urban dialysis facility, which was investigated by the Food and Drug Administration and Health Care Financing Administration, a number of patients experienced hemolysis following chloramine contamination of the water used to prepare dialysate. Forty-four patients required blood transfusions, and some required additional medical intervention. Staff members were alerted to the problem when they noted that the hematocrit levels of the patients were depressed.

The rise in chloramine concentration occurred when the facility increased the capacity of its reverse osmosis (RO) water system approximately three-fold without a corresponding increase in the carbon filtration capability of the system. (The change in the water system was made when the facility converted from an acetate to a bicarbonate dialysate.) As the water flow rates were increased, the in-line charcoal filter became prematurely exhausted and chloramine levels in the water used to prepare the dialysate rose above the AAMI standard of 0.1 ppm (0.1mg/liter).*

Incidents of this kind can be avoided by taking the following precautions:

1. Whenever a change is made in the existing water treatment system, ascertain the capacity of the carbon filter to cope with that change by consulting with a water treatment engineer, or a water contractor who is experienced in the operation of hemodialysis water treatment systems. This will help to assure that the maximum expected level of chloramines from the municipal water supply can be effectively removed with the carbon filter being used.
2. Use charcoal filters containing granular activated carbon (GAC) and replace rather than regenerate the filters when exhausted. It is recommended (and California law requires) that the water treatment system contain two carbon filters in series.

3. Test the water for chloramines as it exits the first filter at least once per patient shift. If the level of chloramines exceeds the 0.1 ppm standard, there should be an immediate test for the chloramine level in the water used to prepare the dialysate.
4. Establish a systematic plan for replacing the filters as they become exhausted. With the filters in series, the exhausted first filter can be replaced with the second, and a new carbon filter placed in the second position.
5. Whenever a carbon filter is replaced, disinfect and thoroughly rinse the filter housing before the non filter is installed.

The incident described above underscores the importance of consulting with a qualified water engineer familiar with the special needs of dialysis facilities when installing a new water system or changing an existing one. Whenever changes are made, it is essential to reevaluate the design of the water system as a whole in order to be certain that it is adequate. This particularly important when water flow rates are changed such as when switching to high-flux dialyzers or when adding patients to an existing water supply. The engineer, along with the facility, should be familiar with pertinent chemical and bacteriological standards such as the AAMI standard and/or local, State and Federal requirements. Arrangements should also be made with the hospital engineering department and/or local water control agency to notify the dialysis facility whenever chlorine changes are anticipated in the water supply.

Sincerely Yours,

John C. Villforth
Director
Center for Devices and
Radiological Health
Food and Drug Administration

Standard for Hemodialysis Systems no. RD-5, 1981, Association for the Advancement of Medical Instrumentation (AAMI), 1901 N. Ft. Meyer Drive, Arlington, VA 22209.