

**Department of  
Veterans Affairs**

**Memorandum**

Date: JAN 28 2013

From: Assistant Deputy Under Secretary for Health for Clinical Operations (10NC)

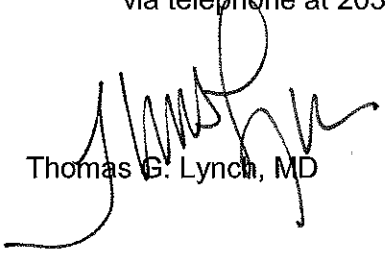
Subj: Dialysis Water Testing and Quality Requirements

To: Network Directors (10N1-23)

1. In response to a recent incident at a VA Dialysis Clinic, this information bulletin provided by 10NC on behalf of the Office of Specialty Care Services Renal-Dialysis Program documents the need for an ongoing, multidisciplinary team approach to ensure that all Association for the Advancement of Medical Instrumentation (AAMI) guidelines on dialysis water testing and quality requirements are being followed.
2. The following is an abbreviated checklist of the key items that need to be evaluated by a facility level End Stage Renal Disease (ESRD) Committee that meets weekly:
  - a. Inorganic solute content.
  - b. Water culture and endotoxins:
    - i. Are sampled and analyzed at least monthly on central Reverse Osmosis (RO) water treatment systems and all portable water treatment systems;
    - ii. Dialysate cultures are performed on at least two Hemodialysis machines per month, with circulation of machine testing in such a way that tests each machine at least once within a year; and
    - iii. Use AAMI recommended water culture technique.
  - c. Chloramines:
    - i. Are tested between carbon tanks for dual carbon tank portable and central ROs, and post carbon tank where portable RO has only a single tank;
    - ii. Verify that the results are negative (<0.1 ppm) before each dialysis shift; and
    - iii. Use AAMI recommended endotoxin assay and technique.
  - d. Water treatment system:
    - i. Assess and document the integrity of the water treatment system daily including temperature, calcium, pre and post tank pressures, alarms, chloramines, and conductivity/resistivity/(TDS); and
    - ii. The process and documentation are verified by a second individual.
  - e. Disinfection of all machines:
    - i. Systematic disinfection of all machines (water treatment and dialysis machines) according to manufacturer guidelines and AAMI recommended standards is occurring and is documented.

## Dialysis Water Testing and Quality Requirements

3. All dialysis water culture and endotoxin results are promptly followed up on by the Dialysis Nurse Manager (or Chief Technician) and Dialysis Medical Director and reviewed by the facility's Infection Control Committee (ICC) on a monthly basis. All culture and endotoxin results, whether positive or negative, shall be reviewed by the facility's ICC. If both positive and negative results are not reported, there is the risk that the absence of a report may be mistaken for negative cultures, when in fact, cultures may not have been obtained.
4. Reviewing water quality is part of the dialysis QAPI review process and documentation.
5. Dialysis equipment (dialysis machines, water treatment equipment, hand held testing devices) is undergoing regular preventative maintenance and a plan of action is in place to ensure emergency equipment repair service is available.
6. Staff competencies are periodically assessed for dialysis water testing and interpretation consistent with scope of practice, which should be reviewed annually.
7. Standard operating procedures exist for the following:
  - a. Performance of and interpretation of water quality tests;
  - b. Equipment disinfection;
  - c. Operation and testing of dialysis equipment (machines, water treatment systems, handheld devices, response to alarms);
  - d. Action plans for abnormal water tests and dialysis equipment repair in case of malfunction;
  - e. Emergency preparedness plan for dialysis unit in case of equipment/facility failure; and
  - f. Reporting requirements: water quality reports should be sent to Infection Control, and, as indicated to the local Office of Quality Improvement, and, for equipment issues to Biomedical Engineering and/or Facilities, and, as indicated to Patient Safety.
8. Questions and requests for further information should be addressed to Susan T. Crowley, MD, National Program Director Renal-Dialysis Program. She can be reached via telephone at 203-932-5711 x3950 or email at [susan.crowley@va.gov](mailto:susan.crowley@va.gov).



Thomas G. Lynch, MD

Attachment and links

**ATTACHMENT**  
**ADDITIONAL INFORMATION**

Medical Director Tool Kit: Developed by the Forum of ESRD Networks' Medical Advisory Council, 2012



Medical Director  
Toolkit- Conditions for

AAMI Dialysis Water Standards: available at  
[http://vaww.ceosh.med.va.gov/01BE/Pages/AAMI\\_Standards\\_Warning.shtml](http://vaww.ceosh.med.va.gov/01BE/Pages/AAMI_Standards_Warning.shtml).

VA Renal SharePoint:  
<http://vaww.infoshare.va.gov/sites/MedicalSurgical/RenalFAC/default.aspx>.