Dialysis Assessment and Response Tool (DART) for Infection Prevention and Control

Water Exposure/Biomedical Practices

This form is intended to aid a DART facilitator in the review of a dialysis facility's infection risks posed by water exposures, biomedical practices, and related policies (Part A). Additionally, questions are included to guide observations of facility/healthcare personnel (HCP) practices (Part B).

Part A. Water Interview Questions

Water systems and monitoring

1. What Association for the Advancement of Medical Instrumentation (AAMI) allowable limits/action level water standards are used by the facility?

Rationale:

"The Association for the Advancement of Medical Instrumentation (AAMI) in conjunction with the International Standards Organization (ISO) have established chemical and microbiological standards for the water used to prepare dialysate, substitution fluid, or to reprocess hemodialyzers for renal replacement therapy."

Examples of different AAMI recommendation action levels and limits can be found on the source webpage.

Source: Water Use in Dialysis: https://www.cdc.gov/dialysis-safety/hcp/recommendations-resources/water-use-in-dialysis.html

CMS Tag Number V213 – "Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits."

Source: CMS ESRD Interpretive Guidance, page 77: https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/esrdpgmguidance.pdf

*CMS Tag Numbers are unique identifiers assigned to specific regulatory requirements within the CMS regulations.

2. Describe the facility action plans in place for water and dialysate microbiological testing results (i.e., colony forming units [CFUs], Limulus Amebocyte Lysate [LALs]) that exceed the AAMI action levels or show upward trends over time.

Rationale

CMS Tag Number V274 – "Facility policy must include requirements to develop and implement a corrective action plan that ensures patient safety if water testing results are outside accepted limits or action levels. A corrective action plan to ensure patient safety must be developed and implemented if any of the results of water chemical analysis or microbial and endotoxin testing for water and dialysate meet the AAMI action levels or are outside the AAMI standards. Water and dialysate monitoring must be reported in the QAPI materials and the medical director must be involved in analyzing and addressing test results outside of expected parameters."

Source: CMS ESRD Interpretive Guidance, page 113:

https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/esrdpgmguidance.pdf

3. How frequently does the facility test for chlorine and chloramines?

- ◯ Every four hours
- ◯ At the beginning of each shift
- ◯ Facility has an automated system to monitor
- ◯ Other (*specify*): _____
- ◯ Unknown
- ◯ Not assessed

4. Does the facility review chlorine monitoring results at their Quality Assessment and Performance Improvement (QAPI) meetings?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

5. Does the facility review monthly microbiological testing at their Quality Assessment and Performance Improvement (QAPI) meetings?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

Rationale:

CMS Tag Number V196 – "Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet." (pg 57)

CMS Tag Number V251 – "Quality control and quality assurance procedures should be established to ensure ongoing conformance to policies and procedures regarding dialysate quality. This clause defines some of the monitoring activities to be conducted at the dialysis facility as part of the quality assurance process." (pgs 103-104)

Item to monitor	What to monitor	Special interval	Normal interval	Specification
Carbon absorption beds	Product water free chlorine and/or total chlorine between the beds	NA	Prior to beginning each patient shift	<0.1 mg/L of total chlorine

CMS Tag Number V252 – "Culture water …weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution." (pg 106)

Source: CMS ESRD Interpretive Guidance, pages 103-104: https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/esrdpgmguidance.pdf

6. Is there a protocol in place to respond to disruptions of water supply? (*select all that apply*)

- ☐ Yes (planned water disruption)
- ☐ Yes (unplanned water disruption)
- ☐ No
- ☐ Unknown
- ☐ Not assessed

If YES (planned and/or unplanned):

6a. What elements are included in this protocol? (*select all that apply*)

- ☐ Identification of alternate water sources (e.g., 24-hour supply of emergency water)
- ☐ Measures to alert HCP and patients to conserve water (e.g., signage)
- ☐ Measures to limit water for critical functions
- ☐ Measures to safely restore water services
- ☐ Post-boil advisory or disruption surveillance for waterborne disease
- ☐ None of the above
- ☐ Unknown
- ☐ Not assessed
- ☐ Other (*specify*): _____

Rationale:

"Remediation Strategies for Disruption System Repair or Emergencies:

a. Whenever possible, disconnect the ice machine before planned water disruptions. Category II B. b. Prepare a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.713, 719 Category IC (JCAHO: EC 1.4)

c. When a significant water disruption or an emergency occurs, adhere to any advisory to boil water issued by the municipal water utility.642 Category IB, IC (Municipal order)

1. Alert patients, families, staff, and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected (e.g., by bringing to a rolling boil for ≥1 minute).642 Category IB, IC (Municipal order)
2. After the advisory is lifted, run faucets and drinking fountains at full flow for ≥5 minutes, or use high-temperature water flushing or chlorination.642, 661 Category IC, II (Municipal order; ASHRAE 12:2000)"

d. Maintain a high level of surveillance for waterborne disease among patients after a boil water advisory is lifted. Category II"

Source: Additional information on addressing water disruptions may be found in Section D.III. of Guidelines for Environmental Infection Control in Health-Care Facilities (cdc.gov)

For more information see: https://www.cdc.gov/water-emergency/hcp/toolkit/index.html

"Keep in close contact with the municipal water supplier because they may choose to "shock" treat (hyperchlorinate) their distribution system to bring it back into compliance with the acceptable standards for drinking water. If the city "shocks" their water system, you may see chlorine/chloramine break through. Review your testing procedures with staff and alert them to be vigilant for potential break through so that patients will be protected from exposure to chlorine/chloramine."

Source: Water Use in Dialysis: https://www.cdc.gov/dialysis-safety/hcp/recommendations-resources/water-use-in-dialysis.html

Wall Boxes

7. Are wall boxes used in the facility to connect the dialysis machines to the treated water supply and drains?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

If YES:

7a. Are dialysis wall boxes cleaned and disinfected at least daily?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed
- ◯ Other (*specify a different time frame*): _____

7b. Are wall boxes cleaned and disinfected after patients have left the station and not during patient care activities?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed
- ◯ Other (*specify*): _____

7c. Are wipes or other supplies used to disinfect the wall box discarded after use and not used to disinfect other surfaces in the dialysis station?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed
- ◯ Other (*specify*): _____

Rationale:

"Dialysis wall boxes are frames recessed into the wall at each hemodialysis station that contain connections for the dialysis machine to receive acid and base concentrates and treated water, and dispose of waste products."

"Wall boxes are part of the immediate patient care environment and are considered contaminated or dirty.

- Wall box surfaces should be disinfected at least daily (e.g., at the end of the day after all patients have dialyzed); cleaning and disinfection might be needed more frequently (e.g., when visibly dirty).
- Cleaning and disinfection of the wall box should be performed after the patient has left the station, and not during patient care activities.
- An Environmental Protection Agency (EPA)-registered hospital disinfectant should be applied to all surfaces of the wall box and any attached hoses. Chemicals should not be mixed; follow product instructions for use.
- Ensure high touch surfaces (e.g., connections for acid, bicarbonate, and reverse osmosis water) are disinfected.
- Wipes or other supplies used to disinfect the wall box should be discarded after use and not used to disinfect other surfaces in the dialysis station.
- More than one disinfectant wipe or application may be needed to ensure all wall box surfaces are visibly wet with disinfectant to achieve contact time specified by the manufacturer.

Source: Dialysis Wall Boxes and Drains: https://www.cdc.gov/dialysis-safety/hcp/recommendations-resources/dialysis-wall-boxes-and-drains.html

8. Does the facility take any measures to reduce the development of biofilms in drains (i.e., machine and wall box drains)?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

If YES:

8a. What measures are taken? (*select all that apply)*

- ☐ Routine maintenance schedule for drains and traps (e.g., drain cleaners, drain gels, enzymatic cleaners)
- ☐ Application of an EPA-registered disinfectant with label claim against biofilms
- ☐ Interventions performed by a qualified plumber aimed at removing clogs
- ☐ Staff education on routine drain maintenance and clog prevention
- ☐ Unknown
- ☐ Not assessed
- ☐ Other (*specify*): _____

Rationale:

"Interventions to decrease the rate of biofilm formation should be considered as a preventive measure on a routine schedule for drains and traps (e.g., drain cleaners, drain gels, enzymatic cleaners). Chemicals should not be mixed; follow product instructions for use."

Source: Dialysis Wall Boxes and Drains: https://www.cdc.gov/dialysis-safety/hcp/recommendations-resources/dialysis-wall-boxes-and-drains.html

"Clean and disinfect sinks and wash basins on a regular basis by using EPA-registered products as set by facility policies."

Source: Guidelines for Environmental Infection Control in Health-Care Facilities, page 140: https://www.cdc.gov/infection-control/media/pdfs/Guideline-Environmental-H.pdf

"Avoid pouring IV fluids, total parenteral nutrition (TPN), antibiotics, body fluids, or unfinished drinks down patient room sinks. These liquids can promote biofilm growth in drains, which may harbor antimicrobial-resistant organisms. Instead, discard these liquids in a:

- Solid waste container
- Hopper or sluice
- Utility sink with extensive flushing"

Source: Considerations for Reducing Risk: Water in Healthcare Facilities: https://www.cdc.gov/healthcare-associated-infections/php/toolkit/water-management.html

Surveillance

9. Does the facility have a surveillance process to detect healthcare-associated infections attributable to water-associated pathogens?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

If YES:

9a. What water-associated pathogens are routinely included in surveillance plans? (*select all that apply*)

- ☐ Gram-negative bacteria (e.g., Pseudomonas, Burkholderia)
- ☐ Nontuberculous mycobacteria (NTM)
- ☐ Fungi (e.g., Aspergillus spp, Fusarium spp)
- ☐ None of the above
- ☐ Unknown
- ☐ Not assessed
- ☐ Other (*specify*):

Rationale:

"Monitor the incidence of infections that may be related to care provided at the facility and act on the data and use information collected through surveillance to detect transmission of infectious agents in the facility."

Source: CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings: https://www.cdc.gov/infection-control/hcp/core-practices/

"Biofilms in wall box drains may contain opportunistic pathogens that can cause healthcare-associated infections (HAIs).

- Conduct routine surveillance (e.g., monthly) for HAIs, including bloodstream infections, and regularly review results.
- Blood cultures positive for Gram-negative organisms commonly found in water-related biofilms should prompt investigation into possible reservoirs in the patient environment, including wall boxes.
- Contact local or state public health authorities to help investigate potential wall box-related infections and clusters."

Source: Dialysis Wall Boxes and Drains: https://www.cdc.gov/dialysis-safety/hcp/recommendations-resources/dialysis-wall-boxes-and-drains.html

Water Exposure

10. Which of the following strategies to prevent contamination of the patient care supplies due to splashing from water sources are practiced (*select all that apply*)?

- ☐ Taps located offset from sink drains
- ☐ Water discharge points at least 10 inches above the sink bottoms in handwashing sinks
- ☐ Patient care items located at least 3 feet from sinks or a splash guard in place to prevent items from becoming wet
- ☐ Medication preparation area located at least 3 feet from sinks or a splash guard is in place
- ☐ Daily cleaning and disinfection of adjacent countertops with an EPA-registered disinfectant
- ☐ Where installed, daily cleaning and disinfection of splash guards
- ☐ No strategies practiced
- ☐ Unknown
- ☐ Not assessed
- ☐ Other (*specify*):

Rationale:

"Splashes can occur when water hits the contaminated drain cover or a person flushes a toilet or hopper. Splashes can spread droplets containing OPPP (Opportunistic Pathogens of Premise Plumbing) to the surrounding environment, patients and providers."

Source: Considerations for Reducing Risk: Water in Healthcare Facilities: https://www.cdc.gov/healthcare-associated-infections/php/toolkit/water-management.html

"Prevent faucets from discharging directly above the drain as this causes splashing (i.e., angle water away from the drain or offset the faucet from the drain). When installing new sinks, consider selecting designs that prevent splashing. (Reference FGI Guideline for Hospitals A2.1-8.4.3.2(1)a.)

Use sinks in patient care areas with adequate depth and the maximum water flow as regulated to prevent splashing."

Sources: FGI Guideline for Hospitals A2.1-8.4.3.2 (1) a., b., c. and A2.1-8.4.3.2 (2) (5), (6); Gestrich, S. A., Jencson, A. L., Cadnum, J. L., Livingston, S. H., Wilson, B. M., & Donskey, C. J. (2018). A multicenter investigation to characterize the risk for pathogen transmission from healthcare facility sinks. Infection control and hospital epidemiology, 39(12), 1467–1469. https://doi.org/10.1017/ice.2018.191; https://www.cdc.gov/healthcare-associated-infections/php/toolkit/water-management.html

11. Do your facility's hand hygiene observations include monitoring whether staff perform hand hygiene after contact with water connections, drains, or wall box components?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

Rationale:

"Staff may lack awareness of infectious risks associated with wall boxes and necessary infection prevention and control measures.

- Educate staff on the risks associated with wall boxes and practices to prevent wall box-related infections.
- Hand hygiene should be performed after coming into contact with wall box or any of its components; reinforce and regularly assess compliance with hand hygiene."

Source: Dialysis Wall Boxes and Drains: https://www.cdc.gov/dialysis-safety/hcp/recommendations-resources/dialysis-wall-boxes-and-drains.html

Biomedical Practices Interview Questions

For this section of questions, it may be helpful to have a biomedical staff member present, but facility leadership should be able to generally answer these questions if the biomedical staff member is not present or available.

12. Which HCP are responsible for performing preventive maintenance of dialysis machines in the facility?

- ◯ On-site biomedical staff
- ◯ Off-site or on call biomedical staff
- ◯ Unknown
- ◯ Not assessed
- ◯ Other (*specify*): _____

13. Describe the facility process for informing biomedical staff that a dialysis machine or piece of equipment needs to be serviced (e.g., machine malfunction, internal blood spill/leak)?

14. Describe how biomedical staff communicate to frontline HCP that machine maintenance is in process and a machine should not be used for patient care?

15. Describe how biomedical staff communicate to frontline HCP that machine maintenance is complete and a machine can be used for patient care?

Rationale:

CMS Tag Number V403 – "All equipment used at the dialysis facility… must be maintained in safe and functional working condition. The facility's program for preventive maintenance and repair of all equipment must be in accordance with the equipment manufacturer's instructions. Staff must operate and maintain the equipment in accordance with manufacturer's instructions. Malfunctioning machines awaiting repair must be removed from service and labeled or tagged to prevent use."

Source: CMS ESRD Interpretive Guidance, pages 163-164: https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/esrdpgmguidance.pdf

Part B. Water Exposure/Biomedical Observations

Ideally, at least two observations of different staff (1 observation each) within the facility are completed for the questions in this section. If direct observations cannot be gathered, then information can be obtained by asking staff for input when they are not providing direct patient care.

Location of Observation #1 _____

Role of Staff Observed: _____

Wall Boxes and/or Machine Drains

1. Are wall boxes present in the facility?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

2. Do staff remove their gloves and clean their hands immediately after coming into contact with the wall box, water connections, or drain components?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

3. Is there any evidence of water drain issues at the patient station, either in a wall box or a designated machine drain (e.g., foaming, foul odors, evidence of splashing, drain flies)?

- ◯ Yes (*specify*): _____
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

Sinks, Drains, and Other Water Features

4. Are patient care supplies protected from splashing (e.g., via splashguards or distance)?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

5. When taps are running, do countertops and patient care supplies remain free from splashing?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

6. Are taps located offset from sink drains to reduce splashing?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

Part B. Water Exposure/Biomedical Observations #2

Location of Observation #2: _____

Role of Staff Observed: _____

Wall Boxes and/or Machine Drains

1. Are wall boxes present in the facility?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

2. Do staff remove their gloves and clean their hands immediately after coming into contact with the wall box, water connections, or drain components?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

3. Is there any evidence of water drain issues at the patient station, either in a wall box or a designated machine drain (e.g., foaming, foul odors, evidence of splashing, drain flies)?

- ◯ Yes (*specify*): _____
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

Sinks, Drains, and Other Water Features

4. Are patient care supplies protected from splashing (e.g., via splashguards or distance)?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

5. When taps are running, do countertops and patient care supplies remain free from splashing?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed

6. Are taps located offset from sink drains to reduce splashing?

- ◯ Yes
- ◯ No
- ◯ Not observed, but endorsed by frontline staff
- ◯ Not observed, not endorsed by frontline staff
- ◯ Not assessed