



**ESRD Update:
Transitioning to New ESRD Conditions for Coverage
Student Manual**

Lesson #9: Water and Dialysate

Learning Objectives

At the conclusion of this lesson, you will be able to:

- List requirements for this Condition
- Describe major changes from previous requirements
- Demonstrate understanding of which commonly cited deficiencies would now be cited in this area
- List survey tasks to be used in evaluating compliance with this Condition

Condition: Water & Dialysate Quality

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Objectives

- List requirements for this Condition
- Describe major changes from previous requirements
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Talk About the "Happy Dance!"

- Adopts RD52:2004 in total!
- From 4 tags to 92 tags!
- A tag for almost anything you could possibly find "wrong" in water / dialysate!
- Clear requirements: for the surveyor and the provider!

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Organization: AAMI meets CMS!

- Tags #'s: V175 to V300 (V278 is the last one)
- AAMI RD52 referenced from V176-260
- Let's look at V176
- And V177
- Now let's look at V180

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Clicker Question!!

If the AAMI language in the regulation column says "recommendation," it is optional for the facility to follow that regulation.

- A. True
- B. False

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Condition Level: V175

V175: Condition level: title only; used ONLY for NISC findings, such as:

- Demonstrated lack of staff training or knowledge re assigned tasks in water/dialysate
- Failure to perform or document Ch/ChI testing accurately; including using expired reagents or strips or ones not sufficiently sensitive to detect unsafe levels
- Unsafe practices in the preparation, labeling or delivery of dialysate
- Failure to address out of range results for safety/quality tests

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Outcomes at the Start

V176: Incorporates AAMI RD52:2004 as regulation

Quality outcomes:

V177: Chemical contaminants: if contaminants are above levels (but not for ch/chl testing any more!)

V201/206: if AAMI testing not done (RO/DI)

V178: Bacteriology of water: max & action levels

V179: Medical director responsible

V180: Bacteriology of dialysate: max & action levels

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Bacteriology: Where Did "Olde" V262 and V263 Go?

- V178-179 = the old 262
- V180 = the old 263
- Action levels and maximums for water and dialysate are now the same
- Action: 50 cfu/ml; maximum: 200 cfu/ml
- EU: action: 1 EU/ml; maximum: 2 EU/ml
- BOTH cultures and endotoxin testing are required

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Chemical Contaminants: Where Did "Olde" V264 Go?

- V177: Results ≠ AAMI & no action taken
 - V201: Analysis not done (RO system)
 - V206: Analysis not done (DI system)
 - V196: primary tag for routine monitoring of chlorine/chloramine
- V197, V270-273 address actions which must be taken if test after first carbon tank is positive

More to come...

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Organization by Survey "Flow"

- Starts with a back up plan! V 182
- "No tag"—look at the tag following V182: overview of the water treatment system
- V184-187: Environment:
 - V184: Secure & restricted
 - V185: Access to ports/meters
 - V186: Alarms in treatment area
 - V187: Schematic diagrams/labels—including components!

Are you smiling yet?

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Organization by Survey "Flow:" Pre Treatment Components

Specifications and monitoring for each, in order of the usual layout:

- V188: Sediment filters (look at this one)
 - V189: Cartridge filters
 - V190-191: Softeners
- Remember, not all components described in these new regulations are "required;" use the applicable tags for the components in use.

Are you smiling yet?

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CARBON TANKS!

Two Tanks Required



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Clicker Question!!

Is every component listed in the new regs for water treatment required at every facility?

- A. Yes
- B. No
- C. I'm not sure

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What Components Are Required?

In-center:

- Always TWO carbon tanks
- RO or DI—expect RO with DI as backup or polisher

At home:

- At least one carbon tank
- RO or DI—at this time, DI is more common at home

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Carbon Adsorption: V192-197

- V192: Two tanks with testing port after each
- V193: Set up of "banks of tanks"
- V194: Media: can not be regenerated; exhaustion = discard; must use iodine # 900
- V195: Minimum 10 minute EBCT

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Carbon Adsorption: V196: Monitoring

- At the beginning of each treatment day
- Prior to beginning of each patient shift (or ~every 4 hours)
- Record results
- Test sufficiently sensitive and specific to detect a maximum level of 0.1 mg/L
- Samples drawn after system has been operating at least 15 minutes

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Test strips used
to test for the
absence of
BLEACH

NOT sensitive enough
to use to test for
chloramine



17

Zero ≠ Zero

- Reacted reagent pad matching the color chart for "zero (0)" indicates substance under test is BELOW sensitivity of the test strip and cannot be detected
- Does not mean substance being tested is actually "zero"
- Does mean the substance is at level less than the lowest color chart value

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Clicker Question!!

Survey finding: test strips in use for testing the water after the first carbon tank for chlorine/chloramine are only sensitive to 0.5 mg/L

Cite this at:

- A. V264
- B. V196
- C. V175
- D. B & C
- E. I wouldn't cite it unless there was an outcome

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Carbon Adsorption

V197: Action taken if first test is positive

- Operation can continue up to 72 hours if samples from second testing port are within limits
- Replace one tank and rotate the tanks or replace both tanks

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More on Monitoring for Chlorine and Chloramine: V270-273

V270-273: CMS language (AAMI ends at V260)

- "No tag" just before V270: redundant of AAMI language at V192 and V197
- V270: Action if second testing port is +
- V271: Use of holding tank water
- V272: Notify the medical director
- V273: Take corrective action

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When Would You Use These Tags?

- V 272: If you identify an episode of ch/chl break-through where there was no evidence the medical director was notified
- V271: If the second test for ch/chl was >0.1mg/L and the holding tank water was used for treatment or reprocessing of dialyzers without testing that water to be sure the levels of ch/chl were below 0.1mg/L

22

Back at the Components...

- Chemical Injection Systems

23

Clicker Question!!

Have you ever surveyed a facility that had a chemical injection system in their water system?

- A. Yes
- B. No
- C. I am not sure
- D. I am not a surveyor

24

V 198: Chemical Injection Systems

- If you find a chemical injection system in use: this tag is here to help you!
- Describes safety requirements
- Details required monitoring, including an alarm in the treatment area

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Treatment Components: RO

V199-201: Reverse Osmosis

- V199: RO makes water that meets AAMI, system monitored, & values recorded daily to permit trending and historical review

V200: Reverse Osmosis

- Quality alarm audible in treatment area
- Continuous reading monitors (Conductivity or TDS)
- "Divert to drain" mechanism

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Reverse Osmosis

V201: Chemical analysis to be done:

- When installed
- When membranes are replaced
- At least annually thereafter
- When seasonal variations in source water suggest worsening quality
- When rejection rate falls below 90%

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Treatment Components: DI

V202-206: Deionization

- V202: Monitored continuously to produce water of 1 megohm/cm or greater resistivity at 25°
- Monitored continuously for temperature by compensated resistivity monitors with audible and visual alarms. Cannot use water less than 1.0 megohm/cm
- Record readings twice each treatment day

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Deionization Treatment Systems

V203: DI

- Alarm audible in patient care area
- Divert to drain mandated

V204: DI

- DI requires carbon before and UF after

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Deionization Treatment Systems

- V205: DI should be used for polish or backup rather than as a primary system in an outpatient facility
- So what?
 - Expect routine use of DI “only” to be rare in outpatient facilities
 - If in use, discuss rationale with medical director

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Post Treatment Components

V207: Ultrafiltration

- Functional: reduce endotoxin/bacteria
- Opaque housing
- Disinfected routinely
- Measure inlet /outlet pressures
- Record pressures and bacteria/endotoxin levels in a log*

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Post Treatment: Storage/Distribution

V208: Design: to control bacteria and for easy and frequent disinfection

V209: Water storage tanks, when used:

- Have a conical /bowl-shaped base*
- Tight fitting lid with an air filter
- Post storage UF or equivalent
- Frequently drained and adequately disinfected*

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Water Distribution Systems

V211:

- Continuous loop with a pump for water distribution made of inert materials
- Flow in the system*
- No "dead ends"

V212:

- System constructed of inert materials: "no added burden"

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Water Distribution Systems

Frequency of monitoring for bacteria and endotoxins:

V213:

- Newly constructed systems or systems with major changes*: weekly for 1 month
- Sample sites
- Results recorded in a log to allow ID of trends

Note: V252: Requires monthly samples routinely

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Bacterial Control: Ultraviolet Irradiators

V214 includes:

- Required dose
- Monitor: meter, on-line monitor, or replace on a pre-determined schedule
- Log sheet for monitoring*

V215 includes:

- Filter post UV for endotoxins required

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Clicker Question!!

Water treatment systems that include an ultraviolet irradiator to reduce the amount of bacteria in the water must include a:

- A. Water softener
- B. Sediment filter
- C. Endotoxin reducing filter post UV
- D. DI system

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Bacterial Control: Ozone Generators

V216:

- System materials must be ozone-resistant
- Concentration/ exposure time must be per manufacturer's DFU
- Ozone levels monitored in water with each use
- Ozone-in-ambient-air test done periodically per manufacturer's DFU

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Bacterial Control: Hot Water Disinfection Systems

V217:

- Delivers water hot enough, long enough
- Delivery system materials heat resistant
- Follow manufacturer's DFU*

V218:

- Monitoring of exposure time & temperature at point farthest from the water heater
- Used for disinfection at frequency per DFU
- Record maintained

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Strategies for Bacterial Control

V219: Disinfect piping:

- Routine low-level disinfection;
- Frequency according to design of system and extent of biofilm present
- Prevent disinfectant from draining prior to completion of contact time

V220: Disinfect the machine supply line with each distribution system disinfection

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All NEW: Concentrate Preparation



Concentrate Mixing Systems

- V222: Bulk storage: safety measures to prevent mix-ups or tampering
- V223: Compatible materials (no copper/brass, etc)
- V224: Require purified water, drain, and a ground fault protected electrical outlet
- V225: Safe environment, including use of PPE as required by DFU

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Clicker Question!!

If you observe a water treatment tech mixing acid concentrate without using PPE, where could you cite this?

- A. Under Infection Control (V115)
- B. Under Physical Environment (V426)
- C. Under Water & Dialysate Quality (V225)

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Concentrate Mixing Systems

V226: Follow DFU:

- Amount of water,
- Number of bags or weight of powder,
- PM/ sanitization, monitoring.

Records must be kept to include date, time, staff ID, and test results, if applicable

V227: Self designed systems: test product before use

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Labeling: of Everything!

V228:

- Mixing tanks: prior to batch preparation; label includes date of preparation and chemical formulation of concentrate
- Bulk storage: Permanently labeled to ID contents
- Jugs: sufficient info to differentiate the contents from other concentrate formulations used at the facility (more variety available = more detail)

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Concentrate Mixing: Records/Testing

V229: Maintain a permanent record of batches produced to include:

- Concentrate formula
- Volume of the batch
- Lot numbers of the powder
- Date / time of mixing
- Any test results (conductivity or specific gravity)*
- ID of staff member responsible for mixing
- Verification of the results*
- Expiration date (if applicable)

V230: System cleaned and disinfected according the DFU

45

Clicker Question!!

Bicarbonate mixing logs should include all of the following information EXCEPT:

- A. Date and time
- B. ID of the person doing the mixing
- C. The names of patients on that shift
- D. Results of tests to verify the mixture

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Acid and Bicarb Mixing

V231: Acid mixing tanks: empty completely before mixing a different formulation

V232: Bicarb mixing tanks: empty completely, designed for ease of disinfection and rinsing

47

Bicarbonate Mixing

V233: Storage times:

- According to DFU
- Minimized
- Avoid mixing fresh bicarb with unused portions of concentrate from a previous batch*

V234: Mixing bicarb:

Avoid Over mixing = \downarrow CO₂ and \uparrow pH

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Additives: Mixing Spikes

V235:

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- Ratio matches (e.g. 35X = 35X)
- Volume considered if liquid
- Completely dissolved if powder

V236: Label and permanent record:

- Added electrolyte
- Final concentration
- Date/time added
- ID of person making the addition
- Patient's name if specific for patient
- Label affixed to the container prior to mixing

C
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m

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Clicker Question!!

With a physician's order, it is okay for a patient care tech to use a "spike" to change the electrolyte concentration of the acid used for dialysis.

- A. Yes
- B. No
- C. Depends (on your state nurse practice act or other state law related to ESRD)

50

Okay, We Got it Mixed!

Time for a ~~STRETCH~~ Break!

51

Getting the Concentrate to the Point of Use

V237: Distribution system materials do not add burden

V238: Elevated tanks: conical bottoms, tight lids, spray mechanism, high/low level alarms

V239: Bicarb systems: disinfection at least weekly

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Bicarb Distribution: Bacterial Control

V240: Use of UV – same requirements except no requirement for a UF to follow

V241: Use of Ozone: same requirements

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Bicarbonate Monitoring

V242: Dialysate culture frequency:

- Weekly with any new bicarbonate distribution system
- Monthly at a minimum
- If elevated bacteria or endotoxin levels found in dialysate, all systems must be evaluated, appropriate action taken, and frequency of monitoring increased till the problem is resolved

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Jugs

V243: Rinse bicarb jugs and pick-up tubes at the end of each treatment day with treated water. Invert jugs to dry and allow tubes to air dry.

V244: Rinse bicarb jugs free of concentrate prior to disinfection; disinfect at least weekly; then drain, rinse, and invert to dry

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Concentrate Distribution

V245:

- Acid piping and outlets color-coded red at the point of use
- If more than 1 type of acid, each line clearly labeled

V246:

- Bicarb piping and outlets color-coded blue at the point of use

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Clicker Question!!

After October 14, 2008, every facility must have all concentrate delivery systems labeled and color-coded.

- A. True
- B. False
- C. They don't have to do this till Feb 2009

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Concentrate Delivery: Safety

V247:

- Each concentrate has its own outlet
- Outlets have a means of minimizing the risk that the wrong concentrate will be connected to an outlet
- Outlets are labeled with the appropriate symbol (i.e., □, ○, △, or ●) to indicate proportioning ratio)
- Color-coded blue=bicarb; red=acid
- Daily check if storage tank is not permanently connected to the distribution piping

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Dialysate Proportioning

V248: Acid and Bicarb match proportioning ratio and match model and set-up configuration of the dialysis machine

Let's look at Table 3...

Most facilities will use only one mixing ratio for all machines; expect all supplies to match that ratio (acid, bicarb, additives).

59

And Now for Using Dialysate...

V250: At the treatment station before starting the treatment of the next patient :

- Follow DFU regarding checking dialysate conductivity
- Check pH with an independent method

60

Clicker Question!!

Regulations at the end of the Condition:
Water & Dialysate Quality address:

- A. Mixing dialysate
- B. Storing dialysate
- C. Labeling dialysate
- D. All of the above

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A Word About Table 6: Monitoring!

- In case you lose your laminate: it is here in the IG—sans tag numbers
- The language here is also included under each component where it applies
- Remember, these are examples—expect the facility to use these or an equivalent method:
 - can't "not do"
 - can do something "the same as."

62

Microbial Testing of Water

V252:

(Remember, we mentioned this one before)

- Frequency of routine microbial testing of water
- Cultures and endotoxins required
- How to sample; sample ports must not be disinfected prior to collecting the sample

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And What About Dialysate?

V253:

- Samples from at least 2 machines monthly; every machine tested at least once/year
- If test above action levels (50 cfu/ 1 EU), investigation outlined
- How to collect samples detailed

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We Have A Tag For:

Samples B4 Disinfection!

V254: Samples must always be collected before sanitization/disinfection of the water treatment system and dialysis machines.

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Repeat Cultures

V255 (Remember that used to be the Condition of PE...)

Now requires Repeat Cultures –including weekly until acceptable results are obtained.

- Samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia
- Outlines how to collect samples after disinfection when required in these circumstances

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More About Cultures

V256: Dip samplers

- May be used WITH a QA program
 - Expect staff training in correct methods of inoculation, incubation and interpretation
 - Verification testing: duplicate samples sent to a certified laboratory at least annually
 - Plates are incubated at 35° for 48 hours

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Still More About Cultures...

V257:

- Refrigerate sample if it cannot be cultured within 1-2 hours
- Can refrigerate up to 24 hours
- Using a calibrated loop to apply the sample to the agar plate is not permitted.

Expect the facility to have notified the lab that the sample is water and they must not use a calibrated loop.

68

And Then LAL...

V258:

- Two tubes run for each assay
- Second tube acts as a positive control
- Can be done on-site or sent to an outside laboratory

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Clicker Question!!

After October 14, 2008, each facility is expected to do monthly testing (cultures AND endotoxins) of water and dialysate.

- A. True
- B. False

70

P & P: Novel Idea!

V259: (Straight from the mouths of AAMI©)

"Policies and procedures that are understandable and accessible are mandatory."

No more "no policy" for ch/chl testing!

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Personnel Training: V260

- Training mandatory
- Training to cover quality testing, risks and hazards of improperly prepared concentrate, bacterial issues
- Operators trained in use of equipment
- Training specific to functions performed
- Periodic audits of operator's compliance
- Ongoing training to maintain knowledge and skills

End of ANSI/AAMI RD 52 requirements

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Clicker Question!!

The whole Condition of Water and Dialysate Quality is based on AAMI RD52:2004.

- A. True
- B. False
- C. Are we done yet?

73

Remember, We Talked About...

CMS added tags about chlorine and chloramine testing:

- V270: Action if second testing port is +
- V271: Use of holding tank water
- V272: Notify the medical director
- V273: Take corrective action

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CMS Added Tags

V274: Corrective action plan: water testing results (chemical, microbial, endotoxin levels) that meet AAMI action levels or deviate from AAMI standards must be addressed with a corrective action plan that ensures patient safety.

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CMS Added Tags

V275: Adverse events: active surveillance of patient reactions during and post dialysis. If indicated:

1. Obtain blood & dialysate cultures and endotoxin levels;
2. Evaluate the water system; and
3. Take corrective action.

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In-center Use of Preconfigured Hemodialysis Systems

V276: Follow FDA-approved labeling for:

- Machine use
- Monitoring of water and dialysate quality

V277: Meet all the RD52:2004 requirements in using that system

V278: Perform bacteriological and endotoxin testing quarterly on the preconfigured system

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THE END!

Almost...

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How Will We Survey For This Condition?

- USE YOUR SURVEY PROCESS LAMINATE!

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Task 1: Presurvey

Outcomes which may be impacted by problems in Water & Dialysate Quality include:

- Anemia management
- Adequacy of dialysis
- Mortality
 - Deaths from Sepsis
- Morbidity
 - Hospitalizations from sepsis

80

Task 3a: Tour and Observations:

- Include the water room and the dialysate mixing and storage areas
- Observe for all those requirements we have reviewed!
 - Area secure (V184)
 - Piping labeled (V187)
 - Components labeled (V187)
 - Appropriate PPE in use (V225)

81

Task 5: Patient Sample Selection

- Choose some lab “outliers” for potassium
- If you noticed 0K+ or 1K+ baths available or in use, include all 0 K+ bath patients and some of the 1K+ bath patients in your sample

82

Task 6: Water/ Dialysate:

- Note that this task is broadened to include dialysate
- Expect to do this task “in pieces”—unlikely one or more staff members can take the time to do it all uninterrupted—remember to lessen your impact on the treatment schedule

Task 6a: Walk through the water treatment components AND the mixing and delivery systems for dialysate

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Task 6b: Review of Water Treatment Logs

- Chemical Analysis (V177, 201, 206)
- Microbial Surveillance (V213, 254)
- Chlorine/Chloramine testing (V196, 197, 270)
- Daily logs (V191, 199, 202)
 - Start up
 - Disinfection
 - Mixing
 - Testing

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Task 6c: Review of Dialysate Prep & Delivery

- Observe batches mixed on site (V226, 229, 234, 233, 228)
- Central delivery: labeling/ safe connections (V245-247); disinfection (V239)
- Jugs: labels (V228, 236); bicarb = rinsed daily/disinfect weekly(V243-244)

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Task 11: Medical Record Review

- Does the dialysate in use match the order?
- If an altered K+ or Ca+ bath is ordered, is the monitoring frequency increased?
- If an altered K+ bath is ordered for part of the treatment, is there evidence the bath was changed as ordered?

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Task 13: QAPI

- Are technical areas included in the reports?
- If a problem is identified, is a plan developed, implemented, and evaluated?

Task 13b: Emergency Prep Review

- Plan for water supply interruption? (V182)

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Task 14: Personnel Record Review

- Include staff responsible for operation and testing of water treatment system
- Expect training specific to tasks assigned (V260, V696)
- Evidence of periodic audits of compliance with water & dialysate procedures (V260)
- Evidence of ongoing training to maintain operator's knowledge & skills (V260)

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Clicker Question!!

If the nurse manager does the water system checks for chlorine and chloramine, she/he would need to have completed training specific to that task.

- A. True
- B. False

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Task 15: Decision Making

- Deficient practices found in Water & Dialysate Quality impact all patients on census
- Consider extent and potential for harm
- One component not labeled very different from one technician not trained, but doing the testing every morning...
- If this Condition is out, likely Medical Director and Governance are also out of compliance

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Clicker Question!!

- Who is ultimately responsible for the operation and use of the water and dialysate delivery systems?
A. The chief technician
B. The medical director
C. The administrator
D. The nurse manager

91

Clicker Question!!

- There were 4 tags for water, now there are:
- A. 1492
 - B. 8 million
 - C. 27
 - D. 92

92

WE MADE IT!!!

Questions?

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Resources

FLOW VELOCITY CALCULATOR

Enter your pipe size in Inches (yellow-1st box), and your loop flow rate (blue-2nd box) in Gallons per Minute

Pipe Size Inches	Flow Rate in GPM	Pipe Area in SF	Flow Rate in CF/Sec	Flow Velocity feet / sec	Meets Standard?
0.75	5	0.00307	0.01114	3.625	Yes

(Based on an Indirect Feed system)

The Formula is $V = Q/A$

Where: V = flow velocity in feet/sec
 Q = flow rate in feet³/sec
 A = cross sectional area of distribution pipe in feet²

The AAMI Recommended Flow Velocity is 3.0 feet per second for indirect feed systems, 1.5 feet per second for direct feed system.

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EBCT CALCULATOR

To calculate the needed amount of carbon to achieve the required EBCT, enter the flow rate in the yellow cell (labeled GPM) below

Enter your flow rate in GPM	Required EBCT in minutes	Below is the required volume of carbon in Cubic Feet	
12.00	5	8.02	For each worker and polisher tank
12.00	10	16.04	Total amount of carbon needed

The Formula is $V = (Q \cdot EBCT) / 7.48$ where V = volume of carbon and Q = flow rate in gallons per minute

To calculate the actual EBCT, enter the flow in the yellow cell (labeled GPM) and the volume of carbon in the blue cell (labeled volume of carbon per tank)

Enter your flow rate in GPM	Enter your volume of carbon, per tank	Below is your actual Empty Bed Contact Time per tank.	Meets AAMI EBCT Standard?
5.00	3.60	5.39	Yes

The Formula is $EBCT = (V/Q) \cdot 7.48$ where V = volume of carbon and Q = flow rate in gallons per minute

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