STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152579	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 05/22/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE BLOOMINGTON MONROE	575 S PATTERSON DR BLOOMINGTON, IN 47403

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V000000	[CORE] This was an ESRD federal recertification survey. Survey dates: May 17, 20, 21, and 22, 2013 Facility #: 005143 Medicaid #: 200389400 Surveyors: Bridget Boston, RN PH Nurse Surveyor, Lead Marty Coons, RN PH Nurse Surveyor Susan E Sparks, RN PH Nurse Surveyor Linda Dubak, RN PH Nurse Surveyor Observer Fresenius Medical Care Bloomington Monroe was found out of compliance with the Conditions for Coverage 42 CFR 494.40: Water and Dialysate Quality, 494.110 Quality Assessment and Performance Improvement, and 494.150: Responsibilities of the Medical Director. Quality Review: Joyce Elder, MSN, BSN, RN May 31, 2013	V000000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V000113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, interview, and review of policies, the facility failed to ensure staff donned personal protective equipment (PPE) and/or changed gloves when contaminated and performed hand hygiene appropriately during the provision of care in 1 (# 1) of 1 observation of a nurse practitioner and in 1 (# 10) 7 patient observations creating the potential to affect all of the facility's staff and 74 current patients. The findings include: 1. Facility policy FMS-CS-IC-II-155-090 A issue date March 20, 2013, titled Hand Hygiene, states "All staff, patient's patient care givers, including physicians and non-physician practitioners, social worker, dietitians and any other indirect patient care staff must follow the same requirements for hand hygiene. Hand hygiene includes either washing hands with soap and water or using waterless alcohol-based antiseptic hand rub with 60-90% alcohol content. Drying effects of alcohol can be counteracted by addition of emollient or lubricants, e.g. 1-3%	V000113	On June 6, 2013 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution. The Clinical Manager is responsible to ensure that all staff members including physicians and non-physician practitioners follow “Hand Hygiene” policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members including the nurse practitioner on the following policy “Hand Hygiene” FMS-CS-IC-II-155-090A with emphasis placed on appropriate glove usage, glove changes and hand hygiene using hand sanitizer. Training was completed on June 7, 2013 and an in-service attendance sheet is available in the facility for review in addition an audit with skills checks will be	06/18/2013

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	glycerol. ... [When to wash hands or use alcohol based hand rub] Before and after direct contact with patients. Entering and leaving the treatment area. Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medication. Immediately after removing gloves. After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. After contact with inanimate objects near the patient. When moving from a contaminated badly site to a clean boy site of the same patient." 2. Observed on 5/20/13: A. At 1:35 PM, nurse practitioner (NP), employee D, was observed to enter the in-center treatment floor without donning any PPE. Without washing or sanitizing her hands or donning gloves, she entered into treatment area # 11 where patient #9 was dialyzing. She then removed a stethoscope from around her neck and listened to the patients lungs and chest, then replaced the stethoscope back around her neck. The NP then touched the patient's ankle and the top of her left foot without wearing any gloves. 1.) At 1:38 PM, at this same observation, employee D indicated she		completed by June 18, 2013. The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 1 week, weekly until conditions are lifted, monthly for 3 months and then as determined by the QAI calendar. These audits will include any physician or non-physician practitioners that are rounding in the facility on the day of the audit. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.	

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	was a nurse practitioner who was going to a meeting when her patient saw her. The patient flagged the employee over to talk. The employee did not deny the lack of hand washing upon entering the in-center treatment floor or the fact she did not sanitized the stethoscope before using it on the patient. 2.) As the NP left the in-center treatment floor, the NP failed to wash or sanitized her hands. B. At 3:30 PM, during initiation of dialysis on patient #10, employee E left the patient still wearing the gloves she had on during the prep of the patient for dialysis, charted on the computer, then went back to the dialysis machine and touched the machine. Still with the same gloves on, the employee then connected the patient to the dialysis machine and started the dialysis machine. The employee then took off the gloves and cleansed her hands.			

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V000115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation and review of facility policy, the facility failed to ensure personal protective equipment (PPE) was utilized in 1 (# 1) of 1 nurse practitioner observations creating the potential to affect all of the facility's 74 current patients. The findings include: 1. Facility's 1-4-12 "Personal Protective Equipment" policy number FMS-CS-IC-II-155-080 A states, "Personal protective equipment such as a full face shield or mask and protective eyewear with full side shield, fluid-resistant gowns and gloves will be worn to protect and prevent employee from blood or other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes, or work clothes when performing procedures during	V000115	The Clinical Manager is responsible to ensure that all staff members follow “Personal Protective Equipment” policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members including the nurse practitioner on the following policy “Personal Protective Equipment” FMS-CS-IC-II-155-080A with emphasis placed on appropriate PPE and glove usage. Training was completed on June 7, 2013 and an in-service attendance sheet is available in the facility for review in addition an audit with skills checks will be completed by June 18, 2013. The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control	06/18/2013

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	which spurting or splattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood)." 2. At 1:35 PM on 5/20/13, nurse practitioner (NP), employee D, was observed to enter the in-center treatment floor without donning any PPE. Without washing or sanitizing her hands or donning gloves she entered into treatment area # 11 where patient #9 was dialyzing. She then removed a stethoscope from around her neck and listened to the patients lungs and chest then replaced the stethoscope back around her neck. The NP then touched the patients ankle and the top of her left foot without wearing any gloves.		audit tool are done daily for 1 week, weekly until conditions are lifted, monthly for 3 months and then as determined by the QAI calendar. These audits will include any physician or non-physician practitioners that are rounding in the facility on the day of the audit. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.	

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V000116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. Based on observation, interview, and review of facility policy, the facility failed to ensure equipment was disinfected before taking into a common area or used on a patient in 1 (# 1) of 1 nurse practitioner observations creating the potential to affect all of the facility's 74 current patients. The findings include: 1. Policy FMS-CS-IC-II-155-123 A, Effective Date, issue date January 04, 2012, titled "Cleaning and Disinfection of the Stethoscope" states, "All reusable instruments and equipment will be thoroughly cleaned and disinfected prior to use on a patient."	V000116	The Clinic Manager addressed cross-contamination issues with stethoscopes and proper disinfection with staff and the nurse practitioner through an in-service conducted by the clinic educator on June 7, 2013. Proper disinfection should be used after use as described in policy “Cleaning and Disinfection of the Stethoscope” FMS-CS-IC-II-155-123A. The clinic Manager will be responsible for ensuring proper disinfection of non-disposable equipment is performed before and after using supplies as evidenced by conducting an infection control audit daily for 1 week, weekly until conditions are lifted, monthly for 3 months and	06/07/2013

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	2. At 1:35 PM on 5/20/13, nurse practitioner (NP), employee D, was observed to enter the in-center treatment floor without donning any PPE. Without washing or sanitizing her hands or donning gloves she entered into treatment area # 11 where patient # 9 was dialyzing. She then removed a stethoscope from around her neck and listened to the patients lungs and chest then replaced the stethoscope back around her neck. The NP failed o disinfect the stethoscope prior to use. At 1:38 PM,employee D indicated she is a nurse practitioner who was going to a meeting when her patient saw her. The patient flagged the employee over to talk. The employee did not deny the fact she did not sanitized the stethoscope before using it on the patient.		then as determined by the QAI calendar. These audits will include any physician or non-physician practitioners that are rounding in the facility on the day of the audit. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate Compliance with this policy will be maintained by the clinic manager on an ongoing basis and will be reviewed with the QAI team and monitored by the Governing Body monthly.	

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V000175	494.40 CFC-WATER & DIALYSATE QUALITY Based on facility product water culture report review, policy review, personnel record review, administrative document review, and interview, it was determined the facility failed to ensure the facility policy was followed and an Action Plan was implemented to address the culture report results of the product water used to prepare dialysate or concentrates and to ensure the dialysate contained a total viable microbial count lower than 200 CFU/ mL and an action level of 20 CFU/ML in 1 of 1 water rooms reviewed with the potential to affect all the facility's patients (See V 178); failed to ensure the medical director followed their policy for monitoring the water bacteriology of the system for product water used to prepare dialysate or concentrates and product water contained a total viable microbial count lower than 200 CFU/mL and an action level of 20 CFU/ML for 1 of 1 facility reviewed with the potential to affect all the facility's patients (See V 179); failed to ensure they promptly took action and failed to notify the medical director when four of five months of cultures were above the action level for 1 of 1 facility reviewed with the potential to affect all in-center patients (See V 180); facility failed to ensure an Action Plan / Corrective Action was developed and	V000175	The Governing Body acknowledges its responsibility to ensure that the water and dialysate quality policies are followed and an action plan was implemented to address the culture report results of the product water used to prepare dialysate or concentrates and to ensure the dialysate contained a total viable microbial count lower then 200 CFU/ml and an action level of 20 CFU/ML, that adequate chlorine reagent test strips are available and appropriately used to check adequate percentage/parts per million of chlorine during disinfections and that staff are adequately trained to ensure the safety of all patients receiving dialysis. The Governing Body, met on June 6, 2013 to review the SOD and develop the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to	06/18/2013

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	implemented in response to the elevated cultures and antitoxins of the product water used to prepare dialysate and concentrates when the total viable microbial count was greater than or equal to 200 CFU / mL and / or was at an action level of 20 CFU / mL for 4 of 5 months of water cultures reviewed with the potential to affect all the facility's patients (See V 213); failed to ensure effective monitoring of the disinfection of the SDS (solution distribution system) between January 2013 and May 2013 which resulted in elevated culture results which reached facility action level and higher of 20 CFU / mL and reached and exceeded allowable limits of 200.0 CFU / mL of the sample product water collected from the bicarbonate distribution system return port for 4 of 5 months reviewed with the potential to affect all in-center patients (See V 219); failed to ensure the routine disinfection of the bicarbonate mixing system was adequate to ensure the product water was within accepted guidelines for 4 of 5 months of results reviewed in 1 of 1 facility reviewed with the potential to affect all current in-center patients (See V 230); failed to ensure the facility provided adequate chlorine reagent test strips and monitored for appropriate use to determine that the adequate percentage / parts per million of chlorine was reached during disinfection		quarterly or as needed meetings. Effective immediately: · The Technical Supervisor or Technical Program Manager will meet with the Clinical Manager prior to each QAI Committee meeting to review all monthly data and technical log results. · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's	

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	of the Bicarbonate system and equipment, per agency policy, for 1 of 1 facility reviewed with the potential to affect all the facility's in-center patients (See V 239); and failed to ensure practices audits showed competence, and included observation for, the conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing, and disinfecting testing at the point of use for staff conducting technical procedures for 6 of 6 training records reviewed of employees conducting testing creating the potential to affect all of the in-center facility's 74 current patients (See V 260). The cumulative effect of these systemic problems resulted in the facility's inability to assure proper testing of the water quality resulting in the potential risk to the patient's health and safety as required by the Condition for Coverage 494.40: Water and Dialysate Quality.		direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V178 describes, in detail, the processes and monitoring steps taken to ensure that facility policy is followed and an action plan is implemented to address the culture report results of the product water used to prepare dialysate or concentrates. · The response provided in V179 describes, in detail, the processes and monitoring steps taken to ensure that the medical director follows policy for monitoring the water bacteriology of the system for product water used to prepare dialysate or concentrates. · The response provided in V180 describes, in detail, the processes and monitoring steps taken to ensure that prompt action is taken and that the medical director is notified when cultures are above action level. · The response provided in V213 describes, in detail, the processes and monitoring steps taken to ensure that corrective action is implemented in response to elevated cultures and antitoxins of the product water used to prepare dialysate or	

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			concentrates. · The response provided in V219 describes, in detail, the processes and monitoring steps taken to ensure effective monitoring of the disinfection of the solution delivery system. · The response provided in V230 describes, in detail, the processes and monitoring steps taken to ensure that the routine disinfection of the bicarbonate mixing system is adequate. · The response provided in V239 describes, in detail, the processes and monitoring steps to ensure that adequate chlorine reagent test strips are provided and monitored for appropriate use to determine that the adequate percentage/parts per million of chlorine was reached during disinfection of the bicarbonate system and equipment. · The response provided in V260 describes, in detail, the processes and monitoring steps to ensure that staff competencies include observations for the conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing, and disinfecting testing at the point of use for all staff conducting technical procedures.	

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V000178	494.40(a) BACT OF H20-MAXIMUM & ACTION LEVELS 4.1.2 Bacteriology of water: max & action levels Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels. Based on facility product water culture report review, policy review, personnel record review, administrative document review, and interview, the facility failed to ensure the facility policy was followed and an Action Plan was implemented to address the culture report results of the product water used to prepare dialysate or concentrates and to ensure the dialysate contained a total viable microbial count lower than 200 CFU/ mL and an action level of 20 CFU/ML in 1 of 1 water rooms reviewed with the potential to affect all the facility's patients. Findings: 1. A policy titled "FMS Technical Services Department Microbiological	V000178	On 5-22-13, the CM, DO & TPM implemented a notification process for all Water & Dialysate results as made available from Spectra Laboratories. Training was completed on Friday 5-24-13 and an in-service attendance sheet is available in the facility for review. The Clinical Manager met with the facility Education Coordinator and the Technical Program Manager to arrange and schedule staff in-services to educate all staff members on the following policy “Microbiological Monitoring of Water used for Dialysis Purposes-Samples” FMS-CS-IC-II-140-600A2, “Microbiological Monitoring of Water Used for Dialysis Purposes”	06/07/2013

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	Monitoring of Dialysate", Effective Date 31-Jul-2009, FMS-TS-IC-I-500-000-A, states, "Purpose To establish FMCNA standards for bacteria and endotoxin in final dialysate and monitor compliance therewith. ... Standards and References Water microbiological contaminants will be monitored using the following action level and allowable limits: Test Bacteria Sample Category Dialysate Action Level 20 CFU/ml Allowable Limit 200 CFU/ml. Policy Samples will be taken under the following conditions: ... Prior to daily cleaning and disinfection. ... Water Results Corrective Actions Corrective actions must be undertaken in the area of the suspected cause for exceeding the action level. ... Test Results Exceeding the Allowable Limit in the event test results are above the allowable limits you must promptly do the following: ... Notify the Medical Director. ... Validation Protocol Water treatment systems, or individual components, will be validated by testing the aforementioned site(s) weekly for a minimum of 4 weeks. Results obtained during this period will be used to assure the systems disinfection protocol is effectively meeting established action levels. ... Disinfection of the R.O. [Reverse Osmosis] or storage tank and distribution piping was required outside of the normal schedule of disinfection to resolve micro biological test results that		FMS-CS-IC-II-140-600A1, "Microbiological Monitoring of Water Used for Dialysis Purposes" FMS-CS-IC-II-140-600C1. Training was completed on June 7, 2013 and an in-service attendance sheet is available in the facility for review. On 5-29-13, the TOM and TPM met to establish a process by which the QAI committee is informed of any water and dialysate results exceeding FMC action levels. Accordingly, Biomed Techs will log onto Korus or obtain hard copies of water and dialysate sample results within 48 hours of posted results. Any results exceeding FMC action levels will be immediately communicated to the CM, MD, DO, TS, TPM and TOM. The QAI committee will take the appropriate corrective action(s) to address the outcome. TS/TPM and Biomed will review all water and dialysate results, weekly with the CM and adjust action plan as needed. Escalations to MD, DO/OM, TOM, will occur if FMC action levels are breached. Notification of communication and action(s) will be documented on the lab result, reviewed at the next QAI meeting and maintained in the Water Quality Manual.	

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	exceeded either the Action level or Allowable Limits. If any Pre disinfection test result meets or exceeds action levels or allowable limits." 2. A facility product water concentration result titled "Bicarbonate Dist Sys. Return" (Bicarbonate Distribution System Return), dated 1/10/13 evidenced a 48 Hr Colony Count of >200.0 AH [Abnormally High] CFU/ML [Colony Forming Units / milliliter]. A. Results dated 1/17/13 were 108.0 CFU and 2.12 EU/mL [endotoxin units / milliliter]. B. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/7/13 05:00, evidenced a 48 Hour (hr) Colony Count of 56.0 AH CFU/ML. Signed by the Medical Director 4/11/13. C. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/14/13 16:50, evidenced a 48 Hr Colony Count of 40.0 AH CFU/ML. Signed by the Medical Director 3/24/13. D. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/21/13 17:00		The Clinical Manager is responsible for ensuring that no staff member performs water or dialysate cultures until a skill's checklist is completed and approved by the Governing Body. The QAI Committee will review a 6 month trend of any water and dialysate results exceeding FMC action level monthly for the next 6 months, to aid in the determination of actions or action plans. The CM is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.	

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	and 21:30 (pre and post disinfection sample), evidenced there was no sample received for a colony and endotoxin to be assessed. The results were signed by the Medical Director and dated 4/11/13. E. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/28/13 16:30, evidenced a 48 Hr Colony Count of 180.0 AH CFU/ML. Signed by the Medical Director 4/25/13. F. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/4/13 15:26, evidenced a 48 Hr Colony Count of 110.0 AH CFU/ML. Signed by the Medical Director 4/25/13. G. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/11/13 14:30, evidenced a 48 Hr Colony Count of 192.0 AH CFU/ML. Signed by the Medical Director 4/25/13. H. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced a 48 Hr Colony Count of greater than 200.0 AH CFU/ML. Unsigned by the Medical Director.			

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	3. Administrative document titled "Action Plan" dated 4/25/13 states, "Opportunity Statement (Focus-baseline data): Some above action level colony counts have been coming back on sds (solution delivery system), They are intermittent. Goal (Focus-measurable goal and time frame): To irradiate any and all issues that may be causing or assisting in the cause of potential bacteria growth. Root Causes (Analyze with Brainstorming - Select 1-2 Root Causes) : Improper collection frequency. A small leak underneath (sic) Bicarbonate tank #1, Improper collection technique. Team Members: [Employee C and Employee I] Bio med Technicians." The Action Plan evidenced the Action Steps were: A. Do an acidified bleach sani (sanitization) on SDS by clinical staff to be completed by 4/25/13. B. The Action Plan evidenced to Repair small leak under tank # 1. Employee C and Employee I to complete. C. The Action Plan evidenced to complete a 10% bleach disinfect by Employee C by 4/28/13. D. The Action Plan evidenced to complete a 4 week validation process by Employee C to be completed by 5/28/13			

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	and start 4/25/13. E. The Action Plan evidenced the Bio Technician, Employee C was to assume the monthly culturing duties. (relieving the clinical staff of the duty) Employee C and Employee J to start 4/29/13. 4. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan. The facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced employee E, a patient care technician, collected the monthly cultures for Week # 2 of the Action Plan. 5. The personnel file for employee E, a patient care technician, date of hire 10/29/12, failed to evidence the employee had been trained to cleanly collect monthly cultures. 6. On May 17, 2013, at 2 PM, Employee C, the Bio Technician, indicated he had trained employee E to collect the water samples though he did not document the training. 7. On May 17, 2013, at 3:10 PM, the			

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	surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the laboratory results dated 5/10/13 from a computer terminal and indicated he was just then aware that the laboratory results were abnormally high from the previous week. 8. On May 22, 2013, at 1:30 PM, Employee J, the Regional Bio Tech, indicated the Action Plan had not been followed or achieved. He indicated there was nothing to present to show that work had been completed or a root cause analysis had been done for the Bicarbonate system. He further indicated a significant amount of work had been done in the work room. When asked to present the documentation, he indicated there was nothing that related to the Bicarbonate system. 9. On May 22, 2013, at 1:30 PM, Employee P, the Regional Operations Manager, indicated the Action Plan had not approved by the QAI but had been emailed to her only. She indicated she did not have computer access to the water sample results and she must wait for the bio technicians to print and present it. 10. On May 22, 2013, at 1:30 PM, Employee A, the clinic nurse manager,			

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	indicated she did not have computer access to the water sample results. She indicated only the bio med technicians and department have computer access to these results and she must wait for those results to be printed and presented to review. 11. On May 22, 2013, at 3:00 PM, Employee J, the Regional Bio Tech, presented the employee file for Employee C after indicating Employee C had been disciplined for his work record in the water room. The discipline related to not completing paperwork correctly in January 2013. The record failed to evidence Employee C was coached and retrained for the bicarbonate system, sanitizing, drawing cultures, documentation, and troubleshooting. 12. On May 22, 2013, at 2:11 PM, Employee O, the Medical Director, indicated she had a folder for water results to be placed in when she is not in the facility. She often has to find the Bio Tech to get the water results as they are not in her folder. She is not called when the results are high and her beeper or her business partner's beeper are on at all times. She indicated the Bio Tech has a problem area with communication with higher level staff.			

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V000179	494.40(a) BACT OF H20-MEDICAL DIRECTOR RESPONSIBLE 4.1.2 Bacteriology of water: med dir resp The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.			
	Based on facility product water concentration document review, policy review, personnel record review, administrative document review, and interview, the medical director failed to ensure the facility followed their policy for monitoring the water bacteriology of the system for product water used to prepare dialysate or concentrates and product water contained a total viable microbial count lower than 200 CFU/mL and an action level of 20 CFU/ML for 1 of 1 facility reviewed with the potential to affect all the facility's patients. Findings: 1. A policy titled "FMS Technical Services Department Microbiological	V000179	On 5-22-13, the CM, DO & TPM implemented a notification process for all Water & Dialysate results as made available from Spectra Laboratories. Training was completed on Friday 5-24-13 and an in-service attendance sheet is available in the facility for review. In addition to the notification process, the Medical Director will be notified of any action level results on her pager. If she is unavailable her partner will be notified. The clinical manager or her designee will be responsible for ensuring that this notification takes place. The Clinical Manager met with the facility Education Coordinator and the Technical Program	06/07/2013

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	exceeded either the Action level or Allowable Limits. If any Pre disinfection test result meets or exceeds action levels or allowable limits." 2. A facility product water concentration result titled "Bicarbonate Dist Sys. Return" (Bicarbonate Distribution System Return), dated 1/10/13 evidenced a 48 Hr Colony Count of >200.0 AH [Abnormally High] CFU/ML [Colony Forming Units / milliliter]. A. Results dated 1/17/13 were 108.0 CFU and 2.12 EU/mL [endotoxin units / milliliter]. B. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/7/13 05:00, evidenced a 48 Hour (hr) Colony Count of 56.0 AH CFU/ML. Signed by the Medical Director 4/11/13. C. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/14/13 16:50, evidenced a 48 Hr Colony Count of 40.0 AH CFU/ML. Signed by the Medical Director 3/24/13. D. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/21/13 17:00		in the Water Quality Manual. The Clinical Manager is responsible for ensuring that no staff member performs water or dialysate cultures until a skills checklist is documented and complete and approved by the Governing Body. The QAI Committee will review a 6 month trend of any water and dialysate results exceeding FMC action level monthly for the next 6 months, to aid in the determination of actions or action plans. The CM is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. As follow up to notification, the MD will review and sign, on or before the next QAI meeting, the monthly Korus Environmental Report including any individual water and dialysate results exceeding FMC action level as previously identified.	

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	and start 4/25/13. E. The Action Plan evidenced the Bio Technician, Employee C was to assume the monthly culturing duties. (relieving the clinical staff of the duty) Employee C and Employee J to start 4/29/13. 4. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan. The facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced employee E, a patient care technician, collected the monthly cultures for Week # 2 of the Action Plan. 5. The personnel file for employee E, a patient care technician, date of hire 10/29/12, failed to evidence the employee had been trained to cleanly collect monthly cultures. 6. On May 17, 2013, at 2 PM, Employee C, the Bio Technician, indicated he had trained employee E to collect the water samples though he did not document the training. 7. On May 17, 2013, at 3:10 PM, the			

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	surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the laboratory results dated 5/10/13 from a computer terminal and indicated he was just then aware that the laboratory results were abnormally high from the previous week. 8. On May 22, 2013, at 1:30 PM, Employee J, the Regional Bio Tech, indicated the Action Plan had not been followed or achieved. He indicated there was nothing to present to show that work had been completed or a root cause analysis had been done for the Bicarbonate system. He further indicated a significant amount of work had been done in the work room. When asked to present the documentation, he indicated there was nothing that related to the Bicarbonate system. 9. On May 22, 2013, at 1:30 PM, Employee P, the Regional Operations Manager, indicated the Action Plan had not approved by the QAI but had been emailed to her only. She indicated she did not have computer access to the water sample results and she must wait for the bio technicians to print and present it. 10. On May 22, 2013, at 1:30 PM, Employee A, the clinic nurse manager,			

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	indicated she did not have computer access to the water sample results. She indicated only the bio med technicians and department have computer access to these results and she must wait for those results to be printed and presented to review. 11. On May 22, 2013, at 3:00 PM, Employee J, the Regional Bio Tech, presented the employee file for Employee C after indicating Employee C had been disciplined for his work record in the water room. The discipline related to not completing paperwork correctly in January 2013. The record failed to evidence Employee C was coached and retrained for the bicarbonate system, sanitizing, drawing cultures, documentation, and troubleshooting. 12. On May 22, 2013, at 2:11 PM, Employee O, the Medical Director, indicated she had a folder for water results to be placed in when she is not in the facility. She often has to find the Bio Tech to get the water results as they are not in her folder. She is not called when the results are high and her beeper or her business partner's beeper are on at all times. She indicated the Bio Tech has a problem area with communication with higher level staff.			

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	13. A policy titled "Revised and Restated Governing Body Bylaws", Revised May 23, 2011, states, "Each Facility shall have its own medical director, who shall be responsible for overseeing the quality of care and professional activities within the Facility."			

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V000180	494.40(a) BACT CONVENT DIALYSATE-MAX & ACTION LEVELS 4.3.2.1 Bacteriology of conventional dialysate: max & action limits Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL. The action level for the total viable microbial count in conventional dialysate should be 50 CFU/mL and the action level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels. Based on facility product water concentration review policy review, personnel record review, administrative document review, and interview, the facility failed to ensure they promptly took action when four of five months of cultures (January, March, April, and May 2013) were above the action level for 1 of 1 facility reviewed with the potential to affect all in-center patients. Findings: 1. A policy titled "FMS Technical Services Department Microbiological Monitoring of Dialysate", Effective Date 31-Jul-2009, FMS-TS-IC-I-500-000-A, states, "Purpose To establish FMCNA standards for bacteria and endotoxin in	V000180	On 5-22-13, the CM, DO & TPM implemented a notification process for all Water & Dialysate results as made available from Spectra Laboratories. Training was completed on Friday 5-24-13 and an in-service attendance sheet is available in the facility for review. The Clinical Manager met with the facility Education Coordinator and the Technical Program Manager to arrange and schedule staff in-services to educate all staff members on the following policy “Microbiological Monitoring of Water used for Dialysis Purposes-Samples” FMS-CS-IC-II-140-600A2, “Microbiological Monitoring of Water Used for Dialysis Purposes”	06/07/2013

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	final dialysate and monitor compliance therewith. ... Standards and References Water microbiological contaminants will be monitored using the following action level and allowable limits: Test Bacteria Sample Category Dialysate Action Level 20 CFU/ml Allowable Limit 200 CFU/ml. Policy Samples will be taken under the following conditions: ... Prior to daily cleaning and disinfection. ... Water Results Corrective Actions Corrective actions must be undertaken in the area of the suspected cause for exceeding the action level. ... Test Results Exceeding the Allowable Limit in the event test results are above the allowable limits you must promptly do the following: ... Notify the Medical Director. ... Validation Protocol Water treatment systems, or individual components, will be validated by testing the aforementioned site(s) weekly for a minimum of 4 weeks. Results obtained during this period will be used to assure the systems disinfection protocol is effectively meeting established action levels. ... Disinfection of the R.O. [Reverse Osmosis] or storage tank and distribution piping was required outside of the normal schedule of disinfection to resolve micro biological test results that exceeded either the Action level or Allowable Limits. If any Pre disinfection test result meets or exceeds action levels or allowable limits."		FMS-CS-IC-II-140-600A1, "Microbiological Monitoring of Water Used for Dialysis Purposes" FMS-CS-IC-II-140-600C1. Training was completed on June 7, 2013 and an in-service attendance sheet is available in the facility for review. On 5-29-13, the TOM and TPM met to establish a process by which the QAI committee is informed of any water and dialysate results exceeding FMC action levels. Accordingly, Biomed Techs will log onto Korus or obtain hard copies of water and dialysate sample results within 48 hours of posted results. Any results exceeding FMC action levels will be immediately communicated to the CM, MD, DO, TS, TPM and TOM. The QAI committee will take the appropriate corrective action(s) to address the outcome. TS/TPM and Biomed will review all water and dialysate results, weekly with the CM and adjust action plan as needed. Escalations to MD, DO/OM, TOM, will occur if FMC action levels are breached. Notification of communication and action(s) will be documented on the lab result, reviewed at the next QAI meeting and maintained in the Water Quality Manual.	

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	2. A facility product water concentration result titled "Bicarbonate Dist Sys. Return" (Bicarbonate Distribution System Return), dated 1/10/13 evidenced a 48 Hr Colony Count of >200.0 AH [Abnormally High] CFU/ML [Colony Forming Units / milliliter]. A. Results dated 1/17/13 were 108.0 CFU and 2.12 EU/mL [endotoxin units / milliliter]. B. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/7/13 05:00, evidenced a 48 Hour (hr) Colony Count of 56.0 AH CFU/ML. Signed by the Medical Director 4/11/13. C. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/14/13 16:50, evidenced a 48 Hr Colony Count of 40.0 AH CFU/ML. Signed by the Medical Director 3/24/13. D. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/21/13 17:00 and 21:30 (pre and post disinfection sample), evidenced there was no sample received for a colony and endotoxin to be assessed. The results were signed by the		The Clinical Manager is responsible for ensuring that no staff member performs water or dialysate cultures until a documented skills checklist is completed and approved by the Governing Body. The QAI Committee will review a 6 month trend of any water and dialysate results exceeding FMC action level monthly for the next 6 months, to aid in the determination of actions or action plans. The CM is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.	

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	Medical Director and dated 4/11/13. E. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/28/13 16:30, evidenced a 48 Hr Colony Count of 180.0 AH CFU/ML. Signed by the Medical Director 4/25/13. F. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/4/13 15:26, evidenced a 48 Hr Colony Count of 110.0 AH CFU/ML. Signed by the Medical Director 4/25/13. G. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/11/13 14:30, evidenced a 48 Hr Colony Count of 192.0 AH CFU/ML. Signed by the Medical Director 4/25/13. H. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced a 48 Hr Colony Count of greater than 200.0 AH CFU/ML. Unsigned by the Medical Director. 3. Administrative document titled "Action Plan" dated 4/25/13 states, "Opportunity Statement (Focus-baseline data): Some above action level colony			

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	counts have been coming back on sds (solution delivery system), They are intermittent. Goal (Focus-measurable goal and time frame): To irradiate any and all issues that may be causing or assisting in the cause of potential bacteria growth. Root Causes (Analyze with Brainstorming - Select 1-2 Root Causes) : Improper collection frequency. A small leak underneath (sic) Bicarbonate tank #1, Improper collection technique. Team Members: [Employee C and Employee I] Bio med Technicians." The Action Plan evidenced the Action Steps were: A. Do an acidified bleach sani (sanitization) on SDS by clinical staff to be completed by 4/25/13. B. The Action Plan evidenced to Repair small leak under tank # 1. Employee C and Employee I to complete. C. The Action Plan evidenced to complete a 10% bleach disinfect by Employee C by 4/28/13. D. The Action Plan evidenced to complete a 4 week validation process by Employee C to be completed by 5/28/13 and start 4/25/13. E. The Action Plan evidenced the Bio Technician, Employee C was to assume			

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	the monthly culturing duties. (relieving the clinical staff of the duty) Employee C and Employee J to start 4/29/13. 4. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan. The facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced employee E, a patient care technician, collected the monthly cultures for Week # 2 of the Action Plan. 5. The personnel file for employee E, a patient care technician, date of hire 10/29/12, failed to evidence the employee had been trained to cleanly collect monthly cultures. 6. On May 17, 2013, at 2 PM, Employee C, the Bio Technician, indicated he had trained employee E to collect the water samples though he did not document the training. 7. On May 17, 2013, at 3:10 PM, the surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the laboratory results dated 5/10/13 from			

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	a computer terminal and indicated he was just then aware that the laboratory results were abnormally high from the previous week. 8. On May 22, 2013, at 1:30 PM, Employee J, the Regional Bio Tech, indicated the Action Plan had not been followed or achieved. He indicated there was nothing to present to show that work had been completed or a root cause analysis had been done for the Bicarbonate system. He further indicated a significant amount of work had been done in the work room. When asked to present the documentation, he indicated there was nothing that related to the Bicarbonate system. 9. On May 22, 2013, at 1:30 PM, Employee P, the Regional Operations Manager, indicated the Action Plan had not approved by the QAI but had been emailed to her only. She indicated she did not have computer access to the water sample results and she must wait for the bio technicians to print and present it. 10. On May 22, 2013, at 1:30 PM, Employee A, the clinic nurse manager, indicated she did not have computer access to the water sample results. She indicated only the bio med technicians and department have computer access to			

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	these results and she must wait for those results to be printed and presented to review. 11. On May 22, 2013, at 3:00 PM, Employee J, the Regional Bio Tech, presented the employee file for Employee C after indicating Employee C had been disciplined for his work record in the water room. The discipline related to not completing paperwork correctly in January 2013. The record failed to evidence Employee C was coached and retrained for the bicarbonate system, sanitizing, drawing cultures, documentation, and troubleshooting. 12. On May 22, 2013, at 2:11 PM, Employee O, the Medical Director, indicated she had a folder for water results to be placed in when she is not in the facility. She often has to find the Bio Tech to get the water results as they are not in her folder. She is not called when the results are high and her beeper or her business partner's beeper are on at all times. She indicated the Bio Tech has a problem area with communication with higher level staff.			

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V000213	494.40(a) DIST SYS-CULTURE/LAL/SITES/FREQ(NEW)/L OG 6.3.3 Water distribution systems: culture/LAL sample sites/frequency (new)/log Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL] 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. Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken. Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3). All bacteria and endotoxin results should be recorded on a log sheet to identify trends			

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	that may indicate the need for corrective action. Based on administrative document review and interview, the facility failed to ensure an Action Plan / Corrective Action was developed and implemented in response to the elevated cultures and antitoxins of the product water used to prepare dialysate and concentrates when the total viable microbial count was greater than or equal to 200 CFU / mL and / or was at an action level of 20 CFU / mL for 4 of 5 months of water cultures reviewed. (January, March, April, and May 2013) with the potential to affect all the facility's patients. Findings: 1. A policy titled "FMS Technical Services Department Microbiological Monitoring of Dialysate", Effective Date 31-Jul-2009, FMS-TS-IC-I-500-000-A, states, "Purpose To establish FMCNA standards for bacteria and endotoxin in final dialysate and monitor compliance therewith. ... Standards and References Water microbiological contaminants will be monitored using the following action level and allowable limits: Test Bacteria Sample Category Dialysate Action Level 20 CFU/ml Allowable Limit 200 CFU/ml. Policy Samples will be taken under the following conditions: ... Prior to daily	V000213	On 6-6-13, the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed immediately and with long term resolution. In addition, a Bicarb Distribution System (SDS) action plan has been created and was approved by the Governing Body on 6-6-13. The Clinical Manager met with the facility Education Coordinator and the Technical Program Manager to arrange and schedule staff in-services to educate all staff members on the following policy "Microbiological Monitoring of Water used for Dialysis Purposes-Samples" FMS-CS-IC-II-140-600A2, "Microbiological Monitoring of Water Used for Dialysis Purposes" FMS-CS-IC-II-140-600A1, "Microbiological Monitoring of Water Used for Dialysis Purposes" FMS-CS-IC-II-140-600C1. Training was completed on June 7, 2013 and an in-service attendance sheet is available in the facility for review. The TS/TPM or assigned Biomed will follow the Bicarb Distribution System (SDS) action plan for bacterial remediation. The TS/TPM will provide weekly	06/07/2013

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	cleaning and disinfection. ... Water Results Corrective Actions Corrective actions must be undertaken in the area of the suspected cause for exceeding the action level. ... Test Results Exceeding the Allowable Limit in the event test results are above the allowable limits you must promptly do the following: ... Notify the Medical Director. ... Validation Protocol Water treatment systems, or individual components, will be validated by testing the aforementioned site(s) weekly for a minimum of 4 weeks. Results obtained during this period will be used to assure the systems disinfection protocol is effectively meeting established action levels. ... Disinfection of the R.O. [Reverse Osmosis] or storage tank and distribution piping was required outside of the normal schedule of disinfection to resolve micro biological test results that exceeded either the Action level or Allowable Limits. If any Pre disinfection test result meets or exceeds action levels or allowable limits." 2. A facility product water concentration result titled "Bicarbonate Dist Sys. Return" (Bicarbonate Distribution System Return), dated 1/10/13 evidenced a 48 Hr Colony Count of >200.0 AH [Abnormally High] CFU/ML [Colony Forming Units / milliliter].		updates of the action plan to the CM. The CM will provide weekly updates to the Governing Body until the condition is lifted, then monthly for three (3) months and quarterly thereafter or as needed.	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE BLOOMINGTON MONROE		STREET ADDRESS, CITY, STATE, ZIP CODE 575 S PATTERSON DR BLOOMINGTON, IN 47403	

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	A. Results dated 1/17/13 were 108.0 CFU and 2.12 EU/mL [endotoxin units / milliliter]. B. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/7/13 05:00, evidenced a 48 Hour (hr) Colony Count of 56.0 AH CFU/ML. Signed by the Medical Director 4/11/13. C. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/14/13 16:50, evidenced a 48 Hr Colony Count of 40.0 AH CFU/ML. Signed by the Medical Director 3/24/13. D. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/21/13 17:00 and 21:30 (pre and post disinfection sample), evidenced there was no sample received for a colony and endotoxin to be assessed. The results were signed by the Medical Director and dated 4/11/13. E. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/28/13 16:30, evidenced a 48 Hr Colony Count of 180.0 AH CFU/ML. Signed by the Medical Director 4/25/13.			

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	F. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/4/13 15:26, evidenced a 48 Hr Colony Count of 110.0 AH CFU/ML. Signed by the Medical Director 4/25/13. G. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/11/13 14:30, evidenced a 48 Hr Colony Count of 192.0 AH CFU/ML. Signed by the Medical Director 4/25/13. H. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced a 48 Hr Colony Count of greater than 200.0 AH CFU/ML. Unsigned by the Medical Director. 3. Administrative document titled "Action Plan" dated 4/25/13 states, "Opportunity Statement (Focus-baseline data): Some above action level colony counts have been coming back on sds (solution delivery system), They are intermittent. Goal (Focus-measurable goal and time frame): To irradiate any and all issues that may be causing or assisting in the cause of potential bacteria growth. Root Causes (Analyze with Brainstorming - Select 1-2 Root Causes) : Improper collection frequency. A small			

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	leak underneath (sic) Bicarbonate tank #1, Improper collection technique. Team Members: [Employee C and Employee I] Bio med Technicians." The Action Plan evidenced the Action Steps were: A. Do an acidified bleach sani (sanitization) on SDS by clinical staff to be completed by 4/25/13. B. The Action Plan evidenced to Repair small leak under tank # 1. Employee C and Employee I to complete. C. The Action Plan evidenced to complete a 10% bleach disinfect by Employee C by 4/28/13. D. The Action Plan evidenced to complete a 4 week validation process by Employee C to be completed by 5/28/13 and start 4/25/13. E. The Action Plan evidenced the Bio Technician, Employee C was to assume the monthly culturing duties. (relieving the clinical staff of the duty) Employee C and Employee J to start 4/29/13. 4. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan.			

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	The facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced employee E, a patient care technician, collected the monthly cultures for Week # 2 of the Action Plan. 5. The personnel file for employee E, a patient care technician, date of hire 10/29/12, failed to evidence the employee had been trained to cleanly collect monthly cultures. 6. On May 17, 2013, at 2 PM, Employee C, the Bio Technician, indicated he had trained employee E to collect the water samples though he did not document the training. 7. On May 17, 2013, at 3:10 PM, the surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the laboratory results dated 5/10/13 from a computer terminal and indicated he was just then aware that the laboratory results were abnormally high from the previous week. 8. On May 22, 2013, at 1:30 PM, Employee J, the Regional Bio Tech, indicated the Action Plan had not been followed or achieved. He indicated there			

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	was nothing to present to show that work had been completed or a root cause analysis had been done for the Bicarbonate system. He further indicated a significant amount of work had been done in the work room. When asked to present the documentation, he indicated there was nothing that related to the Bicarbonate system. 9. On May 22, 2013, at 1:30 PM, Employee P, the Regional Operations Manager, indicated the Action Plan had not approved by the QAI but had been emailed to her only. She indicated she did not have computer access to the water sample results and she must wait for the bio technicians to print and present it. 10. On May 22, 2013, at 1:30 PM, Employee A, the clinic nurse manager, indicated she did not have computer access to the water sample results. She indicated only the bio med technicians and department have computer access to these results and she must wait for those results to be printed and presented to review. 11. On May 22, 2013, at 3:00 PM, Employee J, the Regional Bio Tech, presented the employee file for Employee C after indicating Employee C had been disciplined for his work record in the			

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	water room. The discipline related to not completing paperwork correctly in January 2013. The record failed to evidence Employee C was coached and retrained for the bicarbonate system, sanitizing, drawing cultures, documentation, and troubleshooting. 12. On May 22, 2013, at 2:11 PM, Employee O, the Medical Director, indicated she had a folder for water results to be placed in when she is not in the facility. She often has to find the Bio Tech to get the water results as they are not in her folder. She is not called when the results are high and her beeper or her business partner's beeper are on at all times. She indicated the Bio Tech has a problem area with communication with higher level staff. 13. A policy titled "Revised and Restated Governing Body Bylaws", Revised May 23, 2011, states, "Each Facility shall have its own medical director who shall be responsible for overseeing the quality of care and professional activities within the Facility.			

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V000219	494.40(a) BACT CONTROL-DISINFECT 1X/MO/DWELL 7 Strategies for bacterial control 7.1 General: disinfect monthly/disinfection dwell Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but disinfection must be performed at least monthly. A mechanism should be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period. Based on staff interview and review of facility documents and policy, the facility failed to ensure effective monitoring of the disinfection of the SDS (solution distribution system) between January 2013 and May 2013 which resulted in elevated culture results which reached facility action level and higher of 20 CFU / mL and reached and exceeded allowable limits of 200.0 CFU / mL of the sample product water collected from the bicarbonate distribution system return port for 4 of 5 months reviewed with the potential to affect all in-center patients. (January, March, April, and May) Findings: 1. On May 17, 2013, at 3:10 PM, the	V000219	Effective immediately at the date of the survey, all Hach Steri-chek Residual Chlorine strips were removed from the clinic and replaced with the Water Check RC reagent test strips with bleach indicator. On May 19, 2013, the Technical Program Manager educated all staff on the following policy "Disinfection of Bicarbonate Mixers using Bleach as the Disinfectant" 153-030-018. Staff re-educated on the above policy again on June 7, 2013 with an in-service attendance sheet available in the facility for review. The Clinical Manager is responsible for ensuring compliance by directly observing the staff while disinfecting the	06/07/2013

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	surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the 5/10/13 results from the computer terminal and indicated he was just then aware that the laboratory culture results were abnormally high. He indicated the facility had some elevated cultures from the B 17 port of the Bicarbonate distribution system, but there was no trend. The facility had contributed the results to human error related to these samples and they were the only water cultures the patient care technicians were collecting prior to disinfection of the bicarbonate distribution system which led to the belief that these elevated results were false. 2. On 5/17/13 at 3:55 PM, employee F, a patient care technician, indicated she disinfected the bicarbonate mixer and delivery system (mixes bicarbonate from powder and then delivers bicarbonate to all of the in-center dialysis machines) on April 18, 2013, as documented on the disinfection log. She indicated the facility did not use the hach meter for confirmation of the percentage of bleach solution, that the facility used chlorine reagent strips to ensure the adequate percent of solution was used during disinfection. She retrieved the vial of Residual Chlorine strips from the		bicarbonate system. Any issues of non-compliance will be addressed immediately by the Clinical Manager. The Clinical Manager will report a summary of findings monthly in QAI and the QAI Committee will provide oversight to ensure the correct reagent strips continue to be utilized.	

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	in-center unit and indicated the strips retrieved were used to measure the concentration of bleach. The strips produced were labeled Hach Steri-chek Residual Chlorine Reagent Strips # 811900 and the label provided a guide for four potential readings: 0.0 ppm (parts per million), 0.5 ppm, 1.0 ppm, and 5.0 ppm. Employee F indicated that when the strips turned very dark they knew they had a sufficient amount of chlorine and confirmed the strips registered the maximum of 5 parts per million. Employee C confirmed the chlorine concentration for disinfection was to be 500 parts per million and the reagent strips the patient care technician produced were the appropriate strips and "were used for years" for this purpose. 3. A policy titled "FMCNA Policy and Standards Manual Disinfection Standards for Equipment," Effective Date 04-04-07, number 152-030-017 states, "Solution Delivery System Requirements if Bleach is used as the disinfectant. ... Testing for the presence of bleach. Testing for the presence of bleach in the water in the SDS mix tank will be performed during bleach disinfection. ... Test the solution for the disinfection the Mixer with a residual strip to validate that the solution contains approximately 500 PPM bleach."			

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	4. Facility documents titled "BD - 1 Bicarbonate / SDS Bleach Disinfection Log Form" evidenced the SDS was disinfected weekly since the first week of January 2013 through May 9, 2013. The documents included the initials of the staff member that completed the disinfection and the disinfection agent used was bleach. The documents indicated each individual completing the disinfection obtained a 500 parts per million of bleach. 5. Sample product water culture and endotoxin results labeled as collected from the "BDS - return - Before, B 17" (Bicarbonate Distribution System collected before disinfection from port B 17 located on the bicarbonate mixer) was outside of acceptable range: a. Dated 1/10/13 results were greater than 200.0 CFU (colony forming units)." b. Dated 1/17/13 results were 108.0 CFU and 2.12 EU / mL (endotoxin units / milliliter). c. Dated 3/7/13 results were 56.0 CFU. d. Dated 3/14/13 results were 40.0 CFU. e. Dated 3/28/13 results were 180.0 CFU. f. Dated 4/4/13 results were 110.0 CFU.			

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	g. Dated 4/11/13 results were 192.0 CFU. h. Dated 5/10/13 results were greater than 200.0 CFU. February 2013 testing was within guidelines. 6. May 17, 2013, at 5:15 PM, the clinic manager indicated the facility did not have an Action Plan that addresses the elevated CFU results in January and March 2013. She indicated the action plan was as written by the Bio Technician, dated 4/25/13, to address the elevated water cultures of the bicarbonate system.			

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V000230	494.40(a) MIXING SYSTEMS-CLEANING 6.4.1 Mixing systems: cleaning Concentrate mixing equipment should be either: (1) completely emptied, cleaned, and disinfected according to the manufacturer's instructions; or (2) cleaned and disinfected using a procedure demonstrated by the facility to be effective in routinely producing concentrate meeting [these regulations related to allowable bacterial and endotoxin levels]. The disinfection data should be recorded for each ...disinfection cycle using a dedicated log. Based on interview and review of administrative documents and policy, the facility failed to ensure the routine disinfection of the bicarbonate mixing system was adequate to ensure the product water was within accepted guidelines for 4 of 5 months of results reviewed (January, March, April, and May) in 1 of 1 facility reviewed with the potential to affect all current in-center patients. The findings include: 1. On May 17, 2013, at 3:10 PM, the surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the 5/10/13 results from the computer terminal and indicated he was just then aware that the laboratory culture results	V000230	Effective immediately at the date of the survey, all Hach Steri-chek Residual Chlorine strips were removed from the clinic and replaced with the Water Check RC reagent test strips with bleach indicator. On May 19, 2013, the Technical Program Manager educated all staff on the following policy "Disinfection of Bicarbonate Mixers using Bleach as the Disinfectant" 153-030-018. Staff re-educated on the above policy again on June 7, 2013 with an in-service attendance sheet available in the facility for review. The Clinical Manager is responsible for ensuring compliance by directly observing the staff while disinfecting the bicarbonate system. Any issues of non-compliance will be addressed immediately by the	06/07/2013

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	were abnormally high. He indicated the facility had some elevated cultures from the B 17 port of the Bicarbonate distribution system, but there was no trend. The facility had contributed the results to human error related to these samples and they were the only water cultures the patient care technicians were collecting prior to disinfection of the bicarbonate distribution system which led to the belief that these elevated results were false. 2. On 5/17/13 at 3:55 PM, employee F, a patient care technician, indicated she disinfected the bicarbonate mixer and delivery system (mixes bicarbonate from powder and then delivers bicarbonate to all of the in-center dialysis machines) on April 18, 2013, as documented on the disinfection log. She indicated the facility did not use the hach meter for confirmation of the percentage of bleach solution, that the facility used chlorine reagent strips to ensure the adequate percent of solution was used during disinfection. She retrieved the vial of Residual Chlorine strips from the in-center unit and indicated the strips retrieved were used to measure the concentration of bleach. The strips produced were labeled Hach Steri-chek Residual Chlorine Reagent Strips # 811900 and the label provided a guide for		Clinical Manager. The Clinical Manager will report a summary of findings monthly in QAI and the QAI Committee will provide oversight to ensure the correct reagent strips continue to be utilized.	

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	four potential readings: 0.0 ppm (parts per million), 0.5 ppm, 1.0 ppm, and 5.0 ppm. Employee F indicated that when the strips turned very dark they knew they had a sufficient amount of chlorine and confirmed the strips registered the maximum of 5 parts per million. Employee C confirmed the chlorine concentration for disinfection was to be 500 parts per million and the reagent strips the patient care technician produced were the appropriate strips and "were used for years" for this purpose. 3. A policy titled "FMCNA Policy and Standards Manual Disinfection Standards for Equipment," Effective Date 04-04-07, number 152-030-017 states, "Solution Delivery System Requirements if Bleach is used as the disinfectant. ... Testing for the presence of bleach. Testing for the presence of bleach in the water in the SDS mix tank will be performed during bleach disinfection. ... Test the solution for the disinfection the Mixer with a residual strip to validate that the solution contains approximately 500 PPM bleach." 4. Facility documents titled "BD - 1 Bicarbonate / SDS Bleach Disinfection Log Form" evidenced the SDS was disinfected weekly since the first week of January 2013 through May 9, 2013. The documents included the initials of the			

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	staff member that completed the disinfection and the disinfection agent used was bleach. The documents indicated each individual completing the disinfection obtained a 500 parts per million of bleach. 5. Sample product water culture and endotoxin results labeled as collected from the "BDS - return - Before, B 17" (Bicarbonate Distribution System collected before disinfection from port B 17 located on the bicarbonate mixer) was outside of acceptable range: a. Dated 1/10/13 results were greater than 200.0 CFU (colony forming units)." b. Dated 1/17/13 results were 108.0 CFU and 2.12 EU / mL (endotoxin units / milliliter). c. Dated 3/7/13 results were 56.0 CFU. d. Dated 3/14/13 results were 40.0 CFU. e. Dated 3/28/13 results were 180.0 CFU. f. Dated 4/4/13 results were 110.0 CFU. g. Dated 4/11/13 results were 192.0 CFU. h. Dated 5/10/13 results were greater than 200.0 CFU. February 2013 testing was within			

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	guidelines. 6. May 17, 2013, at 5:15 PM, the clinic manager indicated the facility did not have an Action Plan that addresses the elevated CFU results in January and March 2013. She indicated the action plan was as written by the Bio Technician, dated 4/25/13, to address the elevated water cultures of the bicarbonate system.			

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FRESENIUS MEDICAL CARE BLOOMINGTON MONROE	575 S PATTERSON DR BLOOMINGTON, IN 47403

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V000239	494.40(a) BICARB CONC DISTRIB-WKLY DISINFECT/DWELL/CONC 5.5.4 Bicarbonate concentrate distribution systems: weekly disinfection/dwell times/conc Bicarbonate concentrate delivery systems should be disinfected on a regular basis to ensure that the dialysate routinely achieves the level of bacteriological purity [required by these regulations]. For piped distribution systems, the entire system, including patient station ports, should be purged of bicarbonate concentrate before disinfection. Each patient station port should be opened and flushed with disinfectant and then rinsed; otherwise, it would be a "dead leg" in the system. Appropriate dwell times and concentrations should be used as recommended by the manufacturer of the concentrate system. If this information is not available, bleach may be used at a dilution of 1:100 and proprietary disinfectants at the concentration recommended by the manufacturer for disinfecting piping systems. 6.5 Concentrate distribution: The interval between disinfection should not exceed 1 week. If the manufacturer does not supply disinfection procedures, the user must develop and validate a disinfection protocol. Based on interview and review of policy and documents, the facility failed to ensure the facility provided adequate chlorine reagent test strips and monitored for appropriate use to determine that the adequate percentage / parts per million of	V000239	Effective immediately at the date of the survey, all Hach Steri-chek Residual Chlorine strips were removed from the clinic and replaced with the Water Check RC reagent test strips with bleach indicator.	06/07/2013

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	chlorine was reached during disinfection of the Bicarbonate system and equipment, per agency policy, for 1 of 1 facility reviewed with the potential to affect all the facility's in-center patients. The findings include: 1. On May 17, 2013, at 3:10 PM, the surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the 5/10/13 results from the computer terminal and indicated he was just then aware that the laboratory culture results were abnormally high. He indicated the facility had some elevated cultures from the B 17 port of the Bicarbonate distribution system, but there was no trend. The facility had contributed the results to human error related to these samples and they were the only water cultures the patient care technicians were collecting prior to disinfection of the bicarbonate distribution system which led to the belief that these elevated results were false. 2. On 5/17/13 at 3:55 PM, employee F, a patient care technician, indicated she disinfected the bicarbonate mixer and delivery system (mixes bicarbonate from powder and then delivers bicarbonate to all of the in-center dialysis machines) on		On May 19, 2013, the Technical Program Manager educated all staff on the following policy "Disinfection of Bicarbonate Mixers using Bleach as the Disinfectant" 153-030-018. Staff re-educated on the above policy again on June 7, 2013 with an in-service attendance sheet available in the facility for review. The Clinical Manager is responsible for ensuring compliance by directly observing the staff while disinfecting the bicarbonate system. Any issues of non-compliance will be addressed immediately by the Clinical Manager. The Clinical Manager will report a summary of findings monthly in QAI and the QAI Committee will provide oversight to ensure the correct reagent strips continue to be utilized.	

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	April 18, 2013, as documented on the disinfection log. She indicated the facility did not use the hach meter for confirmation of the percentage of bleach solution, that the facility used chlorine reagent strips to ensure the adequate percent of solution was used during disinfection. She retrieved the vial of Residual Chlorine strips from the in-center unit and indicated the strips retrieved were used to measure the concentration of bleach. The strips produced were labeled Hach Steri-chek Residual Chlorine Reagent Strips # 811900 and the label provided a guide for four potential readings: 0.0 ppm (parts per million), 0.5 ppm, 1.0 ppm, and 5.0 ppm. Employee F indicated that when the strips turned very dark they knew they had a sufficient amount of chlorine and confirmed the strips registered the maximum of 5 parts per million. Employee C confirmed the chlorine concentration for disinfection was to be 500 parts per million and the reagent strips the patient care technician produced were the appropriate strips and "were used for years" for this purpose. 3. A policy titled "FMCNA Policy and Standards Manual Disinfection Standards for Equipment," Effective Date 04-04-07, number 152-030-017 states, "Solution Delivery System Requirements if Bleach			

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	is used as the disinfectant. ... Testing for the presence of bleach. Testing for the presence of bleach in the water in the SDS mix tank will be performed during bleach disinfection. ... Test the solution for the disinfection the Mixer with a residual strip to validate that the solution contains approximately 500 PPM bleach." 4. Facility documents titled "BD - 1 Bicarbonate / SDS Bleach Disinfection Log Form" evidenced the SDS was disinfected weekly since the first week of January 2013 through May 9, 2013. The documents included the initials of the staff member that completed the disinfection and the disinfection agent used was bleach. The documents indicated each individual completing the disinfection obtained a 500 parts per million of bleach. 5. Sample product water culture and endotoxin results labeled as collected from the "BDS - return - Before, B 17" (Bicarbonate Distribution System collected before disinfection from port B 17 located on the bicarbonate mixer) was outside of acceptable range: a. Dated 1/10/13 results were greater than 200.0 CFU (colony forming units)." b. Dated 1/17/13 results were 108.0 CFU and 2.12 EU / mL (endotoxin units /			

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	milliliter). c. Dated 3/7/13 results were 56.0 CFU. d. Dated 3/14/13 results were 40.0 CFU. e. Dated 3/28/13 results were 180.0 CFU. f. Dated 4/4/13 results were 110.0 CFU. g. Dated 4/11/13 results were 192.0 CFU. h. Dated 5/10/13 results were greater than 200.0 CFU. February 2013 testing was within guidelines.			

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V000260	494.40(a) PERSONNEL-TRAINING PROGRAM/PERIODIC AUDITS 9 Personnel: training program/periodic audits A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory. Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer. The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs). Periodic audits of the operators' compliance with procedures should be performed. The user should establish an ongoing training program designed to maintain the operator's knowledge and skills. Based on administrative record review and interview, the facility failed to ensure practice audits showed competence, and included observation for, the conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing, and disinfecting testing at the point of use for staff conducting technical procedures for 6 (E, F, K, L, N, and M) of 6 training records reviewed of employees conducting	V000260	On June 6, 2013, the Director of Operations and Regional Quality Manager met with the Medical Director to review her requirement to ensure that any staff conducting technical procedures for the conducting of water and dialysate testing, dialysate mixing, dialysate pH and rinsing and disinfecting testing at the point of use are properly trained with documentation available. The Clinical Manager met with the facility Education Coordinator and the Technical Program	06/19/2013

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	testing creating the potential to affect all of the in-center facility's 74 current patients. The findings include: 1. The facility's bicarbonate administrative records, Form: BD-1 and Form SDS-1, evidenced employees E, F, K, L, N, and M all performed total chlorine testing of the water and prepared the bicarbonate mixing and bicarbonate bleach disinfection log. 2. The annual training record dated 10-24-12 for employee M, date of hire 2-2-5 (DOH), failed to evidence the employee had been evaluated and observed for conducting the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee M performed the bicarbonate daily system rinse on 4-23-13.		Manager to arrange and schedule staff in-services to re-educate all staff members on the following policies “Total Chlorine Testing using the RPC Ultra low Total Chlorine test strip” FMS-CS-IC-II-140-205A, “Concentrate Mixing and Handling Solution Delivery System” FMS-TS-IC-200-220, “Concentrate Mixing and Handling: Bicarbonate Concentrate Testing” FMS-TS-IC-200-290A, “Testing for Residual Bleach using a Reagent Test Strip” FMS-CS-IC-II-140-800A, and “Disinfection of Bicarbonate Mixers using Bleach as the Disinfectant” 153-030-017. Training was completed on June 7, 2013 and an in-service attendance sheet is available in the facility for review. The TS/TPM or designee will validate all clinical personnel responsible for mixing and quality testing of concentrates and disinfection of the Bicarb delivery system utilizing manufacturer’s procedures and FMC validation skills checklist by 6-19-13. The Clinical Manager will ensure that only validated personnel are assigned to mix concentrates or disinfect the bicarbonate delivery system until all validation of skills is complete.	

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	3. The annual training record dated 11-5-12 for employee L, DOH 5-22-12, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee L performed the bicarbonate mixing on 4-26-13 and 4-29-13. 4. The annual training record dated 11-5-12 for employee N, DOH 12-5-11, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee N performed the bicarbonate daily		The Clinical Manager will report a summary of these training validations in QAI and maintain records in the employee personnel file. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI committee is responsible to monitor compliance.	

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	system rinse on 4-25-13. 5. The annual training record dated 11-5-12 for employee K, DOH 8-30-99, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Bicarb/SDS Bleach Disinfection Log Form" evidenced employee K preformed testing for the presence for bleach and the absence of chlorine bleach at Loop 1 on 5-2-13 and 5-16-13. On 4-27-13, the employee performed bicarbonate mixing. 6. The annual training record dated 10-15-12 for employee F, DOH 1-1-6, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and			

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	conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee F performed the bicarbonate mixing on 4-30-13. 7. The training record dated 2-20-13 for employee E, DOH 10-29-12, and the annual training record dated 4-18-13 failed to evidence the employee had been observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing and disinfecting testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Bicarb/SDS bleach Disinfection Log Form" evidenced employee E performed testing for the presence of bleach and the absence of chlorine bleach at Loop 1 on 5-9-13. 8. The facility manager, employee A, stated, on 5-22-13 at 3:20 PM, "I			

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	have completed the training and the annual updates for the water and on the water system, bicarbonate preparation, and validation for 2012 but not all completed for this year [2013].			

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V000625	494.110 CFC-QAPI Based on administrative document and policy review and interview, it was determined the facility failed to ensure a quality assessment and performance improvement program developed, implemented a process, and monitored to ensure there was a review and evaluation conducted of all patient deaths to determine if there was a relationship to the care received at the facility; developed and implemented a process to review product water sample results timely and developed and implemented a corrective action plan that addressed the elevated culture results of product water samples in 4 of 5 months of results reviewed for 1 of 1 facility with the potential to affect all current patients (See V 628); failed to ensure a quality assessment and performance improvement program addressed medical errors in 6 of 6 months of minutes reviewed creating the potential to affect all of the facility's 74 current patients (See V 634); and failed to ensure they immediately corrected an identified problem with the product water used to prepare dialysate or concentrates to ensure the product water contained a total viable microbial count lower than 200 CFU/mL and an action level of 20 CFU/ML in 1 of 1 water rooms reviewed with the potential to affect all the facility's patients (See V	V000625	The Governing Body acknowledges its responsibility to ensure that Fresenius Medical Care Bloomington has an effective, data driven Comprehensive Quality Assessment and Performance Improvement program that reviews patient deaths, implements a process to review water sample results timely and takes corrective action when elevated, and addresses adverse events. The Governing Body, on June 6, 2013 reviewed the SOD and developed the following Plan of Correction ensuring that the deficiencies are addressed, both immediately and with long term resolution. The following action steps were implemented The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. Effective immediately: · The Clinical Manager (CM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to	06/12/2013

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	640). The cumulative effect of these systemic problems resulted in the facility being out of compliance with the Condition for Coverage 494.110 Quality Assessment and Performance Improvement.		the QAI Committee. · A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. · The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution. · The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. · The Governing Body, at its meeting of June 6, 2013, designated the Regional Quality Manager to serve as Plan of Correction Monitor and provide additional oversight. She will actively participate in each QAI and Governing Body meeting - either personally or via conference call - and submit a status report at each of the referenced Governing Body meetings with a copy to the RVP. This additional oversight is to ensure the ongoing correction of deficiencies - as cited in the Statement of Deficiency - through to resolution as well as ensure the Governance of the facility is presented current and complete data to enhance their governance	

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			oversight role · The Regional Quality Manager will provide education on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A to the QAI committee on June 12, 2013 to include what korus reports will be used to show water culture trends and how to conduct a QAI meeting · Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committee's ongoing monitoring of facility activities. These are available for review at the facility. · The responses provided for V 628, V 634, and V 640 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance	

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V000628	494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. Based on administrative document and policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program developed, implemented a process, and monitored to ensure there was a review and evaluation conducted of all patient deaths to determine if there was a relationship to the care received at the facility; developed and implemented a process to review product water sample results timely and developed and implemented a corrective action plan that addressed the elevated culture results of product water samples in 4 of 5 months of results reviewed (January, March, April, and May 2013) for 1 of 1 facility with the potential to affect all current patients. The findings include: 1. The documents titled Facility Quality Assessment and Performance Improvement (QAPI) dated 11/29/12, 12/20/12, 1/24/13, 2/26/13, 3/28/13, and	V000628	On June 12, 2013 the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A. This education included but was not limited to the following: ·QAI Processes ·Mortality analysis and trending ·Water sample results reviewed timely and trended ·Action plans created to address elevated culture results The Clinical Manager will review the Mortality summary log and trending tool. Reports will be evaluated to determine if any patient death was a result of the care provided by the facility. The Clinical manager and the Technical Supervisor or Technical Program Manager will review all water sample results. Any items identified as not meeting an outcome will have an action plan developed and followed monthly.	06/12/2013

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	4/25/13 failed to evidence the facility developed and implemented a process to review product water sample results timely and implemented a corrective action plan that addressed the elevated culture results of product water samples in January, March, April, and May 2013. The minutes also failed to evidence an investigation was completed into potential causes of individual patient deaths, contributory factors, and any relationship to the care received at the facility. On 5/22/13 at 2 PM, the clinic manager indicated the QAPI minutes failed to evidence an analysis of the cause of death by the QAPI team members to determine if there was any relationship to the care received at the facility or any possible recognized or unrecognized complications that may have contributed to the death. As related to the monitoring of bacteria and endotoxin: 2. On May 17, 2013, at 3:10 PM, the surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the 5/10/13 results from the computer terminal and indicated he was just then aware that the laboratory culture results were abnormally high. He indicated the		The Clinical Manager is responsible to report a summary of findings monthly. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

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	facility had some elevated cultures from the B 17 port of the Bicarbonate distribution system, but there was no trend. The facility had contributed the results to human error related to these samples and they were the only water cultures the patient care technicians were collecting prior to disinfection of the bicarbonate distribution system which led to the belief that these elevated results were false. 3 On 5/17/13 at 3:55 PM, employee F, a patient care technician, indicated she disinfected the bicarbonate mixer and delivery system (mixes bicarbonate from powder and then delivers bicarbonate to all of the in-center dialysis machines) on April 18, 2013, as documented on the disinfection log. She indicated the facility did not use the hach meter for confirmation of the percentage of bleach solution, that the facility used chlorine reagent strips to ensure the adequate percent of solution was used during disinfection. She retrieved the vial of Residual Chlorine strips from the in-center unit and indicated the strips retrieved were used to measure the concentration of bleach. The strips produced were labeled Hach Steri-chek Residual Chlorine Reagent Strips # 811900 and the label provided a guide for four potential readings: 0.0 ppm (parts			

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	per million), 0.5 ppm, 1.0 ppm, and 5.0 ppm. Employee F indicated that when the strips turned very dark they knew they had a sufficient amount of chlorine and confirmed the strips registered the maximum of 5 parts per million. Employee C confirmed the chlorine concentration for disinfection was to be 500 parts per million and the reagent strips the patient care technician produced were the appropriate strips and "were used for years" for this purpose. 4. A policy titled "FMCNA Policy and Standards Manual Disinfection Standards for Equipment," Effective Date 04-04-07, number 152-030-017 states, "Solution Delivery System Requirements if Bleach is used as the disinfectant. ... Testing for the presence of bleach. Testing for the presence of bleach in the water in the SDS mix tank will be performed during bleach disinfection. ... Test the solution for the disinfection the Mixer with a residual strip to validate that the solution contains approximately 500 PPM bleach." 5. Facility documents titled "BD - 1 Bicarbonate / SDS Bleach Disinfection Log Form" evidenced the SDS was disinfected weekly since the first week of January 2013 through May 9, 2013. The documents included the initials of the staff member that completed the			

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	disinfection and the disinfection agent used was bleach. The documents indicated each individual completing the disinfection obtained a 500 parts per million of bleach. 6. Sample product water culture and endotoxin results labeled as collected from the "BDS - return - Before, B 17" (Bicarbonate Distribution System collected before disinfection from port B 17 located on the bicarbonate mixer) was outside of acceptable range: a. Dated 1/10/13 results were greater than 200.0 CFU (colony forming units)." b. Dated 1/17/13 results were 108.0 CFU and 2.12 EU / mL (endotoxin units / milliliter). c. Dated 3/7/13 results were 56.0 CFU. d. Dated 3/14/13 results were 40.0 CFU. e. Dated 3/28/13 results were 180.0 CFU. f. Dated 4/4/13 results were 110.0 CFU. g. Dated 4/11/13 results were 192.0 CFU. h. Dated 5/10/13 results were greater than 200.0 CFU. February 2013 testing was within guidelines.			

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	7. May 17, 2013, at 5:15 PM, the clinic manager indicated the facility did not have an Action Plan that addresses the elevated CFU results in January and March 2013. She indicated the action plan was as written by the Bio Technician, dated 4/25/13, to address the elevated water cultures of the bicarbonate system. 8. On 5/22/13 at 2 PM, employee P indicated employee C wrote the Action Plan dated 4/25/13 at her request on 4/25/13. She indicated the plan was emailed to her the same day, after the QAPI meeting of the same day.			

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V000634	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program addressed medical errors in 6 (November and December 2012 and January, February, March, and April 2013) of 6 months of minutes reviewed creating the potential to affect all of the facility's 74 current patients. The findings include: 1. The documents titled Facility Quality Assessment and Performance Improvement dated 11/29/12, 12/20/12, 1/24/13, 2/26/13, 3/28/13, and 4/25/13 evidenced medication errors and infiltrations had occurred and were reported. The facility's monthly QAPI committee meetings acknowledged that during these 6 months one missed medication, one medication error, one wrong dialyzer, three infiltrations, one fall, one infection, one clotted system, and one prolonged bleed had occurred. The meeting minutes failed to evidence a plan	V000634	On June 12, 2013, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of reeducation on the Quality Assessment and Performance Improvement Program. This education included but was not limited to the following: ·QAI processes including monthly analysis and trending of adverse events ·Adverse Event reporting as defined with the AE policy, analysis and trending ·Reviewing requirements within the QAI Meeting Minute Template On June 12, 2013 the Regional Quality Manager met with the Clinical Manager to review and reinforce the Clinical Manager's responsibility to utilize the QAI Minute Template to report, analyze, trend and develop action plans as necessary for all indicators defined within QAI. Additionally to utilize the Minutes to document all QAI Committee activities with emphasis placed on adverse events as defined within the Adverse Event policy. The Clinical Manager or her designee will review treatment	06/12/2013

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	had been implemented to address and track the identified problems. 2. The QAPI findings were reviewed with the clinical manager on 5/22/13 at 2 PM. The clinical manager was unable to provide any additional documentation and/or information related to the findings. 3. The facility's 04-04-2012 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001 A states, "The Medical Director, Director of Operations, Area Manager, and Clinical Manager are responsible for monitoring and evaluating the effectiveness of the QAI Programs . . . The facility QAI Committee established priorities, develops and implements improvement projects based on established priorities and monitors these projects for effectiveness . . . An improvement plan (or action plan) will be developed as needed for QAI projects implemented by the QAI Committee to facilitate tracking of action items, monitoring, and follow-up . . . All Adverse Events will be reviewed by the QAI committee to ensure appropriate interventions."		sheets daily for 2 weeks, weekly until the Condition is lifted, monthly times 2, then quarterly to ensure that all details of an adverse event or other incident as required with the QAI Meeting Template are reported and documented. Any areas of non-compliance will be addressed immediately including corrective action as appropriate and added to the QAI documentation for that date. The Governing Body, through its ongoing monitoring of the QAI committee, will ensure the immediate and on going identification of potential and actual problems to patient care and take appropriate steps to identify the root causes of problems and to develop, implement and track corrective actions through to resolution of those problems. Any issues/problems will be addressed via the above-specified process, documented in the QAI Minutes, and formally reported to the Governing Body by the Minutes. Minutes of both QAI Committee and Governing Body meetings will be available for review at the facility.	

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V000640	494.110(c) QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES The facility must immediately correct any identified problems that threaten the health and safety of patients. Based on document, policy, and personnel file review and interview, the facility failed to ensure they immediately corrected an identified problem with the product water used to prepare dialysate or concentrates to ensure the product water contained a total viable microbial count lower than 200 CFU/mL and an action level of 20 CFU/ML in 1 of 1 water rooms reviewed with the potential to affect all the facility's patients. Findings: 1. A facility product water concentration result titled "Bicarbonate Dist Sys. Return" (Bicarbonate Distribution System Return), dated 1/10/13 evidenced a 48 Hr Colony Count of >200.0 AH [Abnormally High] CFU/ML [Colony Forming Units / milliliter]. A. Results dated 1/17/13 were 108.0 CFU and 2.12 EU/mL [endotoxin units / milliliter]. B. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/7/13 05:00,	V000640	On June 12, 2013, the Regional Quality Manager scheduled a meeting with all participants of the QAI committee for the purpose of re-educating on the "Quality Assessment and Performance Improvement Program" FMS-CS-IC-II-101-001A and addressing the requirement that the facility must take immediate action when identified problems that threaten the health and safety of patients occur. Education further notes those types of "immediate threats" that warrant immediate action as defined in the Conditions for Coverage. The facility QAI Committee is currently analyzing the last 6 months of water sample results at the QAI Meeting on June 27, 2013 to update the Minutes with the current status as evidenced by trends and log reports including any action plans or updates to current action plans. The Governing Body will also perform an audit of the QAI minutes from 2012 to ensure that there are no other areas in need of improvement and to recognize any negative trends of any	06/12/2013

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	evidenced a 48 Hour (hr) Colony Count of 56.0 AH CFU/ML. Signed by the Medical Director 4/11/13. C. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/14/13 16:50, evidenced a 48 Hr Colony Count of 40.0 AH CFU/ML. Signed by the Medical Director 3/24/13. D. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/21/13 17:00 and 21:30 (pre and post disinfection sample), evidenced there was no sample received for a colony and endotoxin to be assessed. The results were signed by the Medical Director and dated 4/11/13. E. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/28/13 16:30, evidenced a 48 Hr Colony Count of 180.0 AH CFU/ML. Signed by the Medical Director 4/25/13. F. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/4/13 15:26, evidenced a 48 Hr Colony Count of 110.0 AH CFU/ML. Signed by the Medical Director 4/25/13.		outcomes. If identified, the Governing Body will ensure that a root cause analysis of these trends is completed and an action plan developed.	

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	G. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/11/13 14:30, evidenced a 48 Hr Colony Count of 192.0 AH CFU/ML. Signed by the Medical Director 4/25/13. H. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced a 48 Hr Colony Count of greater than 200.0 AH CFU/ML. Unsigned by the Medical Director. 2. Administrative document titled "Action Plan" dated 4/25/13 states, "Opportunity Statement (Focus-baseline data): Some above action level colony counts have been coming back on sds (solution delivery system), They are intermittent. Goal (Focus-measurable goal and time frame): To irradiate any and all issues that may be causing or assisting in the cause of potential bacteria growth. Root Causes (Analyze with Brainstorming - Select 1-2 Root Causes) : Improper collection frequency. A small leak underneath (sic) Bicarbonate tank #1, Improper collection technique. Team Members: [Employee C and Employee I] Bio med Technicians." The Action Plan evidenced the Action Steps were: A. Do an acidified bleach sani			

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	(sanitization) on SDS by clinical staff to be completed by 4/25/13. B. The Action Plan evidenced to Repair small leak under tank # 1. Employee C and Employee I to complete. C. The Action Plan evidenced to complete a 10% bleach disinfect by Employee C by 4/28/13. D. The Action Plan evidenced to complete a 4 week validation process by Employee C to be completed by 5/28/13 and start 4/25/13. E. The Action Plan evidenced the Bio Technician, Employee C, was to assume the monthly culturing duties (relieving the clinical staff of the duty). Employee C and Employee J to start 4/29/13. 3. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan. 4. The facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced employee E, a patient care technician, collected the monthly cultures for Week # 2 of the Action Plan.			

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	5. The personnel file for Employee E, date of hire 10/29/12, failed to evidence the employee had been trained to cleanly do monthly cultures. 6. On May 17, 2013, at 2 PM, Employee C, the Bio Tech, indicated Employee E had not been trained to collect the samples. 7. On May 17, 2013, at 3:10 PM, Employee C, the Bio Tech, retrieved the abnormal 5/10/13 results from the computer at the surveyor's request and indicated he was just aware the labs were abnormally high from last week. 8. On May 22, 2013, at 1:30 PM, Employee J, the Regional Bio Tech, indicated the Action Plan had not been followed or achieved. 9. On May 22, 2013, at 1:30 PM, Employee K, the Regional Operations Manager, indicated the Action Plan had not been approved by the QAI but had been emailed to her only. 10. A policy titled "FMS Technical Services Department Microbiological Monitoring of Dialysate", Effective Date 31-Jul-2009, FMS-TS-IC-I-500-000-A, states, "Purpose To establish FMCNA			

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	standards for bacteria and endotoxin in final dialysate and monitor compliance therewith. ... Standards and References Water microbiological contaminants will be monitored using the following action level and allowable limits: Test Bacteria Sample Category Dialysate Action Level 20 CFU/ml Allowable Limit 200 CFU/ml. Policy Samples will be taken under the following conditions: ... Prior to daily cleaning and disinfection. ... Water Results Corrective Actions Corrective actions must be undertaken in the area of the suspected cause for exceeding the action level. ... Test Results Exceeding the Allowable Limit in the event test results are above the allowable limits you must promptly do the following: ... Notify the Medical Director. ... Validation Protocol Water treatment systems, or individual components, will be validated by testing the aforementioned site(s) weekly for a minimum of 4 weeks. Results obtained during this period will be used to assure the systems disinfection protocol is effectively meeting established action levels. ... Disinfection of the R.O. [Reverse Osmosis] or storage tank and distribution piping was required outside of the normal schedule of disinfection to resolve micro biological test results that exceeded either the Action level or Allowable Limits. If any Pre disinfection test result meets or exceeds action levels			

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	or allowable limits." 11. A policy titled "Quality Assessment and Performance Improvement Program", Effective Date 04-Apr-2012, FMS-CS-IC-I-101-001-A, states, "QAI (Quality Assessment and Performance Improvement Program) Meeting Requirements QAI Program activities for each facility or program include: ... Completion and analysis of the QAI trending tools ... A. Improvement projects will be prioritized by the QAI Committee, considering the prevalence and severity of identified problems and by ranking those which have potential to affect patient health and safety as a higher priority than those that do not have such potential. The facility must take immediate, appropriate actions to address any serious threats and ensure patient safety. Examples of urgent priorities which could post a threat to the health and safety of our patients and require immediate correction include, but are not limited to: Dangerous level of contaminant in product water, Unsafe levels of electrolytes in dialysate."			

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FRESENIUS MEDICAL CARE BLOOMINGTON MONROE	575 S PATTERSON DR BLOOMINGTON, IN 47403

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V000710	Based on administrative document, personnel file, and policy review and interview, it was determined the medical director failed to ensure a quality assessment and performance improvement program developed, implemented a process, and monitored to ensure there was a review and evaluation conducted of all patient deaths to determine if there was a relationship to the care received at the facility; a process was developed and implemented to review product water sample results timely and failed to implement a corrective action plan that addressed the elevated culture results of product water samples; and medical errors and adverse events were addressed in 6 of 6 months of minutes reviewed creating the potential to affect all of the facility's 74 current patients (See V 712); failed to ensure staff were trained to do monthly cultures and practice audits showed competence, and included observation for, the conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing, and disinfecting testing at the point of use for staff conducting technical procedures for 6 of 6 training records reviewed of employees	V000710	The Medical Director understands and acknowledges her role and responsibilities to ensure a quality assessment and performance improvement program as required by the Conditions for Coverage through assuring that a review and evaluation is conducted of all patient deaths, water sample results and adverse events. Therefore, the Medical Director, as a member of the Governing Body met on June 6, 2013, after receipt of the Statement of Deficiencies, to review the Statement and make certain that all identified deficiencies were being addressed, both immediately and with long term resolution. The following action steps were agreed upon and implemented. The Medical Director, as a member of the Governing Body, will meet weekly to monitor the progress of this Plan of Correction as related to the Statement of Deficiencies, until the Condition level deficiencies are lifted, then monthly for an additional three months to make certain that all corrections are being maintained, and then return to quarterly or as needed basis. Effective immediately ·The DO will present a report to	06/12/2013

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	conducting testing creating the potential to affect all of the in-center facility's 74 current patients (See V 713); and failed to ensure the facility followed their policy for product water used to prepare dialysate or concentrates from powder to ensure that the water contained a total viable microbial count lower than 200 CFU/mL and an action level of 20 CFU/ML in 1 of 1 facility reviewed with the potential to affect all the facility's 74 patients (See V 715). The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of this Condition for Coverage 494.150: Responsibilities of the Medical Director.		the Medical Director on the audit/monitoring results and all other actions taken toward the resolution of the Plan of Correction for this SOD at each Governing Body meeting through to the resolution of all identified conditions/deficiencies . ·The Clinical Manager will present monthly reports on these results to the Medical Director as a member of the QAI committee for review and oversight. ·The processes as noted in this POC will be reviewed weekly by the Medical Director as a member of Governing Body and monthly, as a member of QAI with all parties involved in the POC. These meetings will ensure ongoing progress towards resolution of noted deficiencies and that the facility is delivering safe, quality health care services on a daily basis and that Patient Assessments and Plans of Care, as required, are being provided. ·Minutes of the Governing Body and QAI meetings, as well as monitoring forms, In-service sign-in sheets will document these actions and the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. The response provided for V 712, V713 and V715 describes, in detail, the processes, audits and monitoring steps taken to ensure that all deficiencies as cited within the condition are corrected to	

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			ensure ongoing compliance.	

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V000712	494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.	V000712	The Medical Director met with the members of the Governing Body on June 6, 2013 to review her requirements as defined with the Conditions for Coverage and the new Medical Staff Bylaws. She approved the final Plan of Correction to ensure that all citations and responses as cited in relation to QAI, that the QAI Committee provides adequate and thorough monitoring techniques to ensure compliance and that corrective actions have been instituted that ensure resolution of the issues. The Medical Director is responsible to review the monitoring data provided as related to the Plan of Correction to ensure that the activities and weekly reports are documenting resolution of the deficiencies as defined throughout the Plan of Correction. The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director for oversight and review. The Director of Operations is	06/06/2013

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			responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee The Medical Director acknowledges his role to ensure that any issues that do not show resolution, will be reviewed with a new action plan developed until all issues as cited within the Statement of Deficiency have been resolved and resolution sustained.	
	Based on administrative document and policy review and interview, the medical director failed to ensure a quality assessment and performance improvement program developed, implemented a process, and monitored to ensure there was a review and evaluation conducted of all patient deaths to determine if there was a relationship to the care received at the facility; a process was developed and implemented to			

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	review product water sample results timely and failed to implement a corrective action plan that addressed the elevated culture results of product water samples; and medical errors and adverse events were addressed in 6 (November and December 2012 and January, February, March, and April 2013) of 6 months of minutes reviewed creating the potential to affect all of the facility's 74 current patients The findings include: 1. The documents titled Facility Quality Assessment and Performance Improvement (QAPI) dated 11/29/12, 12/20/12, 1/24/13, 2/26/13, 3/28/13, and 4/25/13 failed to evidence the facility developed and implemented a process to review product water sample results timely and implemented a corrective action plan that addressed the elevated culture results of product water samples in January, March, April, and May 2013. The minutes failed to evidence an investigation into potential causes of individual patient deaths, contributory factors, and any relationship to the care received at the facility. The QAPI committee meetings acknowledged during these 6 months one missed medication, one medication error, one wrong dialyzer, three infiltrations, one fall, one infection,			

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	one clotted system, and one prolonged bleed had occurred. The minutes failed to evidence adverse events and medical errors were investigated for potential causes and any possible corrective action. 2. The QAPI findings were reviewed with the clinical manager on 5/22/13 at 2 PM. She was unable to provide any additional documentation and/or information related to the findings. 3. The facility's 04-04-2012 "Quality Assessment and Performance Improvement Program (QAPI)" policy number FMS-CS-IC-I-101-001 A states, "The Medical Director, Director of Operations, Area Manager, and Clinical Manager are responsible for monitoring and evaluating the effectiveness of the QAI Programs . . . The facility QAI Committee established priorities, develops and implements improvement projects based on established priorities and monitors these projects for effectiveness . . . An improvement plan (or action plan) will be developed as needed for QAI projects implemented by the QAI Committee to facilitate tracking of action items, monitoring, and follow-up . . . All Adverse Events will be reviewed by the QAI committee to ensure appropriate interventions."			

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	As related to the monitoring of bacteria and endotoxin: 4. On May 17, 2013, at 3:10 PM, the surveyor requested the results of the most recent product water samples. Employee C, the facility Bio Technician, retrieved the 5/10/13 results from the computer terminal and indicated he was just then aware that the laboratory culture results were abnormally high. He indicated the facility had some elevated cultures from the B 17 port of the Bicarbonate distribution system, but there was no trend. The facility had contributed the results to human error related to these samples and they were the only water cultures the patient care technicians were collecting prior to disinfection of the bicarbonate distribution system which led to the belief that these elevated results were false. 5 On 5/17/13 at 3:55 PM, employee F, a patient care technician, indicated she disinfected the bicarbonate mixer and delivery system (mixes bicarbonate from powder and then delivers bicarbonate to all of the in-center dialysis machines) on April 18, 2013, as documented on the disinfection log. She indicated the facility did not use the hach meter for confirmation of the percentage of bleach solution, that the facility used chlorine			

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	reagent strips to ensure the adequate percent of solution was used during disinfection. She retrieved the vial of Residual Chlorine strips from the in-center unit and indicated the strips retrieved were used to measure the concentration of bleach. The strips produced were labeled Hach Steri-chek Residual Chlorine Reagent Strips # 811900 and the label provided a guide for four potential readings: 0.0 ppm (parts per million), 0.5 ppm, 1.0 ppm, and 5.0 ppm. Employee F indicated that when the strips turned very dark they knew they had a sufficient amount of chlorine and confirmed the strips registered the maximum of 5 parts per million. Employee C confirmed the chlorine concentration for disinfection was to be 500 parts per million and the reagent strips the patient care technician produced were the appropriate strips and "were used for years" for this purpose. 6. A policy titled "FMCNA Policy and Standards Manual Disinfection Standards for Equipment," Effective Date 04-04-07, number 152-030-017 states, "Solution Delivery System Requirements if Bleach is used as the disinfectant. ... Testing for the presence of bleach. Testing for the presence of bleach in the water in the SDS mix tank will be performed during bleach disinfection. ... Test the solution			

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	for the disinfection the Mixer with a residual strip to validate that the solution contains approximately 500 PPM bleach." 7. Facility documents titled "BD - 1 Bicarbonate / SDS Bleach Disinfection Log Form" evidenced the SDS was disinfected weekly since the first week of January 2013 through May 9, 2013. The documents included the initials of the staff member that completed the disinfection and the disinfection agent used was bleach. The documents indicated each individual completing the disinfection obtained a 500 parts per million of bleach. 8. Sample product water culture and endotoxin results labeled as collected from the "BDS - return - Before, B 17" (Bicarbonate Distribution System collected before disinfection from port B 17 located on the bicarbonate mixer) was outside of acceptable range: a. Dated 1/10/13 results were greater than 200.0 CFU (colony forming units)." b. Dated 1/17/13 results were 108.0 CFU and 2.12 EU / mL (endotoxin units / milliliter). c. Dated 3/7/13 results were 56.0 CFU. d. Dated 3/14/13 results were 40.0 CFU.			

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	e. Dated 3/28/13 results were 180.0 CFU. f. Dated 4/4/13 results were 110.0 CFU. g. Dated 4/11/13 results were 192.0 CFU. h. Dated 5/10/13 results were greater than 200.0 CFU. February 2013 testing was within guidelines. 9. May 17, 2013, at 5:15 PM, the clinic manager indicated the facility did not have an Action Plan that addresses the elevated CFU results in January and March 2013. She indicated the action plan was as written by the Bio Technician, dated 4/25/13, to address the elevated water cultures of the bicarbonate system. 10. On 5/22/13 at 2 PM, employee P indicated employee C wrote the Action Plan dated 4/25/13 at her request on 4/25/13. She indicated the plan was emailed to her the same day, after the QAPI meeting of the same day. 11. On May 22, 2013, at 2:11 PM, Employee O, the Medical Director, indicated she has a folder where water results are to be placed to enable her to review when she is in the facility. She			

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	indicated she often must find the Bio Technician to obtain the water results as they are not in the designated folder. She indicated the laboratory does not call her with results outside of acceptable perimeters, nor is she called or contacted by electronic devices - cell phones and beepers - when the results are high. She indicated she did not have access to the computer program in which the water results are stored.			

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V000713	494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance. 3. The facility's bicarbonate administrative records, Form: BD-1 and Form SDS-1, evidenced employees E, F, K, L, N, and M all performed total chlorine testing of the water and prepared the bicarbonate mixing and bicarbonate bleach disinfection log. A. The annual training record dated 10-24-12 for employee M, date of hire 2-2-5 (DOH), failed to evidence the employee had been evaluated and observed for conducting the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee M performed the bicarbonate daily system rinse on 4 -23-13.	V000713	The Medical Director met with the members of the Governing Body on June 6, 2013 to review her requirements as defined within the Conditions for Coverage and the new Medical Staff Bylaws. She approved the final Plan of Correction ensuring that all citations and responses related to the training requirements for the staff performing water and dialysate testing, dialysate mixing, dialysate pH and rinsing and disinfecting testing at the point of use, as detailed in V 260, are complete and address the issues. Additionally, that the QAI Committee provides adequate and thorough monitoring techniques to ensure compliance with all training requirements and that the corrective actions that have been instituted, ensure resolution of these issues. The Medical Director is responsible to review the monitoring data provided as related to the Plan of Correction to ensure that the activities and weekly reports are documenting resolution of the deficiencies as defined throughout the Plan of Correction.	06/06/2013

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	B. The annual training record dated 11-5-12 for employee L, DOH 5-22-12, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee L performed the bicarbonate mixing on 4-26-13 and 4-29-13. C. The annual training record dated 11-5-12 for employee N, DOH 12-5-11, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee N performed the bicarbonate daily		The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director for oversight and review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee The Medical Director acknowledges her role to ensure that any issues that do not show resolution, will be reviewed with a new action plan developed until all issues as cited within the Statement of Deficiency have been resolved and resolution sustained.	

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	system rinse on 4-25-13. D. The annual training record dated 11-5-12 for employee K, DOH 8-30-99, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Bicarb/SDS Bleach Disinfection Log Form" evidenced employee K preformed testing for the presence for bleach and the absence of chlorine bleach at Loop 1 on 5-2-13 and 5-16-13. On 4-27-13, the employee performed bicarbonate mixing. E. The annual training record dated 10-15-12 for employee F, DOH 1-1-6, failed to evidence the employee had been evaluated and observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE BLOOMINGTON MONROE		STREET ADDRESS, CITY, STATE, ZIP CODE 575 S PATTERSON DR BLOOMINGTON, IN 47403	

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	conductivity testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Solution Delivery System Log" evidenced employee F performed the bicarbonate mixing on 4-30-13. F. The training record dated 2-20-13 for employee E, DOH 10-29-12, and the annual training record dated 4-18-13 failed to evidence the employee had been observed for conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing and disinfecting testing at the point of use for staff conducting technical procedures. The FMC Bloomington form titled "Bicarb/SDS bleach Disinfection Log Form" evidenced employee E performed testing for the presence of bleach and the absence of chlorine bleach at Loop 1 on 5-9-13. G. The facility manager, employee A, stated, on 5-22-13 at			

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	3:20 PM, "I have completed the training and the annual updates for the water and on the water system, bicarbonate preparation, and validation for 2012 but not all completed for this year [2013]. Based on document, personnel file, and policy review and interview, the medical director failed to ensure staff were trained to do monthly cultures and practice audits showed competence, and included observation for, the conducting of the water and dialysate testing, dialysate mixing, dialysate pH and rinsing, and disinfecting testing at the point of use for staff conducting technical procedures for 6 (E, F, K, L, N, and M) of 6 training records reviewed of employees conducting testing creating the potential to affect all of the in-center facility's 74 current patients. Findings:			

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	1. Administrative document titled "Action Plan" to address issues with elevated colony counts dated 4/25/13 included a plan for the Bio Technician, Employee C, to assume the monthly culturing duties (relieving the clinical staff of the duty). Employee C and Employee J were to start 4/29/13. A. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan. B. A facility product water concentration result titled "Bicarb Dist Sys. Return", dated 5/11/13 13:07, evidenced that employee E, a PCT, did the monthly cultures week # 2 of the Action Plan. C. The personnel file for Employee E, date of hire (DOH) 10/29/12, failed to evidence the employee had been trained to cleanly do monthly cultures. 2. A policy titled "Revised and Restated Governing Body Bylaws", Revised May 23, 2011, states, "Each Facility shall have its own medical director, who shall be responsible for overseeing the quality of care and professional activities within the Facility."			

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V000715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on document, policy, and personnel file review and interview, the medical director failed to ensure the facility followed their policy for product water used to prepare dialysate or concentrates from powder to ensure that the water contained a total viable microbial count lower than 200 CFU/mL and an action level of 20 CFU/ML in 1 of 1 facility reviewed with the potential to affect all the facility's 74 patients. Findings: 1. A facility product water concentration result titled "Bicarbonate Dist Sys. Return" (Bicarbonate Distribution System Return), dated 1/10/13 evidenced a 48 Hr Colony Count of >200.0 AH [Abnormally High] CFU/ML [Colony Forming Units / milliliter]. A. Results dated 1/17/13 were 108.0 CFU and 2.12 EU/mL [endotoxin units / milliliter].	V000715	The Director of Operations met with the Medical Director on June 6, 2013 to review her requirements as defined in the Condition for Coverage and Medical Staff Bylaws to ensure that all policies and procedures relative to patient admission, patient care, infection control and patient safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers emphasizing review of all water sample results and the need to put corrective action in place when the results are above action level and reviewing all personnel files to ensure staff performing those water cultures have had adequate training that includes a documented return demonstration. The Director of Operations also reviewed the Plan of Correction to be instituted to correct this issue. The Medical Director approved and directed the implementation of the plan as noted below. The facility's patient care staff will be in-serviced on the following	06/06/2013

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	B. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/7/13 05:00, evidenced a 48 Hour (hr) Colony Count of 56.0 AH CFU/ML. Signed by the Medical Director 4/11/13. C. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/14/13 16:50, evidenced a 48 Hr Colony Count of 40.0 AH CFU/ML. Signed by the Medical Director 3/24/13. D. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/21/13 17:00 and 21:30 (pre and post disinfection sample), evidenced there was no sample received for a colony and endotoxin to be assessed. The results were signed by the Medical Director and dated 4/11/13. E. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 3/28/13 16:30, evidenced a 48 Hr Colony Count of 180.0 AH CFU/ML. Signed by the Medical Director 4/25/13. F. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/4/13 15:26, evidenced a 48 Hr Colony Count of 110.0		policies, “Hand Hygiene”, “Personal Protective Equipment”, “Cleaning and Disinfection of the Stethoscope”, “Microbiological Monitoring of Dialysate”, “Disinfection Standards for Equipment” on June 7, 2013 by education with a record of training reviewed by the QAI committee. The Clinical Manager (CM) is responsible to present all data and monitoring/audit results as related to this Plan of Correction to the Medical Director at the QAI Meeting for oversight and review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented to the Medical Director during the monthly QAI Committee Meeting. The Medical Director as Chairperson of the QAI Committee is responsible to analyze the results and direct a root cause analysis with the development of a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee	

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	AH CFU/ML. Signed by the Medical Director 4/25/13. G. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 4/11/13 14:30, evidenced a 48 Hr Colony Count of 192.0 AH CFU/ML. Signed by the Medical Director 4/25/13. H. A facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07, evidenced a 48 Hr Colony Count of greater than 200.0 AH CFU/ML. Unsigned by the Medical Director. 2. Administrative document titled "Action Plan" dated 4/25/13 states, "Opportunity Statement (Focus-baseline data): Some above action level colony counts have been coming back on sds (solution delivery system), They are intermittent. Goal (Focus-measurable goal and time frame): To irradiate any and all issues that may be causing or assisting in the cause of potential bacteria growth. Root Causes (Analyze with Brainstorming - Select 1-2 Root Causes) : Improper collection frequency. A small leak underneath (sic) Bicarbonate tank #1, Improper collection technique. Team Members: [Employee C and Employee I] Bio med Technicians." The Action Plan			

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	evidenced the Action Steps were: A. Do an acidified bleach sani (sanitization) on SDS by clinical staff to be completed by 4/25/13. B. The Action Plan evidenced to Repair small leak under tank # 1. Employee C and Employee I to complete. C. The Action Plan evidenced to complete a 10% bleach disinfect by Employee C by 4/28/13. D. The Action Plan evidenced to complete a 4 week validation process by Employee C to be completed by 5/28/13 and start 4/25/13. E. The Action Plan evidenced the Bio Technician, Employee C, was to assume the monthly culturing duties (relieving the clinical staff of the duty). Employee C and Employee J to start 4/29/13. 3. On May 17, 2013, at 3:00 PM, Employee C, the Bio Technician Tech, indicated he forgot to collect the water sample for cultures to comply with week # 1 of the Action Plan. 4. The facility product water concentration result titled "Bicarbonate Dist Sys. Return", dated 5/10/13 13:07,			

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	evidenced employee E, a patient care technician, collected the monthly cultures for Week # 2 of the Action Plan. 5. The personnel file for Employee E, date of hire 10/29/12, failed to evidence the employee had been trained to cleanly do monthly cultures. 6. On May 17, 2013, at 2 PM, Employee C, the Bio Tech, indicated Employee E had not been trained to collect the samples. 7. On May 17, 2013, at 3:10 PM, Employee C, the Bio Tech, retrieved the abnormal 5/10/13 results from the computer at the surveyor's request and indicated he was just aware the labs were abnormally high from last week. 8. On May 22, 2013, at 1:30 PM, Employee J, the Regional Bio Tech, indicated the Action Plan had not been followed or achieved. 9. On May 22, 2013, at 1:30 PM, Employee K, the Regional Operations Manager, indicated the Action Plan had not been approved by the QAI but had been emailed to her only. 10. A policy titled "FMS Technical Services Department Microbiological			

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	Monitoring of Dialysate", Effective Date 31-Jul-2009, FMS-TS-IC-I-500-000-A, states, "Purpose To establish FMCNA standards for bacteria and endotoxin in final dialysate and monitor compliance therewith. ... Standards and References Water microbiological contaminants will be monitored using the following action level and allowable limits: Test Bacteria Sample Category Dialysate Action Level 20 CFU/ml Allowable Limit 200 CFU/ml. Policy Samples will be taken under the following conditions: ... Prior to daily cleaning and disinfection. ... Water Results Corrective Actions Corrective actions must be undertaken in the area of the suspected cause for exceeding the action level. ... Test Results Exceeding the Allowable Limit in the event test results are above the allowable limits you must promptly do the following: ... Notify the Medical Director. ... Validation Protocol Water treatment systems, or individual components, will be validated by testing the aforementioned site(s) weekly for a minimum of 4 weeks. Results obtained during this period will be used to assure the systems disinfection protocol is effectively meeting established action levels. ... Disinfection of the R.O. [Reverse Osmosis] or storage tank and distribution piping was required outside of the normal schedule of disinfection to resolve micro biological test results that			

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	exceeded either the Action level or Allowable Limits. If any Pre disinfection test result meets or exceeds action levels or allowable limits." 11. A policy titled "Quality Assessment and Performance Improvement Program", Effective Date 04-Apr-2012, FMS-CS-IC-I-101-001-A, states, "QAI (Quality Assessment and Performance Improvement Program) Meeting Requirements QAI Program activities for each facility or program include: ... Completion and analysis of the QAI trending tools ... A. Improvement projects will be prioritized by the QAI Committee, considering the prevalence and severity of identified problems and by ranking those which have potential to affect patient health and safety as a higher priority than those that do not have such potential. The facility must take immediate, appropriate actions to address any serious threats and ensure patient safety. Examples of urgent priorities which could post a threat to the health and safety of our patients and require immediate correction include, but are not limited to: Dangerous level of contaminant in product water, Unsafe levels of electrolytes in dialysate."			