THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

March 12, 2021

The Honorable Henry Kerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

Re: Office of Special Counsel File No. DI-20-000860

Dear Mr. Kerner:

I am responding to your August 4, 2020, letter to the Department of Veterans Affairs (VA) regarding whistleblower allegations that officials at the Central Arkansas Veterans Healthcare System, John L. McClellan Memorial Veterans Hospital, in Little Rock, Arkansas, may have engaged in conduct that constitutes a violation of law, rule or regulation and a substantial and specific danger to public health and safety.

The Acting Under Secretary for Health directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. We investigated this matter from October 8, 2020 and October 20-22, 2020. We substantiate two and do not substantiate two of the whistleblower's four allegations.

We make 11 recommendations to the Central Arkansas Veterans Healthcare System, John L. McClellan Memorial Veterans Hospital. The signed report will be sent to the respective office with a request for an action plan.

Thank you for the opportunity to respond.

Sincerely,

Denis McDonough

Enclosure

DEPARTMENT OF VETERANS AFFAIRS

Washington, DC

Report to the
Office of Special Counsel
OSC File Number DI-20-000860

Central Arkansas Veterans Healthcare System
John L. McClellan Memorial Veterans Hospital
Little Rock, Arkansas

Report Date: February 22, 2021

TRIM 2020-C-33

Executive Summary

The Acting Under Secretary for Health directed the Office of the Medical Inspector (OMI) to assemble and lead a Department of Veterans Affairs (VA) team to investigate whistleblower disclosures made to the Office of Special Counsel (OSC) concerning the Central Arkansas Veterans Healthcare System, John L. McClellan Memorial Veterans Hospital (hereafter, Little Rock), located in Little Rock, Arkansas. The whistleblower alleged Little Rock officials engaged in conduct that constitutes a violation of law, rule or regulation and a substantial and specific danger to public health and safety. Due to infection control concerns related to the Coronavirus Disease 2019 (COVID-19) pandemic, we conducted a tour and walk-through of Little Rock on October 8, 2020, and conducted interviews by phone on October 20-22, 2020.

Specific Allegations of the Whistleblower

1. *The failure of VA nursing staff to conduct and record the results of chlorine concentration tests of dialysis water systems;*

2. *VA management officials approving falsified dialysis machine daily maintenance logs;*

3. *The failure to properly dispose of and store intravenous medications; and*

4. *The regular consumption of food and beverages in an area with high exposure or potential exposure to blood.*

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place and **did not substantiate** allegations when the facts and findings showed the allegations were unfounded. We were **unable to substantiate** allegations when the available evidence was insufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

Conclusion(s) for Allegation 1

- We **substantiated** that VA staff did not consistently conduct and record chlorine concentration tests of the dialysis water system. We found evidence that testing is not consistently occurring at 4:00 p.m. when patients are still receiving dialysis treatment. We also found evidence of missing required information in the daily routine total chlorine monitoring log.

- There is conflicting information in Little Rock Standard Operating Procedures (SOP) and logbook forms regarding chlorine testing. The Little Rock SOP 5D 1.3, *Monitoring the Dialysis Water System*, states testing is performed daily and at each shift. The Little Rock SOP NSG-D017, *Ultra-Low Total Chlorine Testing for Dialysis Water*, does not state how often or when water should be tested. The daily water system log form states chlorine is to be monitored every 4 hours.

- We identified confusion regarding the need for a second verification of the chlorine water testing, as well as various methods to perform the verification. The SOP NSG-D017 does not state that a second visual verification and signature is required. Although staff stated that a second person verification is required, procedures for verification described by staff was inconsistent. VA Memorandum, *Dialysis Water Testing and Quality Requirements*, states only the daily testing requires a second verifier (which includes chloramine testing).

Recommendation(s) to Little Rock

1. Clarify and update SOP NSG-D017, SOP 5D 1.3 and daily water system log to reflect when and how often chlorine testing of dialysis water is conducted. Ensure consistency among the three documents and that they follow Veterans Health Administration (VHA) guidelines. Provide education to staff once complete, monitor for compliance, and address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

2. Determine if all chlorine test results require verification and develop a standardized process that ensures verification of the chlorine test results at the time of testing. Ensure no verification is completed without a visual inspection of the test strip by the verifier. Clarify and update SOP NSG-D017 regarding the requirement for second visual verification and signature. Provide education to staff, then monitor for compliance and address non-compliance with additional training and/or administrative action, including disciplinary action where appropriate.

3. Consider consulting with the VHA National Kidney Program Office for assistance with data collection and documentation.

Conclusion(s) for Allegation 2

- We **were unable to substantiate** that VA management officials approved the falsification of dialysis machine daily maintenance logs.

- The SOP NSG-D004, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Heat Disinfection,* SOP NSG-D005, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Chemical Disinfection*, and SOP NSG-D003, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Acid Cleaning*, include the verbiage "...the operators of the hemodialysis machines are responsible for the chemical disinfection." However, these tasks are often assigned to the health technicians (who are not operators performing hemodialysis). By assigning chemical disinfection duties to the health technicians, who are not hemodialysis machine operators, Little Rock is not in compliance with local SOPs NSG-D0004, NSG-D005 and NSG-D003 which state this responsibility is to be assigned to the machine operators.

- SOP NSG-D003 and SOP NSG-D004 do not include instructions to document completion of the procedures in the dialysis machine daily maintenance log.

- The dialysis machine daily maintenance logs were inconsistently completed and missing information in some cases.

Recommendation(s) to Little Rock

4. Clarify and update SOP NSG-D004, SOP NSG-D005 and SOP NSG-D003 to specify which specific positions/roles are responsible for performing cleaning/disinfection tasks and clarify what tasks can and cannot be delegated.

5. Clarify and update SOP NSG-D003 and SOP NSG- D004 to include documenting results in the dialysis machine daily maintenance log.

6. Research and determine if the BlueStar Premium software can be purchased for the Fresenius 2008T dialysis machines to allow for electronic documentation of the disinfection processes.

7. Provide education to staff regarding the requirement to completely fill out the dialysis machine daily maintenance log to include a signature on all lines of the log. Monitor the logs to ensure 100% completeness for 6 months and address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

Conclusion(s) for Allegation 3

- We **did not substantiate** a failure to properly dispose of and store intravenous medications in the dialysis unit.

- We found no evidence that single-use medication was improperly stored or was administered multiple times among different patients.

- Although a change in practice to label syringes filled with heparin was implemented in August 2020, dialysis staff have not consistently implemented this change.

- The SOP 5D 2.6, *Heparin and Alterative Anticoagulation Administration During Hemodialysis,* does not include the change of practice of labeling syringes filled with heparin.

Recommendation(s) to Little Rock

8. Provide education to the dialysis unit staff regarding the need to label syringes filled with heparin. Monitor for compliance using spot checks/tracers to ensure heparin syringe labeling is occurring when indicated. Address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

9. Update SOP 5D 2.6 to include the requirement for syringe labeling.

Conclusion(s) for Allegation 4

- We **substantiated** the presence of food and a beverage in the dialysis unit clinical area, which is an area with high exposure or potential exposure to blood. However, we did not witness the consumption of these items.

Recommendation(s) to Little Rock

10. Educate all dialysis unit staff regarding the location of the designated clinical area where food and beverage storage and consumption is prohibited and the appropriate location(s) where it is permitted. Address non-compliance with additional training and/or disciplinary action as indicated.

11. Perform monthly tracers to monitor the dialysis unit for the presence or consumption of food and beverages until 6 consecutive months occur without findings. Staff from Quality Management and/or Infection Prevention will provide monitoring assistance and will report any findings to the dialysis nurse manager and the Associate Chief Nurse, Ambulatory Care.

Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Little Rock officials may have engaged in conduct that constitutes a violation of law, rule or regulation and a substantial and specific danger to public health and safety, specifically within the dialysis unit. The National Center for Ethics in Health Care has provided a health care ethics review. We found inconsistent water testing processes and documentation issues in the Little Rock dialysis unit, which is a potential threat to the safety of patients undergoing dialysis; however, we did not find evidence of patient harm resulting from the issues. We also found food and a beverage in the clinical area which appeared to belong to staff. If consumed or stored in the area, this would be a violation of Occupational, Safety and Health Association standards.

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I. Introduction

The Acting Under Secretary for Health directed the Office of the Medical Inspector (OMI) to assemble and lead a Department of Veterans Affairs (VA) team to investigate whistleblower disclosures made to the Office of Special Counsel (OSC) concerning the Central Arkansas Veterans Healthcare System, John L. McClellan Memorial Veterans Hospital (hereafter, Little Rock), located in Little Rock, Arkansas. The whistleblower alleged Little Rock officials engaged in conduct that constitutes a violation of law, rule or regulation and a substantial and specific danger to public health and safety. Due to infection control concerns related to the Coronavirus Disease 2019 (COVID-19) pandemic, we conducted a tour and walk-through of Little Rock on October 8, 2020, and conducted interviews by phone on October 20-22, 2020.

II. Facility Profile

Little Rock is a part of Veterans Integrated Service Network (VISN) 16, South Central VA Health Care Network. The Central Arkansas Veterans Healthcare System consists of two inpatient campuses located at Little Rock and North Little Rock, Arkansas, serving Veterans living in the southern, northern, western and central counties of Arkansas, as well as border counties in surrounding states. Comprehensive health care is provided through primary, tertiary and long-term care in areas of medicine, surgery, mental health, physical medicine and rehabilitation, neurology, dentistry, ophthalmology, geriatrics and extended care and women's health. The Little Rock dialysis unit provides care to inpatients and outpatients within the unit and provides staffing for bedside dialysis as needed. The Little Rock dialysis unit provides care to approximately 70 chronic hemodialysis patients, 12 peritoneal dialysis patients and has recently initiated a home hemodialysis program with one patient currently enrolled.[1] [2]

III. Specific Allegations of the Whistleblower

1. *The failure of VA nursing staff to conduct and record the results of chlorine concentration tests of dialysis water systems;*

2. *VA management officials approving falsified dialysis machine daily maintenance logs;*

3. *The failure to properly dispose of and store intravenous medications; and*

4. *The regular consumption of food and beverages in an area with high exposure or potential exposure to blood.*

[1] Hemodialysis is the procedure of waste removal from the blood by means of diffusion across a semi-permeable artificial membrane. This can be provided by either intermittent or continuous treatments.
[2] Peritoneal dialysis is the procedure of waste removal from the blood by means of osmosis and diffusion across the peritoneal membrane.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of the Medical Inspector, a Senior Medical Investigator and a Clinical Program Manager, all of OMI; the VA San Diego Healthcare System Dialysis Nurse Manager; and a Human Resources (HR) Consultant from the HR Center of Expertise, Office of Workforce Management and Consulting. We reviewed relevant policies, procedures, professional standards, reports, memorandums and other documents listed in Attachment A. We held entrance and exit briefings with VISN 16 and Little Rock leadership which included the following:

- VISN 16 Quality Management Officer;
- Medical Center Director;
- Chief of Staff (CoS);
- Associate Director for Patient Care Services (ADPCS);
- Deputy CoS;
- Deputy ADPCS;
- Associate CoS for Quality, Safety and Value; and
- Accreditation Coordinator.

We interviewed the whistleblower via teleconference on October 6, 2020, and again on October 21, 2020. We also interviewed the following Little Rock staff members:

- Deputy ADPCS;
- Associate Chief Nurse Acute Care Services;
- Associate Chief Nurse Ambulatory Care;
- Nurse Manager, Dialysis Unit;
- Assistant Nurse Manager, Dialysis Unit;
- Registered Nurses (RN), Dialysis Unit (6);
- Nurse Practitioner Dialysis Unit;
- Medical Instrument Technologist (MIT), Dialysis Unit;
- Health Technicians, Dialysis Unit (2);
- Patient Safety Manager;
- Nurse Manager, Infection Prevention;
- Environmental Management Service (EMS) Supervisor; and
- Biomedical Equipment Support Specialist.

V. Findings, Conclusions and Recommendations

Allegation 1

The failure of VA nursing staff to conduct and record the results of chlorine concentration tests of dialysis water systems.

Background

VHA Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs*, dated May 23, 2016, implements guidance governing kidney care services directed to eligible Veterans. The VA Dialysis Program provides eligible Veterans with access to necessary, appropriate and timely care of acute and chronic kidney disease and renal replacement therapy (RRT), evaluation, management and treatment provided by qualified personnel and appropriate and timely referral for kidney transplantation.[3] End stage renal disease is a condition of permanent advanced chronic kidney disease that is treated with either RRT or maximum medical management without dialysis, according to the Veteran's preference. This handbook states in addition to VA policies, all VHA Dialysis Programs must follow the current American National Standards Institute/ Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) requirements for dialysis water and dialysate.[4]

High quality water is an essential component of the provision of hemodialysis. During an average week of hemodialysis, a patient can be exposed to 300-600 liters of water, providing multiple opportunities for potential patient exposure to waterborne pathogens. Adverse patient outcomes, including outbreaks associated with water exposure in dialysis settings, have resulted from patient exposure to water via a variety of pathways; including improper formulation of dialysate with water containing high levels of chemical or biological contaminants, contamination of injectable medications with tap water, and reprocessing of dialyzers with contaminated water. For the health and safety of hemodialysis patients, it is vital to ensure the water used to perform dialysis is safe and clean.[5]

Water treatment systems are designed to produce dialysis-quality water. The types of components used can vary according to the local water quality-defined pretreatment needs, the volume of product water needed by the facility and the chosen water treatment technology. There is not a standard type of water treatment system because water treatment steps are tailored to the local water and the contaminants that must be removed. Water treatment system source water will need to be pretreated before it can be purified. Pretreatment consists of several steps, including temperature adjustment, backflow prevention, pressurization, filtration of grit and sediment, water softening, and carbon filtration for de-chlorination. With the pretreatment steps completed, the feed water is ready for purification. The most common method used to purify water for hemodialysis treatment is reverse osmosis (RO). The RO device is a self-contained unit that uses a high-pressure pump and a semipermeable membrane to purify water. In the RO purification process, pretreated water pressurized by the RO high-pressure pump is forced to flow across and through the RO membrane, which is specifically designed to reject or not allow passage of most dissolved inorganic elements, such as ions of

[3] Renal Replacement Therapy (RRT) is the treatment of either acute kidney injury or end stage renal disease by hemodialysis, hemofiltration, peritoneal dialysis or renal transplantation.
[4] VHA Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs*, dated May 23, 2016.
[5] Centers for Disease Control and Prevention, *Dialysis Safety*. https://www.cdc.gov/dialysis/guidelines/water-use.html.

metals, salts and chemicals, as well as organic materials such as bacteria, viruses and endotoxin.[6]

Carbon filtration is used to remove the chlorine and/or chloramines added to municipal water systems. This process typically involves use of a pair of filter tanks that contain granular-activated carbon (GAC). The first carbon filter tank, called the primary or worker tank, must have adequate capacity to provide a sufficient volume of GAC media to dechlorinate the feed water given the water demands of the dialysis facility. Frequent testing of the feed water flowing from the primary tank outlet is necessary to verify that total chlorine levels remain ≤ 0.1 parts per million (PPM). Thus, the facility team should test total chlorine at the total chlorine sample test port between the two tanks several times a day during clinic operation: at the beginning of each use day, before the start of patient treatment, and no less than every 4 hours throughout each treatment day. The carbon filtration process is critical: chlorine and chloramine exposure can harm patients. Moreover, chlorine compounds are reactive and can damage the RO membrane, the water treatment system component most necessary for purification. Because this step is so essential, a secondary polisher GAC filter tank is placed immediately downstream from the primary worker tank and after the total chlorine sample test port. In the event that the worker filter has a chlorine breakthrough, this series design provides de-chlorination redundancy.[7]

The wellness of patients on dialysis starts with meeting the minimum standards for dialysis water quality. Chemical and metal contaminants that are safe in drinking water for ingestion by healthy patients are not safe in patients on hemodialysis who are exposed to dialysis water in treatment. The associations between illness and dialysis water contaminants is well known. For example, chloramine is widely known to cause hemolysis, anemia and death in patients on dialysis. However, high concentrations of other minerals can also be fatal, such as with aluminum compounds. The pipes and storage tanks of water distribution systems are at risk for microbiologic contamination, and, therefore, need regular disinfection. The general strategy should be for the biomedical technician to keep a strict schedule designed to avoid the proliferation of organisms in purified water. The methods used to provide the scheduled routine disinfection of the water purification equipment and distribution loops will depend, in part, on the type of system and material being disinfected. In the absence of unacceptable bacteria and endotoxin results, distribution equipment should be disinfected no less frequently than every 4 weeks.[8]

The Assistant Deputy Under Secretary for Health for Clinical Operations sent a Memorandum to Network Directors on January 28, 2013, regarding *Dialysis Water Testing and Quality Requirements,* to ensure that all AAMI guidelines on dialysis water

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[6] Kasparek and Rodriguez, *What Medical Directors Need to Know About Dialysis Facility Water Management.* Clinical Journal of the American Society of Nephrology, June 2015, 10(6) 1061-1071; doi: HTTPS://DOI.ORG/10.2215/CJN.18512144.

[7] Ibid.

[8] Ibid.

testing and quality requirements were being followed, including quality assurance measures. A checklist of the key items to be evaluated included the following:

- Inorganic solute content.
- Water culture and endotoxins:
  - Are sampled and analyzed at least monthly on central RO water treatment systems and all portable water treatment systems;
  - Dialysate cultures are performed on at least two hemodialysis machines per month, with circulation of machine testing in such a way that tests each machine at least once within a year; and
  - Use AAMI recommended water culture technique.
- Chloramines:
  - Are tested between carbon tanks for dual carbon tank portable and central RO, and post carbon tank where portable RO has only a single tank;
  - Verify that the results are negative (<0.1 PPM) before each dialysis shift.[9]
- Water treatment system:
  - Assess and document the integrity of the water treatment system daily including temperature, calcium, pre- and post-tank pressures, alarms, chloramines, and conductivity/resistivity/total dissolved solids; and
  - The process and documentation are verified by a second individual.
- Disinfection of all machines:
  - Systematic disinfection of all machines (water treatment and dialysis machines) according to manufacturer guidelines and AAMI recommended standards is occurring and is documented.[10]

The Memorandum further stated that reviewing water quality is part of the dialysis quality assessment performance improvement review process and documentation. Also, staff competencies are periodically assessed for dialysis water testing and interpretation consistent with scope of practice and should be reviewed annually. Standard operating procedures (SOP) will exist for performance and interpretation of water quality tests, equipment disinfection, operation and testing of dialysis equipment, action plans for abnormal water tests and dialysis equipment repair in case of malfunction, emergency preparedness plan and reporting requirements.[11]

The Little Rock SOP 5D 1.3, *Monitoring the Dialysis Water System*, dated September 1, 2020, establishes a procedure for maintaining the hemodialysis water system within chemical and microbial standards for safe dialysis. Procedures described in the SOP include the microbial culture test, endotoxin test, routine maintenance, break in line, unscheduled repair, microbial testing, chloramine testing and hardness testing. Samples for bacterial endotoxins and microbial analysis must be collected, at least monthly, from different locations, in order to assess the microbial quality throughout the

[9] Chlorine and chloramine levels in the water should be tested before the first patient treatment of the day and every four hours after the first patient until the end of day. AAMI: ISO 23500: *Guidance for the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapies*, Arlington, VA, Association for the Advancement of Medical Instrumentation, 2011.
[10] VA Memorandum, *Dialysis Water Testing and Quality Requirements*, dated January 28, 2013.
[11] Ibid.

water distribution system. These results are compared to AAMI standards, logged and maintained in the dialysis unit. Testing for chloramine is performed daily prior to initiating hemodialysis and at each shift. The SOP states performing the daily/shift testing is the responsibility of the RN and medical instrument/hemodialysis technician. The monthly water sample collection from portable RO and dialysis machines is the responsibility of medical instrument/hemodialysis technician and monthly water sample collection from the main RO system is the responsibility of biomedical engineering.[12]

The Little Rock SOP NSG-D017, *Ultra-Low Total Chlorine Testing for Dialysis Water*, dated September 2020, establishes guidelines for testing to confirm removal of chloramines from dialysis water. It states hemodialysis water is tested to confirm removal of chloramines by water treatment systems to the maximum allowable level. Staff will be adequately trained and demonstrate annually the required competencies. The SOP states operators performing hemodialysis are responsible for dialysis water quality and quality control of the test methods. The SOP explains that municipal water contains free chlorine and/or chloramines as disinfectants. Both chlorine and chloramines together are referred to as total chlorine. Although monochloramine is the main chloramine of concern due to its toxicity, removal of all chlorine from dialysis water is essential for safe and effective operation of a dialysis system. The AAMI recommends 0.1 PPM as the maximum allowable contamination of chloramines for the treated water. Following testing, the SOP states the results are to be recorded.[13]

Findings

The Little Rock dialysis unit performs treatment on both inpatients and outpatients in the same unit. Chronic hemodialysis patients are scheduled to arrive on a staggered basis, typically either in the morning or afternoon, as treatment lasts approximately 3-4 hours. Inpatients and emergency department patients are seen throughout the day, sometimes with very little notice to the department. As a result, there is not a set shift (period of time) of patient treatment times and treatment may be ongoing throughout the day depending on the volume of patients. Little Rock utilizes a RO water system. To monitor the system, a complete water system check is performed daily, and chlorine testing is completed throughout the day while dialysis treatment is occurring, and staff annotate these results in separate logbooks. The daily water system testing is completed at the beginning of the day, prior to treatment being initiated, and at the end of the day, when a water hardness test is completed and recorded on the log. A component of the daily water system testing is the total chlorine monitoring, but these results are not listed on the log; the log refers the reader to the total chlorine monitoring form for these results. The daily water system testing log states that staff should conduct the total chlorine monitor every 4 hours. The Little Rock Quality Assessment & Performance Improvement (QAPI) program is an ongoing review of performance measures, measures of water and dialysate quality and safety, and safe machine maintenance. We

[12] The Little Rock SOP 5D 1.3, *Monitoring the Dialysis Water System*, effective date September 1, 2020.
[13] The Little Rock SOP NSG-D017, *Ultra-Low Total Chlorine Testing for Dialysis Water*, approved September 2020.

reviewed the QAPI data from fiscal year (FY) 2019 and 2020 and did not find evidence of patient harm related to water quality.

Staff explained that the chlorine testing is completed at the beginning of the day, prior to initiating dialysis and every 4 hours throughout the day during the hours of dialysis treatment (typically at 4:00 a.m., 8:00 a.m., 12:00 p.m. and 4:00 p.m.). Staff explained they use different methods to remind themselves when to check the water, such as using personal cell phone alarms. Another method utilized in the past was an alarm clock located on the nurses' station. The nurse manager stated that the dialysis unit moved to its current location in 2017 and in the previous unit, a different water system was used which only required checking once per day. Following the move to the new unit with the new water system, the requirements to check the water more frequently were an issue and at times not done consistently. She noted over time the water testing consistency improved and she does not believe it has been an issue in the last couple of years.

We reviewed the daily routine total chlorine monitoring logbooks from October 2019 to September 2020. Generally, it appeared that regular monitoring was occurring and being recorded. However, we did find some irregularities in the logbooks including incomplete entries and missing information. For example, there were 5 missing second verification signatures and 29 missing dates. As part of our tour of the dialysis unit, we went into the dialysis water supply room, which is not in the clinical area, but located nearby, and observed the logbook and noted that chlorine testing had been completed for that day and recorded. Our guide explained that the water is tested using chemical test strips and then compared to the color chart to determine the level, which should be less than or equal to 0.10 PPM.

We were told that verification of the chlorine test results is completed by a second staff person. Dialysis staff members stated that the second-staff verification of the chlorine testing result was being completed in a variety of ways, including in the water supply room at the time and place of testing; at the time of testing with the test strip results being reviewed at the nurses' station; at the time of testing by taking the test strip to a staff member to review and entering the signature on the log at a later point in time; and a secondary signature placed on the log without actual secondary visual verification of the test strip. One dialysis RN stated that there have been instances when she forgot to place her signature on the logbook after verifying the result in the clinical area. She stated she had recalled adding her signature the following day after remembering to do so. The daily assignment sheet annotates which staff member is assigned the task of testing the water each day. One of the dialysis RNs who works as a charge nurse on a regular basis explained that as part of her charge nurse responsibilities, she ensures that the water testing is completed, the log is filled out and there are two verification signatures. If the assigned staff person is busy, she completes the testing herself if needed. She noted when she is testing the water, she always gets a second staff person to verify the results.

There appears to be confusion among staff about the second verification of chlorine water testing. We were told by some staff that licensed staff members do not require

second verification, but unlicensed staff members, such as health technicians, do require verification. The nurse manager stated if the health technician performs the testing, then an RN must verify the test strip, but if the RN performs the testing, there is no need for a second verification due to the RN being licensed. The logbook includes a signature block for the testing staff, labeled "clinician signature," and the verification signature block labeled "licensed signature." The Little Rock SOP NSG-D017 does not state that a second visual verification and signature are required.

Patients who require chronic dialysis management typically receive dialysis treatment 3 days per week, approximately every other day. A typical treatment schedule would be either Monday, Wednesday, Friday or Tuesday, Thursday, Saturday. The Little Rock dialysis unit has the highest number of patients scheduled, approximately 50 patients, on Monday, Wednesday, Friday and a lighter schedule of patients, approximately 16 patients, on Tuesday, Thursday, Saturday. We reviewed a random sample of Little Rock dialysis patients' electronic health records (EHR) and cross referenced those dates with the daily routine total chlorine monitoring logbook. Out of nine records reviewed, we found four instances (44%) where patients were still being dialyzed after 4:00 p.m., but no chlorine water testing was performed at 4:00 p.m. The other five records reviewed did have chlorine water testing performed at 4:00 p.m. The Little Rock SOP NSG-D017 does not state how often or when water should be tested; however, the Little Rock SOP 5D 1.3 does state testing is performed daily and at each shift.

Conclusions for Allegation 1

- We **substantiated** that VA staff did not consistently conduct and record chlorine concentration tests of the dialysis water system. We found evidence that testing is not consistently occurring at 4:00pm when patients are still receiving dialysis treatment. We also found evidence of missing required information in the daily routine total chlorine monitoring log.

- There is conflicting information in Little Rock SOPs and logbook forms regarding chlorine testing. The Little Rock SOP 5D 1.3, *Monitoring the Dialysis Water System*, states testing is performed daily and at each shift. The Little Rock SOP NSG-D017 does not state how often or when water should be tested. The daily water system log form states chlorine is to be monitored every 4 hours.

- We identified confusion regarding the need for a second verification of the chlorine water testing, as well as various methods to perform the verification. The SOP NSG-D017 does not state that a second visual verification and signature are required. Although staff stated that a second person verification is required, procedures for verification described by staff were inconsistent. VA Memorandum, *Dialysis Water Testing and Quality Requirements,* states only the daily testing requires a second verifier (which includes chloramine testing).

Recommendation(s) to Little Rock

1. Clarify and update SOP NSG-D017, SOP 5D 1.3 and the daily water system log to reflect when and how often chlorine testing of dialysis water is conducted. Ensure consistency among the three documents and that they follow VHA guidelines. Provide education to staff and once completed, monitor for compliance and address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

2. Determine if all chlorine test results require verification and develop a standardized process that ensures verification of the chlorine test results at the time of testing. Ensure no verification is completed without a visual inspection of the test strip by the verifier. Clarify and update SOP NSG-D017 regarding the requirement for second visual verification and signature. Provide education to staff once completed, monitor for compliance and address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

3. Consider consulting with the VHA National Kidney Program Office for assistance with data collection and documentation.

Allegation 2

VA management officials approving falsified dialysis machine daily maintenance logs.

Background

Per VHA Handbook 1042.01, equipment operation, maintenance and disinfection practices for all RRT devices (e.g. central and portable water purification equipment, and dialysis or other RRT machines) should be consistent with the equipment Operator's Manual.[14] VA Memorandum, *Dialysis Water Testing and Quality Requirements*, dated January 28, 2013, includes requirements for the systematic disinfection of all dialysis machines according to manufacturer guidelines and documentation of the disinfection.[15]

Little Rock SOP NSG-D005, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Chemical Disinfection*, approved September 2020, establishes guidelines for chemical disinfection of the hemodialysis machines. It states the hemodialysis machines will be cleaned and disinfected according to the manufacturer instructions and VA mandates. The chemical/rinse process disinfects the hydraulic system of the machine and is followed by a rinse cycle to clear the system of residual disinfectant. The operators of the hemodialysis machines are responsible for the chemical disinfection. Chemical disinfection is performed weekly and the machine is treated with bleach to ensure the removal of biofilm. The procedure includes testing for

[14] Ibid.
[15] Ibid.

residual disinfectant prior to starting patient treatment and recording the residual test result.[16]

Little Rock SOP NSG-D003, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Acid Cleaning*, dated September 2020, establishes guidelines for acid cleaning of the hemodialysis machines. Acid cleaning prevents the buildup of bicarbonates inside the machine, a buildup that can have a detrimental effect on performance and treatment efficacy. It is not a method of disinfection. The SOP NSG-D003 states that hemodialysis machines will be cleaned and disinfected according to the manufacturer instructions and VA mandates. The operators of the hemodialysis machines are responsible for the acid cleaning. The acid cleaning is performed daily after use of bicarbonate dialysate and can be accomplished using white distilled vinegar.[17] The SOP does not include instructions to record completion of acid cleaning.

Little Rock SOP NSG-D004, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Heat Disinfection*, dated September 2020, establishes guidelines for heat disinfection of the hemodialysis machines. The heat disinfection process disinfects the hydraulic system using water heated to about 80 degrees Celsius. The SOP states that hemodialysis machines will be cleaned and disinfected according to the manufacturer instructions and VA mandates. The operators of the hemodialysis machines are responsible for the heat disinfection. The heat disinfection is performed daily and after any use ending with a rinse cycle.[18] The procedure does not include instructions to record completion of the heat disinfection.

The Fresenius 2008T BlueStar hemodialysis machine has two methods for verifying when the chemical or heat disinfection was last completed. In the first method, the last disinfection event completed is displayed as a time and date stamp on the machine's screen. The second method is an optional feature on the machine which has the capability to maintain a disinfection log through the BlueStar Premium software. This feature will maintain disinfection log records of heat, chemical and rinse disinfection events for up to 1,200 entries. The data includes the date, time and disinfection type utilized. Disinfection events stored on the machine can be transferred to a universal serial bus (USB) drive to capture and store the data electronically.[19]

Findings

We reviewed the dialysis machine daily maintenance logs from October 2019 to September 2020. The log is a daily form and has a column to list the dialysis machines by machine number and another column to note the method of cleaning/disinfection used. The three different cleaning/disinfection methods used are vinegar, heat and bleach. Cleaning/disinfection using vinegar and heat are performed daily on machines

[16] Little Rock SOP NSG-D005, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Chemical Disinfection*, approved September 2020.
[17] Little Rock SOP NSG-D003, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Acid Cleaning*, approved September 2020.
[18] Little Rock SOP NSG-D004, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Acid Cleaning*, approved September 2020.
[19] Fresenius 2008T Machine Operator's Manual, P/N 490122, Rev. U, *Chapter 5 – Disinfection and Maintenance.*

following usage and bleach cleaning/disinfection is performed weekly. When bleach is used for disinfection, the heat process is not used. If a staff member uses the vinegar and heat method, they are required to document the time of completion and place their initials on the log. If a staff member uses the bleach method, they are required to document in the log if the test strip passes, indicating the bleach process effectively cleaned/disinfected the equipment. Staff annotate in the log the results reported in PPM, the test strip lot number and the staff member's signature.

Our review revealed the logs were completed, but not consistently filled out in the same manner. For example, on April 30, 2020, the signature column was signed with a single signature at the top of the column followed by an arrow which went down the length of the column, apparently indicating this staff person had completed all tasks in the row. We saw numerous variations of signing the signature column: some signed with only initials, some signed in groups with the signature placed vertically instead of horizontally, and at times, the signature block was empty. On numerous dates when the bleach process was performed, the test strip lot number was missing. Information placed in the log was illegible at times. We did not find any evidence that the dialysis machine daily maintenance logs had been falsified.

A health technician stated that the Nurse Manager was very diligent about checking the log to ensure the cleaning/disinfection was completed and the log filled out. The technician stated that if the Nurse Manager noted the log was not filled out, the manager would meet with the staff the next day to discuss it and reinforce the importance of timely completion. The whistleblower stated she was told by the Nurse Manager to fill in the cleaning log if it had not been completed. The whistleblower stated when she refused to fill in the log if she had not completed the cleaning, the Nurse Manager told her to look at the machine's electronic log to determine if the cleaning was completed and then to fill in the log. The whistleblower stated she did not think this was fair, as the person who completed the cleaning should be the one documenting the cleaning. The other dialysis staff we interviewed, both licensed and unlicensed, denied they were instructed to falsify data in these logs.

Our review of the SOPs for the three different cleaning/disinfection methods noted the following verbiage was present in each: "the operators of the hemodialysis machines are responsible for the chemical disinfection;" however, these tasks are often assigned to the two health technicians who are not operators performing hemodialysis. The SOP NSG-D003 and NSG-D004 do not include instructions to document completion of the procedures in the dialysis machine daily maintenance log.

Conclusion(s) for Allegation 2

- We **were unable to substantiate** that VA management officials approved the falsification of dialysis machine daily maintenance logs.

- The SOP NSG-D004, SOP NSG-D005 and NSG-D003 include the verbiage "...the operators of the hemodialysis machines are responsible for the chemical disinfection." However, these tasks are often assigned to the two health technicians

(who are not operators performing hemodialysis). By assigning chemical disinfection duties to the health technicians, who are not hemodialysis machine operators, Little Rock is not in compliance with local SOPs NSG-D0004, NSG-D005 and NSG-D003 which state this responsibility is to be assigned to the machine operators.

- The SOP NSG-D003 and SOP NSG-D004 do not include instructions to document completion of the procedures in the dialysis machine daily maintenance log.

- The dialysis machine daily maintenance logs were inconsistently completed and were missing information in some cases.

Recommendation(s) to Little Rock

4. Clarify and update SOP NSG-D004, SOP NSG-D005 and SOP NSG-D003 to specify which specific positions/roles are responsible for performing cleaning/disinfection tasks and clarify what tasks can and cannot be delegated.

5. Clarify and update SOP NSG-D003 and SOP NSG-D005 to include documenting results in the dialysis machine daily maintenance log.

6. Research and determine if the BlueStar Premium software can be purchased for the Fresenius 2008T dialysis machines to allow for electronic documentation of the disinfection processes.

7. Provide education to staff regarding the requirement to completely fill out the dialysis machine daily maintenance log to include a signature on all lines of the log. Monitor the logs to ensure 100% completeness for 6 months and address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

Allegation 3

The failure to properly dispose of and store intravenous medications.

Background

The Joint Commission Medication Management (MM) standard MM.05.01.09 requires a label on every medication container and notes that a standardized method to label medications and containers promotes medication safety. The elements of performance (EP) for this standard include EP-1, which states medication containers are labeled whenever medications are prepared but not immediately administered, and EP-3, which states all medications prepared in the hospital are correctly labeled with the following:

- Medication name, strength and amount (if not apparent from the container).
- Expiration date when not used within 24 hours.
- Expiration date and time when expiration occurs in less than 24 hours.

- The date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.[20]

The Joint Commission standard MM.01.01.03 defines high-alert medications as medications that bear a heightened risk of causing significant patient harm when they are used in error and, as a result, require special safeguards to reduce the risk of errors. The standard MM.01.01.03, EP-2, requires the hospital to follow a process for managing high-alert and hazardous medications. Examples of high-alert medications include opioids, insulin, anticoagulants and neuromuscular blocking agents.[21]

Findings

In response to a complaint filed with the Joint Commission, and at the request of the facility, a subject matter expert from another facility within VISN 16 completed a comprehensive program review of the Little Rock dialysis services in July 2020. The focus of this dialysis program review included safety monitoring, water checks, access and termination procedures, and infection prevention measures. The review also included individual and patient system tracer activities. During tracer activities of the dialysis program review, it was noted that syringes containing heparin, a high-alert medication, were not labeled but these syringes were placed near or on dialysis machines. The dialysis nurse manager confirmed this observation and reported the current dialysis unit practice was to verify the heparin dosage, but not to label the syringes the heparin was drawn up into. The results of the review were discussed with facility leadership and recommendations provided. The recommendation made to address this finding included a requirement for staff to label heparin syringes that are placed on the dialysis machines. In August 2020, labels were ordered for this use and staff implemented this change in practice in the dialysis unit. These actions were annotated on the dialysis program review action plan to address findings of the review. The results of this review were provided to The Joint Commission and subsequently The Joint Commission considered the complaint resolved and closed out the case in August 2020.

During our tour of the dialysis unit, we reviewed all medications in the medication cart in the clinical area. The medication located in the cart are small vials containing only enough medication for a single use. The only multi-use medication vials present in the unit was insulin which was stored in the medication room. During our tour, we saw an RN actively administering heparin to a patient but did not see any unlabeled syringes on dialysis machines. We did not see any improper disposal of medications while on the unit. The dialysis unit uses the Bar Code Medication Administration (BCMA) process when administering medications. This process involves using the computer to scan the medication and the patient's bar code prior to administration. This action documents the medication administration in the EHR. Nurses stated aside from the heparin which infuses over the course of treatment, medications are drawn up and immediately given to patients and documented in the EHR using the BCMA process.

[20] TJC standard MM.05.01.09, EP-3.
[21] TJC standard MM.01.01.03, EP-2.

Nursing staff explained that heparin is given as a bolus initially and then given continually using a pump over the course of the dialysis treatment.[22] The infusing syringe of heparin is the one that requires labeling per the new change in practice. One nurse stated that even though all staff knew the syringe had heparin in it, it was brought to their attention that the syringe should be labeled and that is when the change in practice to label the syringe was initiated. Nurses indicated that outside of the heparin used for infusion, when medications are prepared, they are immediately given to patients. We heard that nursing staff did not consistently label heparin syringes, with some staff stating since the change in practice was initiated, they regularly label the heparin syringe, and some stating they do not always do so.

Little Rock SOP 5D 2.6, *Heparin and Alterative Anticoagulation Administration During Hemodialysis*, dated September 1, 2020, provides procedural guidelines for the safe administration of bolus and maintenance heparin or management of anticoagulation in the absence of heparin to prevent clotting during hemodialysis. This SOP states heparin can be given either continuously via an infusion pump or intermittently through bolus and maintenance doses. The procedure to administer heparin includes loading a 10-milliliter syringe with the heparin and placing it onto the dialysis machine heparin pump. The SOP does not include the process to label the syringe prior to infusing.[23]

Conclusion(s) for Allegation 3

- We **did not substantiate** a failure to properly dispose of and store intravenous medications in the dialysis unit.

- We found no evidence that single-use medication was improperly stored or was administered multiple times among different patients.

- Although a change in practice to label syringes filled with heparin was implemented in August 2020, dialysis staff have not consistently implemented this change.

- The SOP 5D 2.6 does not include the change of practice of labeling syringes filled with heparin.

Recommendation(s) to Little Rock

8. Provide education to the dialysis unit staff regarding the need to label syringes filled with heparin. Monitor for compliance using spot checks/tracers to ensure heparin syringe labeling is occurring when indicated. Address non-compliance with additional training and/or administrative action including disciplinary action where appropriate.

9. Update SOP 5D 2.6 to include the requirement for syringe labeling.

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[22] A bolus is a large dose of a substance given by injection for the purpose of rapidly achieving the needed therapeutic concentration in the bloodstream.
[23] Little Rock SOP 5D 2.6, *Heparin and Alterative Anticoagulation Administration During Hemodialysis*, effective date September 1, 2020.

Allegation 4

The regular consumption of food and beverages in an area with high exposure or potential exposure to blood.

Background

The Occupational, Safety and Health Association's (OSHA) bloodborne pathogens standard prohibits the consumption of food and drink in areas in which work involving exposure or potential exposure to blood or other potentially infectious material takes place, or where the potential for contamination of work surfaces exists.[24] The Little Rock *Exposure Control Plan for Bloodborne Pathogens*, dated December 30, 2019, provides guidance to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030. The Exposure Control Plan states:

> *"Eating, drinking, applying cosmetics, lipstick and lip balm, or inserting contact lenses are prohibited in areas where exposure to blood and body fluids is likely. Lounges, restrooms, conference rooms, and other areas are provided for these activities. Service Chiefs will identify areas where it is safe for employees to eat or drink in their respective services and will monitor this activity."*[25]

Findings

During our tour of the dialysis unit, the manager advised us that food and beverages were permitted to be consumed by patients undergoing dialysis treatment in the clinical area. Food and beverages provided for patients are stored in a storage room located outside the clinical area. Per the Nurse Manager, staff are not permitted to have food and beverages in the dialysis clinical area, including the nurses' station, as the entire area is considered a treatment area. Staff are permitted to store their food and beverages in their lockers or in the staff breakroom, located down the hall from the dialysis clinical area.

During our tour of the dialysis clinical area, we identified one water bottle at a computer workstation and one small candy bar wrapped in a paper towel at the nurses' station, both within the clinical area. We did not witness staff consuming these items during the time of our tour. Presence of these items indicates that consumption was a potential threat and would be in violation of OSHA standard 29 CFR 1910.1030(d)(2)(ix) and the Little Rock Exposure Control Plan for Bloodborne Pathogens. The environment of care (EOC) team conducts rounds on the dialysis unit every 6 months. We reviewed the findings of the EOC rounds from October 2018 through October 2020. During the October 2018 EOC rounds it was noted that the team found one bottle of water on a desk in the treatment area. There were no further findings associated with food or beverages in the remaining EOC rounds.

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[24] 29 CFR 1910.1030(d)(2)(ix), www.osha.gov.
[25] The Little Rock *Exposure Control Plan for Bloodborne Pathogens*, effective date December 30, 2019.

The Nurse Manager stated that she has found water bottles on occasion in the clinical area and immediately removed them. When asked what she has done to address this employee behavior, the nurse manager stated she asks who the item belongs to, and then advises them it is not permitted in the clinical area. She stated she consistently reminds staff that food and drink in the clinical area are not allowed. She identified an alcove area with lockers directly off the clinical area as an issue in the past with staff placing beverages on the windowsill located there. She emphasized to staff that area was also considered a clinical area and not to place food or beverages there. She noted that it is the charge nurse's responsibility to monitor for the presence of staff food and beverages in the clinical area and if present, to address it immediately and notify the Nurse Manager. The Nurse Manager stated since the advent of the COVID-19 pandemic, in March 2020, she has not had to address the issue of food or beverages in the clinical area. Staff interviewed denied the regular consumption of food or beverage in the clinical area and stated these are consumed either in the breakroom, outside of the dialysis unit or in the cafeteria. Staff stated the issue is regularly reinforced by the Nurse Manager.

Conclusion(s) for Allegation 4

- We **substantiated** the presence of food and a beverage in the dialysis unit clinical area, which is an area with high exposure or potential exposure to blood. However, we did not witness the consumption of these items.

Recommendation(s) to Little Rock

10. Educate all dialysis unit staff regarding the location of the designated clinical area where food and beverage storage and consumption is prohibited and the appropriate location(s) where it is permitted. Address non-compliance with additional training and/or disciplinary action as indicated.

11. Perform monthly tracers to monitor the dialysis unit for the presence or consumption of food and beverages until 6 consecutive months occur without findings. Staff from Quality Management and/or Infection Prevention will provide monitoring assistance and will report any findings to the dialysis nurse manager and the Associate Chief Nurse, Ambulatory Care.

VI. Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Little Rock officials may have engaged in conduct that constitutes a violation of law, rule or regulation and a substantial and specific danger to public health and safety, specifically within the dialysis unit. The National Center for Ethics in Health Care has provided a health care ethics review. We found inconsistent water testing processes and documentation issues in the Little Rock dialysis unit which is a potential threat to the safety of patients undergoing dialysis; however, we did not find evidence of patient harm resulting from the issues. We also found food and a beverage

in the clinical area which appeared to belong to staff. If consumed or stored in the area; this would be a violation of OSHA standards.

Attachment A

29 CFR 1910.1030(d)(2)(ix), www.osha.gov.

VHA Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs*, dated May 23, 2016.

VA Memorandum, *Dialysis Water Testing and Quality Requirements*, dated January 28, 2013.

Little Rock *Exposure Control Plan for Bloodborne Pathogens*, effective date December 30, 2019.

Little Rock SOP NSG-D003, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Heat Disinfection*, approved September 2020.

Little Rock SOP NSG-D005, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Chemical Disinfection*, approved September 2020.

Little Rock SOP NSG-D003, *Cleaning and Disinfection of the Fresenius 2008K & 2008T Hemodialysis Machine – Acid Cleaning*, approved September 2020.

Little Rock SOP 5D 1.3, *Monitoring the Dialysis Water System*, effective date September 1, 2020.

Little Rock SOP NSG-D017, *Ultra-Low Total Chlorine Testing for Dialysis Water*, approved September 2020.

Little Rock SOP 5D 2.6, *Heparin and Alterative Anticoagulation Administration During Hemodialysis*, effective date September 1, 2020.

Fresenius 2008T Machine Operator's Manual, P/N 490122, Rev. U, *Chapter 5 – Disinfection and Maintenance.*

AAMI: ISO 23500: *Guidance for the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapies*, Arlington, VA, Association for the Advancement of Medical Instrumentation, 2011

Centers for Disease Control and Prevention, *Dialysis Safety*. https://www.cdc.gov/dialysis/guidelines/water-use.html

Kasparek and Rodriguez, *What Medical Directors Need to Know About Dialysis Facility Water Management*. Clinical Journal of the American Society of Nephrology, June 2015, 10(6) 1061-1071; doi: HTTPS://DOI.ORG/10.2215/CJN.18512144.

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Key to Interviewees

- [redacted] Deputy Associate Director for Patient Care Services
- [redacted]Associate Chief Nurse Acute Care Services
- [redacted]Associate Chief Nurse Ambulatory Care
- [redacted]Nurse Manager, Dialysis Unit
- [redacted]Assistant Nurse Manager, Dialysis Unit
- [redacted]RN Dialysis Unit
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- [redacted]MIT, Dialysis Unit
- [redacted]Health Technician, Dialysis Unit
- [redacted]Health Technician, Dialysis Unit
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- [redacted]Nurse Manager, Infection Prevention
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- [redacted]Environmental Management Service (EMS) Supervisor