DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

APR 7 2015

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-14- 1588

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Ann Arbor Department of Veterans Affairs (VA) Medical Center (hereafter, the Medical Center), Ann Arbor, Michigan. Shelia Griffin, a whistleblower, alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule or regulation, and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

The Secretary asked that the Interim Under Secretary for Health refer the whistleblower's allegations to the Office of the Medical Inspector, who coordinated a VA team that conducted a site visit to the Medical Center on January 12–15, 2015.

VA did not substantiate the whistleblower's six allegations regarding sterile processing employees failing to wear protective equipment, failing to properly perform sterilization procedures, and failing to have instruments ready for emergency procedures, managers failing to train or evaluate employees properly, and inadequate cleaning of the processing area. However, VA did make 14 recommendations for improving sterile processing at the Medical Center.

Findings from the current investigation are contained in the enclosed report, which I am submitting for your review.

Thank you for the opportunity to respond.

Sincerely,

Jose D. Riojas
Chief of Staff

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Report to the
Office of Special Counsel
OSC File Number DI-14-4705

Department of Veterans Affairs
Ann Arbor Healthcare System
Ann Arbor, Michigan

Report Date: April 6, 2015

TRIM 2014-D-1559

Executive Summary

The Interim Under Secretary for Health (I/USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Department of Veterans Affairs (VA) Ann Arbor Healthcare System (hereafter, the Medical Center). Shelia Griffin (hereafter, the whistleblower), who consented to the release of her name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health and safety. The VA team conducted a site visit to the Medical Center on January 12–15, 2015.

Specific Allegations of the Whistleblower

1. Staff do not wear proper personal protective equipment;

2. Staff do not perform sterilization procedures correctly, increasing the possibility of contamination;

3. Instruments needed for emergency operations are sometimes unavailable;

4. SPS managers routinely sign off on evaluations assessing staff competencies without conducting appropriate reviews;

5. Employees lack the appropriate training to perform their job duties; and

6. The SPS unit space is rarely cleaned, leading to an accumulation of dust and dirt in clean/sterile areas.

VA **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. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After a careful review of findings, VA makes the following conclusions and recommendations.

Conclusion for Allegation 1

- VA **did not substantiate** the allegation that staff do not wear appropriate personal protective equipment (PPE).

Recommendation to the Medical Center

1. Continue to monitor compliance with appropriate use of PPE to protect employees and address any incident of identified noncompliance that occurs in the future.

Conclusions for Allegation 2

- VA **did not substantiate** the allegation that staff incorrectly perform sterilization procedures, increasing the possibility of infection.

- VA **did not substantiate** the allegation that the practice of separating instruments into numerous trays increases the possibility of infection; rather, the team found the practice increases the likelihood of complete cleaning. This practice is in compliance with Centers for Disease Control (CDC) and Association of Medical Instrumentation (AAMI) guidelines incorporated into the Veterans Health Administration (VHA) policy.

- VA **did not substantiate** the allegation that staff are not in compliance with these guidelines. In the past, the staff did not consistently load the sterilizer per CDC guidelines. Currently, staff are in compliance with these guidelines.

- VA **did not substantiate** the allegation that staff were wrapping trays and instruments improperly.

- VA **did not substantiate** the allegation that unavailable, missing, or wrong equipment, or evidence of contamination had a significant impact on surgical start times, (0.06%).

Recommendations to the Medical Center

2. Continue to monitor staff compliance with the revised sterilizer loading standard operating procedure (SOP), VHA-V11-506-SPS-SOP-5000-DO, *Standard Operating Procedure for Set-Up and Operation of Getinge 833HC (Autoclave)*, September 30, 2014, and take the appropriate action to address noncompliance.

3. Continue to monitor sterile processing service (SPS) trays for unavailable, missing, or wrong equipment, and evidence of contamination and address incident reports appropriately.

4. Continue to monitor the impact of SPS issues on operating room (OR) start times.

Conclusions for Allegation 3

- VA **did not substantiate** the allegation that instruments needed for emergency operations are unavailable because of SPS processing issues.

- The SPS unit does not have a written SOP for the management of "hot list" instruments; however, all interviewed staff could articulate the management of "hot list" items.

Recommendations to the Medical Center

5. Develop a written SOP for reprocessing instruments on the "hot list." Continue to provide training, monitor for compliance, and take appropriate actions to address any identified incidents of noncompliance that may occur in the future.

6. Continue to review Censitrak data, incident reports generated by the OR, etc., to identify incidences of delayed reprocessing of items on the "hot list." If delays occur, determine the causes and implement any needed corrective action.

7. Review all emergency ophthalmology and neurosurgery cases done between May 1, 2013 and April 30, 2014, to determine whether any OR delays resulted from the unavailability of unique instruments secondary to SPS processing issues and were not reported, and if necessary, take appropriate action.

Conclusions for Allegation 4

- VA **did not substantiate** the allegation that SPS managers routinely sign off on evaluations assessing staff competencies without conducting appropriate reviews.

- SPS does not utilize a standard competency evaluation form.

- The variability of documentation on competency evaluation forms found in current folders makes interpretation confusing.

Recommendation to the Medical Center

8. Standardize the competency evaluation form.

9. Train both evaluators and employees on the utilization of the competency evaluation form.

10. Monitor the implementation of the standardized competency evaluation form for completeness and accuracy of documentation, and provide additional training and take appropriate actions as indicated.

Conclusions for Allegation 5

- VA **did not substantiate** the allegation that employees lacked appropriate training to perform their duties.

- Some staff did not recognize in-services and other educational presentations provided by the Medical Center as training.

- A published training schedule would help employees recognize educational events as training.

- The Medical Center's SPS quality assurance (QA) program met or exceeded standards.

- Staff did not recognize many of their daily work functions (mechanical/electronic controls and chemical and biologic indicators) were a part of a QA program.

Recommendations to the Medical Center

11. Reinforce with staff that in-services and new equipment orientation are forms of training.

12. Develop and routinely publish a training schedule.

13. Routinely report results of QA monitoring at staff meetings, ensuring the term "quality assurance" is used to describe the monitoring that staff currently conducts on a daily basis.

Conclusions for Allegation 6

- VA **did not substantiate** the allegation that the SPS area was not cleaned thoroughly on a regular basis.

- Concerns voiced about trash piling up during the evening shift warrants investigation.

Recommendation to the Medical Center

14. Conduct an assessment to determine whether the volume of trash accumulation during the evening shift warrants an evening shift trash collection, and if indicated, initiate evening shift trash collection.

Summary Statement

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the Office of General Counsel (OGC) has provided a legal review, and the Office of Accountability Review (OAR) has examined the issues from a Human Resources (HR) perspective to establish accountability, when appropriate, for improper personnel practices. VA found no

violations of law, rule, or regulation, no violation of VA or VHA policy, and no substantial or specific danger to public health and safety. No action (such as changes in VA rules, regulations, or practices, or disciplinary action) will be taken or is planned as a result of this investigation.

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I. Introduction

The I/USH requested that OMI assemble and lead a VA team to investigate allegations lodged with OSC concerning the Medical Center. The whistleblower, who consented to the release of her name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on January 12–15, 2015.

II. Facility Profile

The VA Ann Arbor Healthcare System consists of the Medical Center and three community-based outpatient clinics. The Medical Center is a tertiary care facility and provides a full range of patient care services, including medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, geriatrics and extended care, and dentistry. Comprised of 105 inpatient beds and 46 Community Living Center beds, the Medical Center maintained an average daily census of 87, had an 82.9 percent occupancy rate, had 504,542 outpatient visits, and performed 4,731 surgical procedures during fiscal year (FY) 2014.

The Medical Center has active medical school affiliations with the University of Michigan Medical School and the University of Toledo College of Medicine. Over 800 University of Michigan residents and students train at the Medical Center each year. There are also nursing student affiliations with the University of Michigan, University of Toledo, Eastern Michigan University, Madonna University, and Washtenaw Community College, as well as affiliations with the University of Michigan in dentistry, dental hygiene, pharmacy, social work, psychology, and physical therapy. Overall, the Medical Center has over 85 affiliations and supports a health services research and development program, and a Geriatric Research, Education, and Clinical Center.

III. Specific Allegations of the Whistleblower

1. Staff do not wear proper personal protective equipment;

2. Staff do not perform sterilization procedures correctly, increasing the possibility of contamination;

3. Instruments needed for emergency operations are sometimes unavailable;

4. SPS managers routinely sign off on evaluations assessing staff competencies without conducting appropriate reviews;

5. Employees lack the appropriate training to perform their job duties; and

6. The SPS unit space is rarely cleaned, leading to an accumulation of dust and dirt in clean/sterile areas.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of: (b) (6) MD, Deputy Medical Inspector; (b) (6) RN, OMI Clinical Program Manager; (b) (6) Health Systems Specialist, VHA National Program Office for Sterile Processing; and (b) (6) HR Specialist with OAR. VA reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. The team arrived at the facility unannounced, met briefly with leadership, and began a tour of the SPS area within 20 minutes of arrival at the Medical Center. We held an entrance briefing the following morning with Medical Center leadership, conducted another unannounced tour, and convened an exit briefing with Medical Center and Veterans Integrated Service Network (VISN) 11 leadership on the last day of the visit.

VA initially interviewed the whistleblower via teleconference on January 12, 2015. We also interviewed the following Medical Center employees on site:

- (b) (6), Patient Safety Manager/VISN 11 Patient Safety Officer
- (b) (6), RN, Associate Director Patient Care Services
- (b) (6), Chief, SPS
- (b) (6), Former Chief, SPS
- (b) (6), Assistant Nurse Manager SPS
- (b) (6), MD, Chief, Surgery
- (b) (6), Nurse Administrator Surgery Service (NASS)
- (b) (6), MD, Program Director, Infection Control
- (b) (6), RN, Infection Control Coordinator
- (b) (6), Chief, Safety
- (b) (6), Associate Chief Nurse/Chief, Quality
- (b) (6), Surgical Quality Nurse
- (b) (6), Lead, Medical Supply Technician (MST)
- (b) (6), MST
- (b) (6), MST
- (b) (6), Jr., MST
- (b) (6), MST
- (b) (6), MST
- (b) (6), MST
- (b) (6), Facilities Maintenance Supervisor
- (b) (6), Facilities Management Officer
- (b) (6), Housekeeping Supervisor
- (b) (6), Housekeeping Aide
- (b) (6), HR Officer
- (b) (6), HR Specialist
- (b) (6), HR Specialist

VI. Findings, Conclusions, and Recommendations

Allegation 1

Staff does not wear appropriate protective equipment.

Findings

The aim of sterile processing is to ensure medical and surgical instruments are cleaned and sterilized (when indicated) to prevent transmission of pathogens to patients, minimize risks to staff, and preserve the value of the items being reprocessed. Sterile processing includes the decontamination, cleaning, and sterilization of instruments. According to the Occupational Safety and Health Administration (OSHA) regulation, decontamination is the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles, and the surface of the item is rendered safe for handling, use, or disposal.[1]

Decontamination, where dirty instruments and equipment are processed and prepared for cleaning, takes place in an area separate from preparation and sterilization. Decontamination involves the use of physical or chemical procedures to remove, inactivate, or destroy bloodborne pathogens on an item's surface. Because all the instruments in this room are considered dirty, all staff members in this area are required to wear the appropriate PPE. According to OSHA, "protective equipment, including PPE for eyes, face, head and extremities, protective clothing,...will be provided, used and maintained...wherever it is necessary to prevent injury or impairment in the function of any part of the body through absorption, inhalation or physical contact; PPE is specialized clothing or equipment worn by an employee for protection against a hazard."[2] Staff members enter the decontamination area via a small anteroom, where PPE is stored and a sink is available for hand washing. Prior to leaving the decontamination area, staff members remove their PPE near the exit, discard them in a waste basket near the door, and proceed out of the area into the anteroom where they can wash their hands. During both unannounced tours of SPS, the team observed all staff wearing the appropriate PPE. They were cleaning instruments wearing face masks and shields that adequately covered their faces. The team did not observe any staff wearing decontamination PPE in areas outside the decontamination area. Staff members stated that they have not observed other persons in the decontamination areas wearing inappropriate PPE. They also affirmed that if anyone attempted to enter the decontamination area without proper PPE they would be stopped and sent out to don the proper equipment, and that this is not a frequent occurrence.

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[1] 29 C.F.R. 1910.1030 OSHA Bloodborne Pathogens Standards, Toxic and Hazardous Substances.
[2] 29 C.F.R. 1910.132 (a) Subpart 1- Personal Protective Equipment.

Conclusion for Allegation 1

- VA **did not substantiate** the allegation that staff does not wear appropriate PPE.

Recommendation to the Medical Center

1. Continue to monitor compliance with appropriate use of PPE to protect employees and address any incident of identified noncompliance that occurs in the future.

Allegation 2

Staff does not perform sterilization procedures correctly, increasing the possibility of infection.

In order to ensure the cleanliness and sterility of inventory processed and stored in the SPS and Material Support Division (MSD) areas, staff must adhere to specific standards. These standards include those noted in Handbook 1761.02, *VHA Inventory Management*; the *VHA Design Guide for Supply, Processing and Distribution*; the Medical Center Standard Operating Procedures (SOP), Environmental Control of Storage Area, and Inventory Distribution; and standards developed by the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), and the Association for Professionals in Infection Control and Epidemiology (APIC).

After use, dirty instruments are returned to SPS for decontamination, cleaning, and sterilization. Per CDC and AAMI guidelines, prior to washing, instruments with removable parts should be disassembled, and hinged instruments should be opened.[3] The cleaning process includes inspection for gross soiling, opening and positioning for complete cleaning, and grouping of instruments based on their composition (metal vs. plastic). Complete opening and disassembling of instruments increases the surface area that will be exposed for cleaning, increasing the likelihood that instrument's surfaces will be cleaned completely. Instruments are then placed in automatic washers for cleaning and drying. They are transferred to the preparation area and then reassembled, packaged, and prepared for sterilization.

During her interview, the whistleblower raised a concern about staff separating instruments into too many processing trays, and as a result, reassembly after cleaning requires more time than if the instruments were in fewer trays. Staff members maintained they separate instruments into numerous trays in an effort to ensure that they are cleaned completely. Most stated that this Medical Center's instruments were separated into more trays than at their previous places of employment. They agreed that it takes more time to reassemble the instruments from multiple trays, and believed the benefit of placing them in multiple trays for complete cleaning outweighed the increased amount of time needed to reassemble after cleaning. The CDC and AAMI guidelines promote the use of processes that will increase the likelihood of complete

[3] CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. AAMI: www.aami.org

cleaning. Neither set of guidelines has requirements for the minimal number of instruments that should be in each tray.

After removing items from the washer units, the staff packages and sterilizes them. Packaging involves preparing instruments for sterilization by wrapping them in different types of coverings, such as peel-open pouches, sterilization wraps made of woven and nonwoven polypropylene or polyethylene, and metal containers. Once the instruments are packaged, they are placed in the sterilizer, with metal containers on the lowest shelf, wrapped items above the metal containers, and peel-open pouches above the wrapped items.

The whistleblower alleged that "staff does not load sterilization machines properly, without regard for CDC guidelines." Staff admitted that approximately 1 year ago, sterilizers had not been consistently loaded according to the accepted guidelines. When this inconsistency was brought to the attention of SPS management, the SOP was revised as VHA-V11-506-SPS-SOP-5000-DO, *Standard Operating Procedure for Set-Up and Operation of Getinge 833HC (Autoclave)*, September 30, 2014, that states "It is the practice of the SPS Dept. at the Ann Arbor VA to place peel packs on the top rack, wrapped items in the middle, and containers on the bottom." All staff members were able to articulate this current practice.

The packing allows sterilization to take place, protecting the instruments during sterilization, and maintains sterility until the instruments are used. Per the International Association of Healthcare Central Service Materiel Management (IAHCSMM) guidelines, the wrapper must be large enough to completely contain the contents, not so loose that aerosol can get into the package, but not so tight as to impede sterilant penetration entry or exit.[4] The whistleblower alleged that staff do not wrap sterilized instruments properly, resulting in numerous instruments in storage areas with gaps and tenting in their wrapping. The team inspected numerous wrapped trays in the sterile processing area and sterile storage area and found no evidence of improper wrapping; the external indicators on these trays indicated that the items were sterile. We found no incident reports from the operating rooms (OR) regarding improperly wrapped items or trays.

The Medical Center submits quarterly data to the VA National Surgery Office for analysis in the VA Surgical Quality Improvement Program (VASQIP) on the rates of morbidity and mortality (M&M) in Veterans undergoing surgical procedures, as part of its Quality Assurance Program. (Such records are generally protected from disclosure in accordance with 38 United States Code § 5705, "Confidentiality of medical quality-assurance records.")[5] Review of its VASQIP data for FY 2013 revealed no M&M rates higher than expected when compared to similar VA medical centers. VA's review of the

[4] International Association of Healthcare Central Service Materiel Management. Central Service Technical Manual, 7th Edition. 2007,

[5] The VASQIP system is used to create reports regarding quality of the surgical care given to VA patients. VASQIP analyzes major surgical procedures with detailed clinical preoperative risk and procedural and outcomes data. VASQIP identifies the range of statistically acceptable outcome rates for mortality and morbidity for overall and specialty surgical procedures performed and assessed by any one facility.

Medical Center's Infection Control Committee meeting minutes found no evidence of elevated infection rates in patients who underwent surgical procedures.

As part of its quality improvement program, the Medical Center elicits and monitors feedback from end users of the equipment. The OR uses the electronic patient incident reporting (ePIR) system to identify issues with the quality of instrument processing, timeliness, availability of instruments, and proper assembly of the different trays. During FY 2014, there were 29,258 containers, and 100,582 peel packers processed in SPS in support of 4,731 procedures performed. OR reported five incidents of having received trays from SPS with missing, wrong, or unavailable instruments and two incidents of having received contaminated trays, which were not used. Three of these incidents resulted in a delay in the start of surgery.

Conclusions for Allegation 2

- VA **did not substantiate** the allegation that staff incorrectly perform sterilization procedures, increasing the possibility of infection.

- VA **did not substantiate** the allegation that the practice of separating instruments into numerous trays increases the possibility of infection; rather the team found the practice increases the likelihood of complete cleaning. This practice is in compliance with CDC and AAMI guidelines incorporated into VHA policy.

- VA **did not substantiate** the allegation that staff are not in compliance with these guidelines. In the past, the staff did not consistently load the sterilizer per CDC guidelines. Currently, staff are in compliance with these guidelines.
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- VA **did not substantiate** the allegation that staff were wrapping trays and instruments improperly.

- VA **did not substantiate** the allegation that unavailable, missing, or wrong equipment, or evidence of contamination had a significant impact on surgical start times (0.06%).

Recommendations to the Medical Center

2. Continue to monitor staff compliance with the revised sterilizer loading SOP, VHA-V11-506-SPS-SOP-5000-DO, *Standard Operating Procedure for Set-Up and Operation of Getinge 833HC (Autoclave)*, September 30, 2014, and take the appropriate action to address noncompliance.

3. Continue to monitor SPS trays for unavailable, missing, or wrong equipment, and evidence of contamination and address incident reports appropriately.

4. Continue to monitor the impact of SPS issues on OR start times.

Allegation 3

Instruments needed for emergency operations are sometimes unavailable.

When the OR performs emergency operations, SPS must have the needed instruments available. Although most instruments are readily available, some instruments may be defined as unique if they are infrequently used or in limited supply. At the Medical Center, these unique instruments are kept on a "hot list." In order to track where instruments are, and to effectively manage their inventory, SPS staff scans all instruments arriving for decontamination, cleaning, and sterilization. Since December 2013, when an instrument from the "hot list" is scanned, an alert is sent through SPS's automated tracking system, Censitrac®, to the computers in the decontamination and preparation areas to notify staff of the item's arrival. To ensure sure even greater visibility, decontamination area staff write the name of the "hot list" item on a dry-erase board. Staff are expected to clean and process a "hot list" instrument immediately so it will be available for re-use as soon as possible. Staff has been informed verbally about this expectation, but there is no SOP for this practice.

During her interview, the whistleblower alleged she observed frequent occurrences in which SPS staff left instruments clean but unsterilized over the course of several shifts, and in one instance, the whistleblower was required to return to the facility to assist with sterilization of an instrument needed for a neurosurgery case. No staff members, including former and current SPS management, were able to recollect such an instance, and as the whistleblower had not identified any specific patient case, the team could not pursue this allegation further.

During interviews and tours, all staff members were able to articulate the "hot list" process and show us what the alert looks like on their workstation screens. From VA team interviews with the Chief, Surgery, and the NASS, as well as our reviews of the VISN Quality Assurance Report and ePIRs submitted by the OR during the time the whistleblower had been employed, we found no indication that an emergency surgery has been delayed or that a patient needing emergent surgery had to be transferred to a different facility because needed equipment was not sterilized and ready for use.

The whistleblower reported two instances in which instruments were not available for surgery when needed; the type of surgery was known (ophthalmology and neurosurgery) but not the patient information. The VA team's review of the ePIR's submitted by the OR revealed one orthopedic case for which a unique instrument was unavailable because it had been sent out of the facility to be repaired, and not because it was in SPS unprocessed. There were no reported ophthalmologic cases in which instruments were not available for surgery.

The whistleblower alleged that the unavailability of unique instruments from SPS is a result of lax supervision by managers; VA has found no evidence of these instruments being unavailable for emergency surgeries.

Conclusions for Allegation 3

- VA **did not substantiate** the allegation that instruments needed for emergency operations are unavailable because of SPS processing issues.

- The SPS unit does not have a written SOP for the management of "hot list" instruments; however, all interviewed staff could articulate the management of "hot list" items.

Recommendations to the Medical Center

5. Develop a written SOP for reprocessing instruments on the "hot list." Continue to provide training, monitor for compliance, and take appropriate actions to address any confirmed incidents of noncompliance that occur in the future.

6. Continue to review Censitrak data, incident reports generated by the OR, etc., to identify incidences of delayed reprocessing of items on the "hot list." If delays occur, determine the causes and implement any needed corrective action.

7. Review all emergency ophthalmology and neurosurgery cases done between May 1, 2013 and April 30, 2014, to determine whether any OR delays resulted from the unavailability of unique instruments secondary to SPS processing issues and were not reported, and if necessary, take appropriate action.

Allegation 4

SPS managers routinely sign off on evaluations assessing staff competencies without conducting appropriate reviews.

Competency training and assessment is an important tool for ensuring SPS staff receive adequate training and are able to demonstrate how various tasks are performed. Competency evaluation involves providing training and then assessing the employee's understanding and ability to perform the task being taught. Assessment of competency includes direct observation of the employee performing a task or skill, his or her ability to describe in sequence the correct steps taken to perform the task, the rationales for each step, and mechanisms for troubleshooting. The evaluator can assess the employee's competency while speaking with and observing the employee completing a task without announcing to the employee that an assessment is being done. The unannounced assessment gives the evaluator an opportunity to evaluate how well an employee is able to perform tasks in the working environment. At other times, the evaluator may do an announced assessment.

The Medical Center uses competency training forms to keep track of competencies completed and any need for additional training. These forms contain a column for the first evaluator's initials, indicating that training had been provided and that the employee is competent. A second column is for the employee to initial, indicating that training had

been received and that he or she feels competent to perform the task. An additional space is provided for an evaluator to confirm the competency. If the evaluator does not believe the employee is competent to perform a certain task, he or she does not initial that space and arranges for additional training. When employees believe they are competent to perform certain tasks, they initial those tasks. When they do not believe they are competent, they must not initial the task, but rather inform the evaluator that they need additional training. After the additional training is provided, the employee's competency is re-assessed and documented.

The whistleblower alleged that staff members are instructed to initial their competency evaluations, indicating they have been trained and are competent, even if they have not been evaluated. With the exception of one, all staff members stated that they had never been instructed by evaluators or management to initial a competency for which they had not been trained or evaluated. The dissenting staff member reported that another employee had said that he had been instructed to initial competencies for which he had not been trained. We interviewed this other staff member and found that he had not been asked to initial a competency for which he lacked training, but rather, he had declined to initial competencies for some equipment with which he was not familiar, because he wanted additional training. That training was scheduled, but because of workload, had not been completed, and this employee was not performing the particular task until he received that training. He affirmed that he had not been instructed to initial a competency for which he was not evaluated.

Other staff members were not aware of any evaluations having been signed by SPS management without the managers first having conducted a review or evaluation of the employee. Management stated they did not sign off competency evaluations without conducting such reviews or evaluations. The whistleblower voluntarily reported that, in her position as assistant chief of SPS, she did sign off competencies without evaluating the employee.

The team's review of SPS staff members' competency folders revealed variations in the forms for charting competency assessments. Some sheets have a space for "monitoring" that we were told was to be used for an ongoing competency assessment, while other forms did not. Some evaluators initialed in the "monitoring" column for an initial competency review, and one evaluator was not able to clearly articulate how to document initial competency assessments versus ongoing monitoring. One employee's competency folder contained numerous competencies that the evaluator had initialed but the employee had not initialed. According to the employee, some were competencies he had intended to initial but had not had the time to go back and sign the form; the remaining were competencies for tasks for which he had requested additional training. He is not currently assigned to perform any tasks for which he has not yet received training.

Conclusions for Allegation 4

- VA **did not substantiate** the allegation that SPS managers routinely sign off on evaluations assessing staff competencies without conducting appropriate reviews.

- SPS does not utilize a standard competency evaluation form.

- The variability of documentation on competency evaluation forms found in current folders makes interpretation confusing.

Recommendation to the Medical Center

8. Standardize the competency evaluation form.

9. Train both evaluators and employees on the proper utilization of the competency evaluation form.

10. Monitor the implementation of the standardized competency evaluation form for completeness and accuracy of documentation, and provide additional training and take appropriate actions if and as indicated.

Allegation 5

Employees lack the appropriate training to perform their job duties.

All SPS staff members completed VHA's mandatory first level training for reprocessing instruments that teaches staff how to identify, disassemble, reassemble, decontaminate, clean, and sterilize instruments. Staff who successfully complete first level training are considered Level 1 certified. Some staff have also received the advanced training, known as Level 2; the Medical Center has scheduled those who have not yet completed Level 2 to complete this training in the near future. SPS management provides or arranges for additional staff training year round. Training is provided about instruments, equipment reprocessed in SPS, changes in processes and practices, and relevant non-SPS Medical Center policies. Training is provided by in-services done by Medical Center staff, or product representatives, and is prescheduled or presented as needed.

The whistleblower alleged that employees lack the appropriate training to perform their duties. The team's review of employee competency folders included evidence that staff are provided training at least annually. While staff members stated they are not provided training, they all reported completing Level 1 training, and some stated they also completed Level 2 training. All stated they frequently receive in-services and just-in-time training. When asked what training they thought they needed, none were able to articulate any area of training deficiency. Staff also stated they had not considered in-services as training, even though they are given information to apply to their assigned work duties and tasks. SPS does not publish a training schedule. Our review of

documented concerns from the OR and VASQIP data revealed no persistent issues directly linked to a lack of staff training.

Proper sterilization of instruments is a critical aspect of infection control. In order to assure the sterilization process is effective and reliable, SPS monitors quality assurance (QA) measures. QA measures include mechanical/electronic controls monitoring, chemical indicators, and biological indicators. Mechanical/electronic controls indicate the process parameters for sterilization (time, temperature and pressure) in the area close to the probe inside the sterilizer; per AAMI guidelines, these should be reviewed and recorded after each sterilization cycle. Mechanical/electronic controls do not indicate whether sterilization is taking place inside the wrapped package. Chemical indicators monitor one or more of the process parameters of the sterilization cycle, and indicate if an item has been exposed to the sterilization process. One of the chemical indicators used at the Medical Center is the Bowie-Dick Indicator, which tests all three of the process parameters and is conducted by testing the air in an empty chamber. The AAMI guidelines state that Bowie-Dick testing should be done each day a vacuum sterilizer is used; the Medical Center is compliant with this testing. Biological indicators use bacterial spores to assess the sterilizer's ability to kill specific strains of highly resistant organisms. Biological indicators are placed inside a test pack, and the test pack is placed in a fully loaded chamber with other packs. AAMI guidelines state biological indicator testing should be done daily; per review of documentation and staff reports, the Medial Center exceeds standard and does this testing with every load.

During her interview, the whistleblower alleged that SPS did not conduct QA activities. Some interviewed staff members reported that QA activities were not being conducted in SPS; however, they reported they conduct biological indicators on each sterilized load, they conduct Bowie-Dick testing every morning, they include in each tray a count sheet that has a space for the end user to document any quality issues, and they randomly spot check trays for any problems. During our interviews and unannounced tours, all staff members were able to articulate the different types of sterilization testing done in SPS, how to interpret the QA testing results, and which steps to take if test results were not within the acceptable range. The Medical Center provided documented QA results and actions taken to address results that were outside of acceptable ranges.

Conclusions for Allegation 5

- VA **did not substantiate** the allegation that employees lacked appropriate training to perform their duties.
- Some staff did not recognize in-services and other educational presentations provided by the Medical Center as training.
- A published training schedule would help employees recognize educational events as training.
- The Medical Center's SPS QA program met or exceeded standards.

- Staff did not recognize many of their daily work functions (mechanical/electronic controls and chemical and biologic indicators) were a part of a QA program.

Recommendations to the Medical Center

11. Reinforce with staff that in-services and new equipment orientations are forms of training.

12. Develop and routinely publish a training schedule.

13. Routinely report results of QA monitoring at staff meetings, ensuring the term "quality assurance" is used to describe the monitoring that staff currently conducts on a daily basis.

Allegation 6

The SPS space is rarely cleaned, leading to an accumulation of dust and dirt in clean/sterile areas.

Cleaning the SPS area involves cleaning floors and walls, dusting vents, dumping trash and sharps, and cleaning the locker room and offices. The whistleblower alleged that the SPS area was not cleaned thoroughly on a regular basis. Environmental Management Services (EMS) supervisors and staff stated that SPS is cleaned during the day shift and night shift; currently, EMS only provides service on the evening shift if requested by SPS staff. With one exception, all staff members stated that EMS keeps the SPS area and locker rooms clean. The member who did not agree stated the area was not clean, but then attributed the appearance of the area, including the decontamination area, to clutter and not dust or dirt (the SPS is currently under construction for expansion). Most staff recommended EMS collect trash during the evening shift as well, as it sometimes piles up. During both unannounced tours, all areas, including the corners in all rooms, were noted to be clean and dust free with no overflowing trash receptacles; the vents in all areas were clean and dust free.

The current chief and former chief stated they do not leave their offices unlocked for cleaning; instead, they request that EMS only clean and vacuum when they are present, since employee personally identifiable information is kept in their offices. Both chiefs stated they contact EMS when they wanted their offices clean, but leave their trash cans outside of their offices at the end of each day. None of the supervisory staff expressed concerns about cleanliness in the SPS area or EMS's responsiveness to requests for cleaning, vacuuming, or trash removal.

Conclusions for Allegation 6

- VA **did not substantiate** the allegation that the SPS area was not cleaned thoroughly on a regular basis.

- Concerns voiced about trash piling up during the evening shift warrants investigation.

Recommendation to the Medical Center

14. Conduct an assessment to determine whether the volume of trash accumulation during the evening shift warrants an evening shift trash collection; and if indicated, initiate evening shift trash collection.

VI. Summary Statement

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the OGC has provided a legal review, and the OAR has examined the issues from an HR perspective to establish accountability, when appropriate, for improper personnel practices. VA found no violations of law, rule, or regulation, no violation of VA or VHA policy, and no substantial or specific danger to public health and safety. No action (such as changes in VA rules, regulations, or practices, or disciplinary action) will be taken or is planned as a result of this investigation.

Attachment A

29 C.F.R 1910.1030 OSHA Bloodborne Pathogens Standards, Toxic and Hazardous Substances.

29 C.F.R. 1910.132(a) OSHA Standards Subpart 1–Personal Protective Equipment.

American Association of Medical Instrumentation (AAMI) Standards (www.aami.org)

American Journal for Infection Control. *The Guidelines for Design and Construction of Hospital and Healthcare Facilities.* 2010 (www.ncbi/nlm/nih.gov)

Association for peri-Operative Registered Nurses (AORN) Perioperative Standards and Recommended Practices, 2012.

International Association of Healthcare Central Service Materiel Management. Central Service Technical Manual, 7th Edition, 2007.

Medical Center Construction Plans for the New SPS and MSD Areas

Medical Center Current Floor Plan for SPS

Medical Center Electronic Patient Incident Reports Generate by the Operating Room

Medical Center EMS Cleaning Schedules for SPS Prep Room and Decontamination Area

Medical Center Infection Control Minutes.

Medical Center Operating Room Caseload and Cancellation Reports

Medical Center SPS Competency Folders

Medical Center SPS Management Board Meeting Minutes

Standard Operating Procedure for *Set-Up and Operation of* Getinge 833HC (Autoclave) (SOP for Loading Sterilizers)

The Centers for Disease Control (CDC). *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008 (www.cdc.gov).

The Joint Commission Official Accreditation Report. VA Ann Arbor Healthcare System . Unannounced OQM Event: 9/11/2014–9/11/2104.

VA Ann Arbor Healthcare System Policy Memorandum 90-13, *Dress Attire for Logistic and Sterile Processing Staff,* November 15, 2013.

VA Ann Arbor Healthcare System Standard Operating Procedure, *Environmental Control of Storage Areas,* 2014.

VA Ann Arbor Healthcare System Sterile Processing Services (SPS) Infection Control Policy and Procedures, 2009,

VA National Surgery Quality Improvement Program (VASQIP) FY 2014

VHA Design Guide for Supply, Processing and Distribution, 2010.

VHA Directive 2009-004,*Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities,* 2009.

VHA Directive 2011-036, *Safety and Health during Construction,* 2011.

VHA Handbook 1761.02, *VHA Inventory Management,* 2009.

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