



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficient Staffing and
Competencies in Sterile
Processing Services at the
VA Black Hills Healthcare
System, Fort Meade Campus
South Dakota



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess an allegation that the Associate Director for Patient Care Services endangered patient safety by placing an unqualified and inexperienced leader as the Acting Chief of Sterile Processing Services (SPS) at the Fort Meade Campus of the VA Black Hills Healthcare System (facility), South Dakota.¹

The OIG requested that the Veterans Integrated Service Network (VISN) review the allegation and provide documentation to support the response. In April 2019, the VISN reported that the Associate Chief Nurse detailed to the Acting Chief of SPS position lacked SPS experience and provided the OIG seven issue briefs related to SPS since July 2017. The OIG team determined that the facility either took appropriate actions to address the identified problems or the identified problems fell outside the scope of this review in six of the seven issue briefs. In one issue brief, the OIG team noted a concern that some surgical instruments were sterilized with an incomplete process because SPS leaders failed to identify changes in the manufacturer's instructions.² The OIG identified an additional concern regarding multiple changes in SPS leadership. The OIG initiated a hotline in June 2019 to address the allegation and additional OIG-identified concerns.

The OIG did not substantiate that the Associate Director for Patient Care Services placed an unqualified and inexperienced staff member in the Acting Chief of SPS role or that this decision endangered patient safety. The Veterans Health Administration (VHA) does not have requirements for staff detailed to an acting role that address background, experience, or training. Facility leaders indicated they chose the Acting Chief of SPS based on leadership experience and workload, and that the detailed Associate Chief Nurse met those requirements. The Acting Chief of SPS had access to the VISN SPS Lead and the Associate Director for Patient Care Services for additional guidance and support related to sterile processing.

¹ VA Black Hills Healthcare System consists of two campuses located in Fort Meade and Hot Springs, South Dakota. The facility's SPS is responsible for the reprocessing (cleaning, decontamination, and sterilization) of critical instruments (instruments that are placed into the bloodstream or normally sterile body areas) and semi-critical instruments (instruments that touch non-intact skin or mucous membranes) and reusable medical equipment in preparation for use on the next patient.

² Issue briefs provide facility, VISN, and Veterans Health Administration leaders clear, concise, and accurate information about a situation or an event. The facility was unable to determine when the incomplete reprocessing of surgical instruments began, so facility leaders elected to begin their review from the date of the last manufacturer's instructions for use update in February 2011.

The OIG reviewed the issue briefs submitted during the time of the Associate Chief Nurse's detail to the Acting Chief of SPS position and determined that no patients were harmed.³

Facility leaders failed to comply with a 2009 Memorandum from the Deputy Under Secretary for Health for Operations and Management which directed all complexity Level 1 or 2 facilities to have an assistant chief position in the sterile processing department by September 30, 2009.⁴ In 2015, the facility changed from a complexity Level 3 to a complexity Level 2, but facility and SPS leaders did not sign the revised SPS organizational chart with the added assistant chief of SPS position until August 2019.⁵ Leaders did not add the assistant chief position as they believed they were going to return to a Level 3 complexity.

Facility leaders failed to ensure a reliable process was in place to identify changes in manufacturer's instructions. Moreover, from 2011 to 2017, SPS staff reassembled the arthroscopes and cystoscopes prior to sterilization contrary to manufacturer's instructions.⁶ According to the August 2, 2017, issue brief, an SPS staff member identified the concern and brought it to the attention of the former Chief of SPS. Once identified, the former Chief of SPS corrected SPS processes to comply with the instructions, retrained staff, and notified facility leaders. The OIG concluded that once the issue was identified, the facility, VISN, and VHA took appropriate actions to address the problem, evaluate associated risk, consult with the required experts, and made a decision based on their risk analysis that patient exposure risk was minimal, and no further actions were needed.

A possible reason for the facility's failure to identify the change to manufacturer's instructions was a series of acting and permanent chiefs of SPS with varying degrees of knowledge and experience of SPS.

³ VHA defines an adverse event as "untoward [events], therapeutic misadventures, iatrogenic injuries, or other adverse occurrences." The Acting Chief of SPS told the OIG of being informed on the day of resignation from the detailed position that previously an unsterilized cystoscope had been used on a patient. The patient was notified of the incident and the facility reported that there was no evidence of harm.

⁴ VA Deputy Under Secretary for Health for Operations and Management (10N) Memorandum, *Filling SPD Assistant Chief Positions*, June 11, 2009. VHA changed the name of the department from Sterile Processing and Distribution to SPS on December 21, 2011.

⁵ VHA Office of Productivity, Efficiency, and Staffing (OPES), *Facility Complexity Level Model Fact Sheet*, December 15, 2017. "Facilities are categorized into one of five groups: 1a (most complex), 1b, 1c, 2, and 3 (least complex)." VHA describes Level 2, medium complexity as, "[f]acilities with medium volume, low risk patients, few complex clinical programs, and small or no research and teaching programs." VHA describes Level 3, low complexity as a, "[f]acility with low volume, low risk patients, few or no complex clinical programs, and small or no research and teaching programs."

⁶ Merriam-Webster, *Definition of arthroscope*. An arthroscope is a scope that is inserted through an incision near a joint for a visual examination, diagnosis, and treatment. <https://www.merriam-webster.com/dictionary/arthroscope>. (The website was accessed on October 17, 2019.) Merriam-Webster, *Definition of cystoscope*. A cystoscope is a rigid scope used for inspecting and passing instruments into the bladder and urethra. <https://www.merriam-webster.com/dictionary/cystoscope>. (The website was accessed on October 17, 2019.)

The lack of stable SPS leadership contributed to the failure to review and update SPS staff competencies. At the time of the OIG's site visit, two of the five experienced SPS staff members had current competencies on the seven instruments and sets of instruments reviewed.

The OIG made three recommendations that the Facility Director 1) complies with VHA requirements that Level 1 and 2 facilities have an assistant chief of SPS on staff, 2) ensures SPS leaders track changes to manufacturer's instructions, update standard operating procedures, and retrain staff, and 3) ensures that SPS leaders maintain up-to-date staff competencies for reprocessing and monitors compliance.

Comments

The VISN and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
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Abbreviations

OIG	Office of Inspector General
SPS	Sterile Processing Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted an inspection to assess an allegation that the Associate Director for Patient Care Services endangered patient safety by placing an unqualified and inexperienced leader over the Sterile Processing Services (SPS) at the Fort Meade Campus of the VA Black Hills Healthcare System (facility) in South Dakota.¹

Facility Background

The facility is designated as a Level 2, medium complexity facility, and is part of Veterans Integrated Service Network (VISN) 23.² The facility operates nine community based outpatient clinics located in South Dakota, Nebraska, and Wyoming. From October 1, 2017, through September 30, 2018, the facility served 17,708 patients and reported having a total of 289 hospital operating beds, including 38 inpatient beds, 10 inpatient mental health beds, 108 domiciliary beds, 104 community living center beds, and 29 compensated work-therapy and transitional residence beds.

Allegation and Related Concerns

In February 2019, the OIG received an allegation regarding endangered patient safety caused by the Associate Director for Patient Care Services designating an unqualified and inexperienced leader as the Acting Chief of SPS. The OIG requested that the VISN review the allegation and provide documentation to support the response. In April 2019, the VISN reported that while the Associate Chief Nurse appointed to the Acting Chief of SPS position lacked SPS experience, the Associate Chief Nurse had leadership experience. The OIG was provided seven issue briefs related to SPS since July 2017.³ Upon review, the OIG team determined that the facility either took appropriate actions to address identified problems or the identified problems fell outside of the scope of the review in six of the seven issue briefs. In one issue brief, the OIG noted that

¹ VA Black Hills Healthcare System consists of two campuses located in Fort Meade and Hot Springs, South Dakota. The facility's SPS is responsible for the reprocessing (cleaning, decontamination, and sterilization) of critical instruments (instruments that are placed into the bloodstream or normally sterile body areas), semi-critical instruments (instruments that touch non-intact skin or mucous membranes), and reusable medical equipment in preparation for use on the next patient.

² VHA Office of Productivity, Efficiency, and Staffing, *Facility Complexity Level Model Fact Sheet*, December 15, 2017. Veterans Health Administration (VHA) describes Level 2, medium complexity as, "Facilities with medium volume, low risk patients, few complex clinical programs, and small or no research and teaching programs." VHA describes Level 3, low complexity as, "Facility with low volume, low risk patients, few or no complex clinical programs, and small or no research and teaching programs."

³ Issue briefs provide facility, VISN, and VHA leaders clear, concise, and accurate information about a situation or an event. Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017.

some surgical instruments were sterilized with an incomplete process because of a failure of SPS leaders to identify changes in manufacturer's instructions for sterilization.⁴ While reviewing the facility's actions taken to address the incomplete sterilization process, the OIG identified an additional concern regarding multiple changes in SPS leadership.

Scope and Methodology

The OIG initiated the inspection on June 6, 2019, and conducted a site visit the week of August 12, 2019.

The OIG team interviewed facility leaders; select VISN staff; Chiefs of SPS and Surgery; the former Acting Chief of SPS; former Reusable Medical Equipment Coordinators; Managers of Patient Safety, Risk Management, and Organizational Improvement; SPS technicians; and relevant staff.

Members of the OIG team conducted a tour of the SPS area.

OIG staff reviewed applicable Veterans Health Administration (VHA) directives, memoranda, facility policies and procedures; quality assurance documents and reviews; relevant meeting minutes from January 2017 through June 2019; and SPS competency folders.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue.

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

⁴ The facility was unable to determine when the incomplete reprocessing of surgical instruments began, so facility leaders elected to begin their review from the date of the last manufacturer's instructions for use update in February 2011 and followed up on the issue until it was resolved.

Inspection Results

1. Unqualified and Inexperienced SPS Leadership

The OIG did not substantiate that the Associate Director for Patient Care Services placed an unqualified and inexperienced leader as the Acting Chief of SPS or that this decision endangered patient safety.

VHA and the facility policies lack requirements addressing background, experience, or training for a staff member or leader in an acting role.⁵ Facility leaders told the OIG during interviews that their process to detail staff into an acting role included examining previous experience and workload.

The Associate Director for Patient Care Services detailed an Associate Chief Nurse to the Acting Chief of SPS position beginning in November 2018 for 120 days. The Acting Chief of SPS was to provide leadership to SPS staff. Although the Associate Chief Nurse did not have direct sterile processing experience, the Associate Director for Patient Care Services considered the Associate Chief Nurse to be an experienced leader who had a record of success in previous leadership roles. Additionally, the Associate Chief Nurse had access to the VISN SPS Lead and the Associate Director for Patient Care Services for additional guidance and support related to sterile processing.

Although the OIG did not receive the names of patients who were allegedly endangered due to the detail of the Associate Chief Nurse to the Acting Chief of SPS, the OIG reviewed facility issue briefs submitted during the time of the detail and determined that no patients were harmed.⁶

Additional Finding

The OIG identified that facility leaders failed to comply with a 2009 Memorandum from the Deputy Under Secretary for Health for Operations and Management, which directed all

⁵ VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016; Facility Policy ADPCS-09, *Use and Reprocessing of Reusable Medical Equipment (RME)*, May 26, 2010; Facility Policy ADPCS-09, *Use and Processing of Reusable Medical Equipment (RME)*, February 2013.

⁶ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA defines an adverse event as an “untoward [events], therapeutic misadventures, iatrogenic injuries, or other adverse occurrences.” The Acting Chief of SPS told the OIG of being informed on the day of resignation from the appointed position that previously an unsterilized cystoscope had been used on a patient. The patient was notified of the incident and the facility reported that there was no evidence of harm. The Associate Chief Nurse told the OIG of leaving the Acting Chief of SPS position in early or mid-February 2019.

complexity Level 1 or 2 facilities to have an assistant chief position in SPS by September 30, 2009.⁷

On March 20, 2015, VHA approved the 2014 Facility Complexity Level Model, which changed the facility's complexity designation from a Level 3 to a Level 2. With this re-designation, the facility would be required to hire an assistant chief of SPS.⁸ The VISN SPS Lead reported repeatedly having reminded facility leaders that they were required to hire an assistant chief. The VISN SPS Lead also reported that in most cases, an assistant chief would act as chief of SPS in the event of a vacancy. The VISN SPS Lead told the OIG that facility leaders thought that they would return to a Level 3 complexity and therefore would not need an assistant chief. According to the VISN SPS Lead, the facility hired a reusable medical equipment coordinator to assist with the demands of the chief of SPS. In 2016, the VISN SPS Lead consulted with the National SPS Office over the appropriateness of the facility having a reusable medical equipment coordinator instead of an assistant chief. According to the VISN SPS Lead, National SPS leaders did not support the facility having a reusable medical equipment coordinator instead of an assistant chief. The VISN SPS Lead informed the OIG that the reusable medical equipment coordinator was a good interim step but told facility leaders that they would need to hire an assistant chief if the facility's complexity level did not return to a Level 3.

The SPS organizational chart signed by the Facility Director on February 15, 2019, did not include an assistant chief position. Although notified by the VISN SPS Lead of the requirement for an assistant chief, the facility did not revise the SPS organizational chart until April 1, 2019, and it was not signed by SPS and facility leaders until after the OIG visit in mid-August 2019.⁹

2. Leaders' Actions After Identifying Incomplete Sterilization Processes

The OIG determined that facility leaders did not identify updated manufacturer's instructions for use (instructions) in the reprocessing of some surgical instruments from 2011 to 2017. Once the problem was identified, the former Chief of SPS retrained staff on the corrected process, reprocessed affected surgical instruments using the corrected instructions, and notified facility

⁷ VA Deputy Under Secretary for Health for Operations and Management (10N) Memorandum, *Filling SPD Assistant Chief Positions*, June 11, 2009. VHA changed the name of the department from Sterile Processing and Distribution to SPS on December 21, 2011.

⁸ VHA Office of Productivity, Efficiency, and Staffing (OPES), *Facility Complexity Level Model Fact Sheet*, December 15, 2017. "Facilities are categorized into one of five groups: 1a (most complex), 1b, 1c, 2, and 3 (least complex)."

⁹ SPS and facility leaders signed off on the revised SPS organizational chart on August 29, 2019. The OIG was told that the Chief of SPS was in the process of hiring an assistant chief for SPS.

leaders. Through the formal evaluation process, VHA determined that patient exposure risk was minimal, and no further action was required.

VHA and facility policies require that reusable medical equipment is reprocessed according to the manufacturer's instructions.¹⁰ At the time the instructions were changed in 2011, facility policy required that manufacturer's updates be monitored monthly by an assigned member of the SPS staff.¹¹ While the OIG was on-site, the Chief of SPS told the OIG that the current process involved two assigned SPS staff members monitoring changes to manufacturer's instructions, updating standard operating procedures, and having the Chief of SPS review the updates.

On February 3, 2011, a manufacturer released a change to the instructions for all arthroscopes and cystoscopes, which required the instruments to remain disassembled for sterilization, then reassembled in the sterile field.¹² Facility leaders failed to ensure a reliable process was in place to identify changes in manufacturer's instructions; and SPS staff continued to reassemble the instruments prior to sterilization contrary to manufacturer's instructions.

According to the August 2, 2017, issue brief, an SPS staff member identified concerns with reassembling stopcocks prior to sterilization in March.¹³ The staff member brought this to the attention of the former Chief of SPS who reviewed the manufacturer's instructions, changed processes within SPS, and educated the Operating Room Nurse Manager and SPS staff about the change in process. These steps were completed by March 7, 2017, for arthroscopes.¹⁴ Due to the involvement of multiple small pieces of equipment that needed to be disassembled for the

¹⁰ VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009 and Facility Policy ADPCS-09, *Use and Reprocessing of Reusable Medical Equipment (RME)*, May 26, 2010 were both in effect in 2011 when the instructions were changed. VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016, and Facility Policy ADPCS-09, *Use and Processing of Reusable Medical Equipment (RME)*, February 2013, were in effect at the time the facility discovered the error in 2017. The facility updated its policy in March 2019. The VHA directives and facility policies provide the same guidance related to reprocessing of reusable medical equipment.

¹¹ Facility Policy ADPCS-09, May 26, 2010.

¹² Merriam-Webster, *Definition of arthroscope*. An arthroscope is a scope that is inserted through an incision near a joint for a visual examination, diagnosis, and treatment. <https://www.merriam-webster.com/dictionary/arthroscope>. (The website was accessed on October 17, 2019). Merriam-Webster, *Definition of cystoscope*. A cystoscope is a rigid scope used for inspecting and passing instruments into the bladder and urethra. <https://www.merriam-webster.com/dictionary/cystoscope>. (The website was accessed on October 17, 2019). Infection Control Today, *AORNs Recommended Practices for Maintaining a Sterile Field is Up for Review and Public Comment Through March 25, 2005*, March 2, 2005. A sterile field is the area around the incision site or the site an instrument is introduced into the body that has been prepared for the use of sterile equipment and supplies.

¹³ Venes, Donald. *Taber's Cyclopedic Medical Dictionary*, 22nd ed. Philadelphia: F.A. Davis Company, January 1, 2013. A stopcock is a "valve that regulates the flow of fluid from a container."

¹⁴ Merriam-Webster, *Definition of arthroscopy*. Arthroscopy is "a minimally invasive surgical procedure involving [a] visual examination of the interior of a joint [using] an arthroscope to diagnose [and] treat various conditions or injuries of [the] joint." <https://www.merriam-webster.com/dictionary/arthroscopy>. (The website was accessed on October 17, 2019.)

sterilization of cystoscopes, additional equipment was purchased to ensure appropriate accounting and sterilization of equipment. Facility leaders were notified later of the incomplete sterilization process within SPS. Facility staff reported that corrective actions, the reprocessing (cleaning and sterilization) of all affected equipment, and the retraining of all relevant staff, was completed by July 2017.

Facility leaders, in accordance with VHA and facility policy, submitted an issue brief to the VISN addressing potential patient exposure risk.¹⁵ In compliance with VHA policy, the VISN referred the issue brief to VHA leaders, and VHA leaders referred on to the Clinical Episode Review team, a Subject Matter Expert Panel, and finally to a Clinical Review Board to evaluate the matter.¹⁶ The Acting Principle Deputy Under Secretary for Health approved the Clinical Review Board's recommendation that no further action was required.

In November 2017, the former Chief of SPS reported the action item as "closed" in the Reusable Medical Equipment Oversight Committee meeting minutes.

On April 20, 2018, VHA issued a memorandum specifically addressing the reprocessing (cleaning and sterilization) of arthroscopes and cystoscopes. The memorandum reinforced that these instruments needed to be disassembled during the cleaning and sterilization process and should be reassembled in a sterile field. In addition, all instruments with moving parts that cannot be disassembled are to remain in the open or loosened position during the cleaning and sterilization process.

The OIG concluded that once the issue was identified, the facility, VISN, and VHA took appropriate action to evaluate and address the problem and associated risk, consulted with the required experts, and made a decision based on their risk analysis.

¹⁵ Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017. VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012 (corrected copy). This handbook was rescinded on October 31, 2018 and replaced with VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Facility Policy COS-21, *Disclosure of Adverse Events to Patients*, September 22, 2015. Unable to determine how long the SPS staff used the incomplete equipment reprocessing, the facility reported extrapolating patient information from February 2011 when the manufacturer's instructions had been changed.

¹⁶ VHA Handbook 1004.08.

Possible Reason for Delay in Instruction Updates

The OIG identified a possible reason for the facility's delay in implementing the 2011 updated instructions.

Facility leaders and staff reported that over the past several years, SPS had a series of acting and permanent chiefs with varying degrees of experience working within SPS. From August 2010 through February 2019, the facility employed three permanent SPS Chiefs with tenures ranging from 21 to 30 months, and eight Acting Chiefs. At the time of the OIG site visit, the SPS Chief had been in place for five months. SPS staff experienced limited to no continuity of leadership for more than eight years.

According to VHA, the Associate Director for Patient Care Services provides oversight, leadership, and is organizationally responsible for SPS operations.¹⁷ Although responsible, the Associate Director for Patient Care Services at the time of the site visit informed the OIG of not assuming the position until March 2017, approximately six years after the change to the manufacturer's instructions.

The lack of stable SPS leadership contributed to the failure to review and update SPS staff competencies. Between July 2018 and April 2019, a former reusable medical equipment coordinator explained to the OIG that when emails that contained changes to manufacturer's instructions were received, the standard operating procedure was updated and submitted to the Chief or Acting Chief of SPS and the Associate Director for Patient Care Services for approval. Once approved, the former reusable medical equipment coordinator would train staff on the new process and staff would not be able to reprocess the equipment until they had completed the required competency and it had been signed off. The previous reusable medical equipment coordinator, who reported holding the position from January 2017 through April 2018, told the OIG that the reusable medical equipment coordinator's primary responsibilities included developing standard operating procedures for the reusable medical equipment and educating staff. However, prior to January 2017, the OIG could not ascertain how staff were alerted to changes in manufacturer's instructions, how standard operating procedures were updated, or how staff were trained on the updated procedures because of a lack of stable SPS leadership and a reusable medical equipment coordinator.

At the time of the site visit, the OIG team noted that of five experienced SPS staff members located at the Fort Meade campus, two staff members had completed all competencies on the

¹⁷ VHA Handbook 1116(2).

seven instruments and sets of instruments reviewed.¹⁸ The other three experienced SPS staff members did not have current competencies in 52.4 percent of the seven reviewed instruments and sets of instruments.¹⁹ The Chief of SPS at the time of the site visit informed the OIG that the Chief of SPS conducted a staff in-service, had staff complete return demonstrations, and brought all missing competencies up-to-date in September 2019. The Chief of SPS also presented the OIG a plan to implement a competency tracking system that would send notifications when competencies were due to expire.

The facility has taken action to ensure consistent leadership within SPS by hiring a full-time Chief of SPS and is reportedly recruiting for an assistant chief of SPS. Following the OIG site visit, the Chief of SPS reported ensuring that all SPS staff had current competencies and was developing an action plan to track them.

Conclusion

The OIG did not substantiate that the Associate Director for Patient Care Services placed an unqualified and inexperienced staff member in the SPS acting chief role, or that this decision endangered patient safety. Facility leaders indicated they chose the Acting Chief of SPS based on leadership experience and workload, and that the detailed Associate Chief Nurse met those requirements. The Acting Chief of SPS had access to the VISN SPS Lead and the Associate Director for Patient Care Services for additional guidance and support related to sterile processing. The OIG reviewed the issue briefs submitted during the time of the Associate Chief Nurse's detail to the Acting Chief of SPS position and determined that no patients were harmed.

Facility leaders failed to comply with a 2009 Memorandum from the Deputy Under Secretary for Health for Operations and Management, which directed all complexity Level 1 or 2 facilities to have an assistant chief position in SPS by September 30, 2009. The facility changed from a complexity Level 3 to a Level 2 in 2015, but facility and SPS leaders did not sign the revised SPS organizational chart with the added assistant chief of SPS position until August 2019.

Facility leaders failed to ensure a reliable process was in place to identify changes in manufacturer's instructions; and SPS staff continued to reassemble the instruments prior to sterilization contrary to manufacturer's instructions from 2011 to 2017. Once the problem was

¹⁸ The OIG reviewed the seven instruments and instrument sets used at the facility involving arthroscopes and cystoscopes including: 1) Arthrex Arthroscopy Set; 2) Olympus Arthroscopic Telescopes/Sets; 3) Karl Storz aka Resectoscopes, Urethrotome, Rigid Cystoscope and all Storz accessories; 4) Richard Wolf Ultrathin and Compact Uretero-Renoscope, Ultrathin Fiber Optic Cysto-Urethroscope; 5) Olympus CYF-5R and CYF-5 Cystonephrofiberscope, CYF-V2 and CYF-VH Cysto-Nephro Videoscope; 6) Gyrus ACMI Flexible Ureteroscope DUR-8E; and 7) STORZ Karl Storz-Endoskope Uretero-renaloscope, Ureteroscope. New SPS staff have one year to complete their training and competencies. Competencies are updated annually or every three years, or when the manufacturer's instructions change.

¹⁹ The OIG did not include three new staff members who were still within the orientation period since it would not be expected that all their competencies would be complete.

identified, the former Chief of SPS corrected SPS processes to comply with the instructions, retrained staff, and notified facility leaders. The facility, VISN, and VHA took appropriate actions to address the problem, evaluated associated risk, consulted with the required experts, and made a decision based on their risk analysis.

A possible reason for the facility's failure to identify the change to manufacturer's instructions was a series of acting and permanent chiefs of SPS with varying degrees of knowledge and experience of SPS. The lack of stable leadership contributed to the failure to review and update SPS staff competencies. At the time of OIG's site visit, two of the five experienced SPS staff members had current competencies on the seven instruments and sets of instruments reviewed.

Recommendations 1–3

1. The VA Black Hills Healthcare System Director complies with Veterans Health Administration requirements that Level 1 and 2 facilities have an assistant chief of Sterile Processing Services on staff.
2. The VA Black Hills Healthcare System Director ensures that Sterile Processing Services leaders track changes to manufacturer's instructions, updates standard operating procedures, retrain staff as needed, and monitors compliance with Veterans Health Administration policy.
3. The VA Black Hills Healthcare System Director ensures that Sterile Processing Services leaders maintain up-to-date staff competencies for reprocessing, and monitors compliance with Veterans Health Administration policy.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 26, 2020

From: Director, VA Midwest Health Care Network (10N23)

Subj: Healthcare Inspection—Deficient Staffing and Competencies in Sterile Processing Services at the
VA Black Hills Healthcare System, Fort Meade Campus, South Dakota

To: Director, Office of Healthcare Inspections (54HL08)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

I have reviewed and concur with the findings and recommendations in the OIG DRAFT report entitled, Healthcare Inspection- Deficient Staffing and Competencies in Sterile Processing Services at the VA Black Hills Healthcare System, Fort Meade Campus, South Dakota.

(Original signed by:)

Robert P. McDivitt, FACHE
Director

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 20, 2020

From: Director, VA Black Hills Healthcare System (568/00)

Subj: Healthcare Inspection—Deficient Staffing and Competencies in Sterile Processing Services at the
VA Black Hills Healthcare System, Fort Meade Campus, South Dakota

To: Director, VA Midwest Healthcare Network (10N23)

I concur with the OIG recommendations contained herein and submit the Facility Director's response as attached.

(Original signed by:)

Sandra L. Horsman
Director, VA Black Hills Health Care System

Facility Director's Response

Recommendation 1

The VA Black Hills Healthcare System Director complies with Veterans Health Administration requirements that Level 1 and 2 facilities have an assistant chief of Sterile Processing Services on staff.

Concur.

Target date for completion: May 1, 2020

Director Comments

The VA Black Hills Healthcare System Director initiated the recruitment process for the Sterile Processing Service Assistant Chief on April 15, 2019. The vacancy was announced on the USAJobs website on August 6, 2019 and closed on August 27, 2019 at a level of GS 8/9. There were six internal candidates that the Human Resources Office deemed not qualified for the position requirements. There were also eleven external candidates, with three qualified for the role. No selection made. The position was then submitted for recruitment again January 2, 2020 with a USAJobs announcement posted on January 28, 2020. The announcement closed on February 3, 2020 with five internal candidates and ten external candidates identified. Human Resources deemed that none of the applicants were qualified for the position. As of February 19, 2020, the position has not yet been posted for a third time. The position is currently to be posted as a GS 9 with a salary range of \$52,905 to \$68,777. We will continue to post this position until we are able to fill with a qualified candidate.

Recommendation 2

The VA Black Hills Healthcare System Director ensures that Sterile Processing Services leaders track changes to manufacturer's instructions, updates standard operating procedures, retrains staff as needed, and monitors compliance with Veterans Health Administration policy.

Concur.

Target date for completion: May 1, 2020

Director Comments

The VA Black Hills Health Care System has revised processes and procedures related to the ongoing review, updates to and changes within manufacturer instructions for all equipment processed through the Sterile Processing Service. The processes for the revision and approval of all standard operating procedures (SOPs) within the Sterile Processing Service, along with the education of staff about new and revised procedures have also been updated. Oversight and

review of new and revised SOPs are processed through the Reusable Medical Equipment Committee for discussion and monitoring of compliance with VHA and facility policies. 100% of SOPs are current. A weekly updated listing of new or newly revised Instructions for Use and revisions is received from the VHA Office of Sterile Processing. The Lead Technician and Sterile Processing Service Chief review and pull the SOPs requiring updating. Development of new SOPs and revisions to existing SOPs are completed by the Lead Technician.

Recommendation 3

The VA Black Hills Healthcare System Director ensures that Sterile Processing Services leaders maintain up-to-date staff competencies for reprocessing, and monitors compliance with Veterans Health Administration policy.

Concur.

Target date for completion: July 1, 2020

Director Comments

The VA Black Hills Health Care System has completed a 100% review of Sterile Processing Service staff competencies with documentation maintained in the service competency folders. As of October 1, 2019, 100% of Sterile Processing Service staff received education and verification of competency in compliance with VHA policy. Processes have been updated for the ongoing review of staff competencies and any delinquencies are tracked and reported through the Associate Director of Patient Care Services for action. All Standard Operating Procedures (SOPs) have a risk assessment completed for the frequency of competency validation required. It is assigned either a 1-year or 3-year competency evaluation score and is then submitted through the approval process. The education and competency validation for the new or revised SOP is completed by Sterile Processing Service staff. The SOP, upon approval and completion of training, is entered into the Censitrac and document control systems with the competency schedule for tracking. The SPS staff is in the process of moving from a paper-based system to two electronic tracking mechanisms. Current status of 90% completion of recording within Censitrac and initiation phase for the document control entry of staff competencies. 100% of Sterile Processing Service SOPs have been loaded into the document control system. When an instrument is scanned, Censitrac will not allow continuation of sterilization if the SOP is due for revision and updating based on the risk assessment or if the employee is not current for competency verification.

OIG Contact and Staff Acknowledgments

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