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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care System

Albuquerque, New Mexico

HEALTHCARE INSPECTION | REPORT # 17-04593-10 | OCTOBER 31, 2018

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding concerns in Sterile Processing Services (SPS) at the New Mexico VA Health Care System (Facility), Albuquerque, New Mexico.

The complainant alleged

- Employees tampered with equipment processes in SPS;
- Sterilized sets from SPS were missing instruments, incorrectly stored, or damaged;
- Surgical procedures were being delayed or canceled due to unavailable sterilized sets;
- Equipment processing delays related to a staffing shortage occurred when the SPS staffing contract terminated March 31, 2017;
- SPS staff did not complete training; and
- Leaders were aware of issues in SPS and had not adequately addressed them.

A 2015 Administrative Investigation Board (AIB) concluded that tampering with SPS equipment processes had occurred in fiscal year (FY) 2015. The then-Facility Director did not take action on the finding as he reportedly did not consider the supporting evidence conclusive. To evaluate whether tampering had occurred since 2015, the OIG conducted an unannounced site visit, interviewed Facility staff, and reviewed pertinent Facility documents and meeting minutes. The OIG did not substantiate that tampering with equipment was occurring in SPS.

The OIG substantiated that 38 of the 356 SPS sterile sets inspected were missing instruments. However, the OIG did not substantiate that sterile sets were incorrectly stored or damaged. The sterile sets that were missing instruments were not consistently labeled as to which instruments were missing.

Although OIG inspectors did not observe damaged sets, they noted that Facility staff had reported damaged sterile sets and instruments to Patient Safety Services via electronic Patient Event Reports. Veterans Health Administration (VHA) and Facility policy required the Patient Safety Manager to report and document adverse events or "close calls" to the National Center for Patient Safety using a software application called WebSPOT[1] in order to allow identification of emerging patient safety issues nationwide.

The OIG reviewed the Facility's March 2015–September 2017 reports to the National Center for Patient Safety and determined that not all electronic Patient Event Reports related to SPS issues

[1] VHA Handbook 1050.01, *National Patient Safety Improvement Handbook*, March 4, 2011.

were entered into WebSPOT. As not all Facility-reported events were captured in WebSPOT, the identification of the emerging trends related to these events could not be fully identified and remedied.

The OIG substantiated that surgical procedures were delayed or canceled due to unavailable sterile instruments and equipment. The OIG identified 169 operations (total of 169 unique patients) that were delayed or canceled from March 1, 2015, through September 30, 2017. OIG clinical staff reviewed the patients' electronic health records. An OIG physician determined that while no patient experienced an adverse clinical outcome, three patients were exposed to increased risks for adverse clinical outcomes due to unavailable or incomplete sterile instrument sets.[2] Patient 1 had to be awakened from general anesthesia before surgery could begin and Patient 2 received spinal anesthesia before the procedure was canceled. Patient 3 had to be transferred to a non-VA facility for surgery due to unavailable sterile instrument sets.

The OIG substantiated that shortages in SPS staffing occurred when a contract for medical supply technicians (MSTs) with an external agency lapsed in April 2017. MSTs are primarily responsible for the reprocessing of reusable medical equipment (RME). After an increase in the number of SPS full-time employees in November 2016, the Facility was unable to fill all the MST positions with permanent staff and entered into a contract with an external agency. The contract lapsed, in part, because of a lack of oversight related to changes in SPS leadership when permanent staff could not be recruited. This led to a decrease in the number of available contracted MSTs for two months beginning in May 2017.

The OIG team noted an increase in the number of surgical delays and cancellations for the two months after the termination of the April 2017 contract. However, the OIG could not establish that the surgical delays were related to SPS staffing.[3]

SPS staff must be trained on how to appropriately reprocess each item of RME; different items generally require very specific and detailed instructions for reprocessing. The Facility is responsible for maintaining standard operating procedures (SOPs) that address the reprocessing of each item and that are consistent with RME manufacturers' instructions, which may change over time. As SPS employees serve a vital role in the realm of patient safety, it is crucial that they are knowledgeable and well trained so that only properly cleaned instruments touch the

[2] The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays and cancellations associated with deficiencies identified and discussed in this report may impact the convenience and quality of care received by veterans, some of whom travel long distances to seek care from a VA healthcare facility. The OIG was unable to quantify the frustration, confusion, or disturbances in a patient's activities of daily living that may have resulted from these deficiencies and focused its evaluation of patient harm in terms of adverse clinical outcomes.

[3] The OIG reviewed the electronic health records of the 20 patients whose surgeries were delayed during this time frame and did not identify either a risk for, or an actual adverse clinical outcome related to the delays.

patient.[4] Facility managers must verify at regularly defined intervals that SPS staff are able to demonstrate the ability to reprocess an item (competency) and document each staff member's competency to reprocess an item in accordance with manufacturers' instructions for use.[5]

The OIG substantiated that documentation of the initial training of SPS staff hired after March 23, 2016, was missing. Documentation of required ongoing training of SPS staff for FY 2017 was incomplete or missing. During the review of ongoing training records, the OIG also found that documentation of competencies for staff who reprocessed RME was incomplete or missing.

Following the implementation of a March 23, 2016, VHA policy outlining SPS procedures, all new SPS employees were required to complete the SPS Level 1 training program within 90 days of hire (initial training). The OIG determined that 13 of the 29 Facility's SPS staff were assigned to SPS after March 23, 2016. Four of the 13 Facility employees (31 percent) did not have the required Level 1 training.

Requirements for contract staff training were set forth in the contract statements of work. Contract staff were required to hold certifications from a specific accrediting body or have comparable military training. Of the five contracted MST staff working at the Facility in September 2017, the Facility was not able to produce certification documentation for one of the contracted staff.

The OIG determined that ongoing training that was required to be offered monthly (in-service education sessions that focused on technical aspects of SPS work) was not provided every month in FY2017.[6] The sessions that were offered did not include all required elements, and attendance was low.[7]

VHA policy requires a risk analysis (RA) be performed annually to identify potential SPS problems or process failures.[8] The RA should include potential sources of a process failure, estimates of the likelihood that such a failure will occur, an evaluation of the consequences if the failure does occur, and how prepared the Facility is to manage the failure. The RA should also include proposals for risk management strategies to mitigate risks and control for potential process failures. The use of SPS staff competency assessments is one strategy for mitigating

[4] VHA Directive 1116(2). *Sterile Processing Services (SPS),* March 23, 2016.

[5] VHA Directive 1116(2). Competencies focus on the knowledge, skills, and abilities required until the employee is deemed proficient to work independently.

[6] In-service education sessions were not offered in November, December, or June.

[7] VHA Directive 1116(2). Required elements were an attendance roster, objectives, and a brief description of the content to be covered.

[8] VHA Directive 1116(2).

risks related to the improper cleaning of RME. Competency assessments for RME identified on the RA as high-risk should be performed and documented annually.[9]

The OIG reviewed the Facility's 2017 SPS RA that was erroneously dated September 22, 2016.[10] The OIG noted two of the Facility endoscopes that met criteria for being categorized as high risk[11] were not listed for annual competencies. The competency assessment interval had been changed from every year to every three years.

To determine if SPS staff had documented competencies to perform job duties, the OIG selected 14 specific items of RME and reviewed the corresponding SOPs and competency assessments. The OIG found that 5 of the 14 (36 percent) selected items of RME did not have a corresponding SOP.

The OIG reviewed the available SPS staff competency assessments for the nine RME items that had corresponding SOPs.[12] Competency assessments were not documented for four RME items. For the remaining five RME items, less than half of the SPS staff had documented competency assessments.

The OIG substantiated that Veterans Integrated Service Network (VISN) and Facility leaders were aware of quality of care concerns in SPS and determined that the VISN did not provide effective oversight and the Facility did not effectively implement proposed action plans, as evidenced by the number of recurring and ongoing findings. VISN and Facility leaders were notified of 450 findings described in nine Facility SPS inspection reports performed from October 2014 through May 2017. The highest number of findings was in the SPS administrative and gastroenterology categories. The SPS administrative findings included a lack of policies and procedures, staff training and competencies, and instrument tracking.

The Facility was re-aligned from VISN 18 to VISN 22 in October 2016. VISN 22 staff told the OIG that VISN leaders relied on Facility leaders and staff to review the action plan items and provide evidence of compliance. While VISN leaders monitored the plans, they did not take additional actions. Due to the number of findings, the OIG team determined that VISN leaders

[9] VHA Directive 1116(2).

[10] The RME Coordinator informed the OIG that the 2016 date was an error and the plan was completed on September 22, 2017.

[11] DUSHOM Memorandum, *Competency Assessment for Employees Reprocessing Critical and Semi-Critical Reusable Medical Equipment*, April 11, 2017. This memo provides guidance regarding high-risk RME that might be prone to problems or used infrequently. Such RME were to have competency assessments conducted and documented annually.[11] "Examples of problematic RME/instruments include but are not limited to lumened instruments, take-apart instruments, endoscopes, robotics orthopedic systems, [and] implants trays."

[12] The OIG determined that 28 SPS and five contract staff were assigned to SPS and available to reprocess RME. The 33 staff members included SPS supervisory or other staff who were trained and held competencies to process RME in addition to the 30 MST SPS staff whose primary job was to process RME.

should have had a higher level of concern and taken action (for example, conferred with a subject matter expert or conduct additional inspections).

The OIG determined that Facility efforts to address the deficiencies were not organized or complete. Facility action plans for the findings from the external inspections did not contain documentation that clearly delineated what findings were related to each action plan and the number of closed action plans. The Chief of Quality, Safety and Value informed the OIG that "some of the action plan tracking documents were lost" due to SharePoint issues. Items also frequently could not be closed out and were rolled up into the next action plan. An action plan tracker with all items (open and/or closed) on all the action plans was not available.

Multiple changes in Facility and SPS leaders have occurred since 2015. Eighteen different Facility leaders assumed key roles from January 2015 through September 2017. From July 2015 through September 2017, eight different individuals were assigned to the Acting Chief of SPS position.[13] The OIG concluded that frequent management turnover in both Facility and SPS leadership positions was a factor in failing to ensure that "clear lines of responsibility and accountability" for the purposes of ensuring "a standardized process for proper reprocessing and maintenance of RME within VA medical facilities" as articulated in VHA Directive 1161.[14]

The Nurse Executive, who assumed her position in March 2016, confirmed she was aware of problems within SPS upon her arrival.[15] The Nurse Executive is tasked with "providing oversight, organizational responsibility, and leadership of the local SPS operations" and is responsible for "[ensuring] the proper critical and semi-critical RME processes are in place in all clinical areas."[16] Four of the nine inspection reports referenced above were completed after March 2016. According to the Nurse Executive, the inability to recruit and maintain competent SPS leaders and staff impacted her ability to improve SPS processes.

When interviewed, the Chief of Staff indicated that he did not have the ability to change SPS processes as that service was not aligned under the Chief of Staff. The Facility organizational structure was consistent with VHA policy regarding SPS alignment. The SPS Chief reported to the Nurse Executive who reported to the Facility Director. While SPS was not aligned under the Chief of Staff at the Facility, VHA's expectation as outlined by VHA Directive 1116(2) is that the Chief of Staff "partner" with the Nurse Executive on RME processes.

[13] Facility leaders have found it difficult to recruit individuals from other geographical locations who were willing to re-locate (possibly due to differences in location pay) or from within the local area who had the required expertise.

[14] VHA Directive 1116(2).

[15] At this Facility, there is a four-person leadership model—Director, Associate Director, Chief of Staff and Associate Director of Patient Care Services (Nurse Executive). According to VHA Directive 1116(2), the Associate Director for Patient Care Services/Nurse Executive is responsible for "[p]roviding oversight, organizational responsibility, and leadership of the local SPS operations" among other duties.

[16] VHA Directive 1116(2).

The Facility Director has overall responsibility for ensuring Facility compliance with SPS processes.[17] When interviewed, the Facility Director was knowledgeable about the multiple inspections and findings, and identified a major outstanding issue was construction of a new SPS suite.

While the Nurse Executive and two Acting Chiefs of SPS stated that the Facility Director was supportive when they reported SPS issues, the OIG team determined that SPS issues related to training, competencies, staffing, and RME processing have persisted.

The OIG made eight recommendations to the Facility Director related to missing instrument procedures, verification of items in sterile sets, accurate patient safety event reporting, SPS training, maintenance of an accurate RME list, up-to-date manufacturers' instructions and SOPs, staff competencies, and a review of the SPS contract. The OIG made four recommendations to the VISN Director related to implementing actions from previous reviews, overseeing implementation of this report's recommendations, reviewing the Facility's SPS risk assessment, and establishing a process to identify when independent verification by VISN staff is necessary to ensure the Facility implements action plans related to SPS recommendations.

Comments

The Interim Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans. (See Appendixes A and B, pages 34–42 for the Directors' comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.

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[17] VHA Directive 1116(2).

Contents

Abbreviations

AIB	Administrative Investigation Board
EHR	electronic health record
ePERs	electronic Patient Event Reports
FY	fiscal year
MST	medical supply technician
NCPS	National Center for Patient Safety
NPOSP	National Program Office for Sterile Processing
OIG	Office of Inspector General
RA	risk analysis
RME	reusable medical equipment
SPS	Sterile Processing Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding concerns in Sterile Processing Services (SPS) at the New Mexico VA Health Care System (Facility), Albuquerque, New Mexico.

Background

The Facility, which consists of the Facility and 13 community based outpatient clinics, is part of Veterans Integrated Service Network (VISN) 22. The Facility was previously aligned with VISN 18. After Veterans Health Administration (VHA) underwent reorganization, the Facility was formally aligned with VISN 22 in October 2016. The Facility is affiliated with the University of New Mexico School of Medicine.

In fiscal year (FY) 2017, the Facility served over 64,000 patients with a broad range of emergency, inpatient, and outpatient needs. The Facility is a Level 1b tertiary referral center with a 24-hour Emergency Department. According to Facility-reported data, staff performed more than 10,221 surgical procedures from January 2015 through September 2017, with the majority of procedures performed by providers in the Orthopedics, Ophthalmology, and Urology Departments.

SPS

The VHA National Program Office for Sterile Processing (NPOSP)

> is a distinct program office under the VHA Deputy Under Secretary for Health for Operations and Management [DUSHOM] that is responsible for establishing policy regarding reprocessing of critical and semi-critical reusable medical equipment (RME). Proper reprocessing of RME within VA facilities necessitates written and accessible facility policy and procedure…[18]

The NPOSP provides oversight of SPS and RME activities and requires that one VISN-led full SPS inspection be conducted yearly that is separate from any NPOSP-led inspection. [19] A second Facility-led SPS inspection must occur and be separate from any NPOSP inspection. Finally, an additional Facility-level SPS inspection by either the Facility or VISN must occur. The

[18] VHA Directive 1116(2), *Sterile Processing Services (SPS),* March 23, 2016.

[19] DUSHOM Memorandum, *Information and Instructions for FY 2017 SPS Inspections*, December 23, 2016.

inspections must be at least 90 days apart. The inspections generate reports with findings and action plans that may require Facility, VISN, NPOSP, and VHA activity.[20]

The VISN Director appoints a VISN SPS Management Board that oversees reprocessing at all VISN facilities, ensures training is provided, and that a quality assurance program is in place. Within individual medical facilities, the facility Director is responsible for ensuring compliance with SPS policies and procedures related to the sterilization of instruments and equipment.[21] Each facility's SPS oversees the reprocessing, maintenance, and storage of reusable equipment.[22]

SPS Quality Assurance Program

An SPS Quality Assurance program must be in place to ensure appropriate and safe reprocessing is being performed.[23] Quality assurance measures must be documented and monitored. For example, quality measures in SPS can include the timeliness of equipment sterilization, the number of defective equipment packaging returns, and the accuracy of instruments in assembled kits. According to Facility policy, Performance Improvement and Patient Safety staff are responsible for "tracking, trending and reporting any performance improvement, risk management or patient safety issues identified as related to RME."[24]

Training and Competency

SPS staff must be trained on how to appropriately reprocess each item of RME; different items generally require very specific and detailed instructions for reprocessing. SPS leaders are charged with ensuring that all individuals are competent to complete assigned tasks.[25] Standard operating procedures (SOPs) that address the reprocessing of each item and that are consistent with RME manufacturers' instructions, which may change over time, must be maintained.

Facility managers must verify at regularly defined intervals that SPS staff are able to demonstrate the ability to reprocess an item (competency) and document each staff member's competency to

[20] DUSHOM Memo, December 23, 2016.

[21] VHA Directive 1116(2).

[22] VHA Directive 1116(2).

[23] VHA Directive 1116(2); New Mexico VA Health Care System Memorandum 129-2, *Use and Reprocessing of Reusable Medical Equipment that Require High Level Disinfection or Sterilization*, January 31, 2014 which was in effect during the timeframe of the events discussed in this report until 2017; see also, New Mexico VA Health Care System Memorandum 129-2, *Use and Reprocessing of Reusable Medical Equipment that Require High Level Disinfection or Sterilization*, March 3, 2017 that has the same or similar language as the 2014 Memorandum on these issues.

[24] New Mexico VA Health Care System Memorandum 129-2, 2014 and 2017.

[25] VHA Directive 1116(2).

reprocess the item in accordance with manufacturers' instructions for use.[26] RME includes instruments or objects introduced directly into the bloodstream or other normally sterile body areas (critical items) and those that come in contact with non-intact skin or mucous membranes (semi-critical items).[27]

Training

VHA policy requires all new SPS employees to complete the SPS Level 1 training program within 90 days of hire (initial training). (See Issue 5 for discussion of the SPS training program.)[28] Facility policy requires ongoing training and documentation of training when RME manufacturers issue significant changes to instructions for use and whenever new or different equipment is used.[29] Employees in SPS must receive ongoing training and verification of the adequacy of that training to properly clean equipment in order to ensure that only properly cleaned instruments touch patients. To that end, the importance of adhering to the specific cleaning instructions of various equipment necessitates that training is adequate and up to date.

Competency

VHA policy states, "[c]ompetency assessment is an ongoing process, and competencies must be assessed when an employee begins working in SPS, during the orientation period, and throughout employment in SPS."[30] Per VHA policy, SPS management must verify each SPS employee's individual competency by at least two of the following three methods: requiring a return demonstration, observing the employee conducting the cleaning process, or witnessing the employee's verbal understanding of the specific competency.[31] Facility policy identifies reprocessing activities, including high-level disinfection, sterilization,[32] and proper cleaning of equipment, as critical elements of an SPS employee's performance.[33]

[26] VHA Directive 1116(2). Competencies focus on the knowledge, skills, and abilities required until the employee is deemed proficient to work independently.

[27] VHA Directive 1116(2).

[28] VHA Directive 1116(2).

[29] New Mexico VA Health Care System Memorandum 129-2, 2014 and 2017.

[30] VHA Directive 1116(2).

[31] VHA Directive 1116(2).

[32] VHA Directive 1116(2). High-level disinfection is a process that uses a sterilant for a shorter contact time than that used for sterilization and that kills all microbial organisms but not necessarily large numbers of bacterial spores. Sterilization is the complete destruction or elimination of all living microorganism, accomplished by physical methods, chemical agents, radiation, or mechanical methods.

[33] New Mexico VA Health Care System Memorandum 129-2, 2014 and 2017.

Patient Safety

VHA defines patient safety as "ensuring freedom from accidental or inadvertent injury during health care processes."[34] The National Patient Safety Improvement Program's goal is to prevent harm to patients. According to policy, "[t]his is accomplished by taking steps in the way things are done so that the level of faith and trust in the VHA patient safety system is established and behaviors designed to prevent adverse events become a part of all-employee behavior."[35] All adverse events require reporting and documentation in the VHA Patient Safety Information System, using the "WebSPOT" software application. WebSPOT must be used to track and monitor reported events. Data concerning the reported events must be entered into WebSPOT by the Facility Patient Safety Manager or designated staff at VA medical facilities to ensure the accuracy of the data recorded.[36]

Leadership

Effective leaders are central to the health and success of an organization. "Leading Change" and "Leading People" are two of the five executive core qualifications for senior executives in the federal government.[37,38] Leaders establish the organization's culture through their words, expectations for action, and behavior.[39] VHA SPS policy outlines Facility leaders' roles and responsibilities specifically related to the Facility Director; Chief of Staff (COS); Associate Director for Patient Care Services/Nurse Executive; Chief of SPS; and the Surgical Work Group, Clinical Executive Board, and Infection Control Committees.[40]

Allegations

In May and June 2017, the OIG received allegations regarding concerns in SPS at the Facility. Specifically, the areas of concern were

- Employees tampered with equipment processes in SPS,

[34] VHA Handbook 1050.01, *National Patient Safety Improvement Handbook*, March 4, 2011. This Handbook was scheduled for recertification on or before the last working day of March 2016, but it has not yet been recertified.

[35] VHA Handbook 1050.01. Adverse events that may be candidates for a root cause analysis are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical Facility, outpatient clinic, or other VHA Facility.

[36] VHA Handbook 1050.01.

[37] Office of Personnel Management, *Senior Executive Service Executive Core Qualifications.* http://www.opm.gov/policy-data-oversight/senior-executive-service/executive-core-qualifications/. (The website was accessed on October 10, 2017.)

[38] Most facility/system directors and COSs are senior executives and must meet executive core qualification requirements.

[39] Schyve, Paul M., M.D., Leadership in Healthcare Organizations. A Guide to Joint Commission Leadership Standards. A Governance Institute White Paper, Winter 2009; 3.

[40] VHA Directive 1116(2).

- Sterilized sets from SPS were missing instruments, incorrectly stored, or damaged,
- Surgical procedures were being delayed or canceled due to unavailable sterilized sets,
- A shortage of staff caused equipment processing delays when the SPS staffing contract was terminated March 31, 2017,
- SPS staff did not complete training, and
- Leaders were aware of issues in SPS and had not adequately addressed them.

Scope and Methodology

The OIG initiated its review in August 2017 and conducted an unannounced site visit September 27–29, 2017. The OIG conducted an additional site visit November 28–30, 2017.

The OIG interviewed the NPOSP Director, VISN 22 managers including the Quality Management Officer and SPS Lead, Facility leaders including the Director, Associate Director of Patient Care Services/Nurse Executive, Associate and Assistant Directors, Chiefs of Staff, Quality, Safety and Value (QSV Chief) and Anesthesiology, Acting Chiefs of Surgical Services and SPS, a former Chief of SPS and the Assistant Chief of SPS. Staff interviewed included multiple surgeons, RME coordinators, SPS day shift supervisor and technicians, Operating Room (OR) nurse manager and staff, Patient Safety Officer, and Human Resource Officer.

The OIG team reviewed VHA and Facility policies; SPS staff recruitment documents; the September 2015 New Mexico VA Health Care System Administrative Board of Investigation (AIB); 2015 SPS Staffing Analysis; April 2016, through September 2017 SPS employee contract; March 1, 2015, through September 27, 2017, electronic Patient Event Report (ePER) data;[41] SPS employee competencies and FY 2017 training record; selected SPS RME standard operating procedures (SOPs); October 29, 2015, VA Office of the Medical Inspector site visit report; June 2015 through September 2017 VISN and October 2014 through May 2017 NPOSP reports; patient electronic health records (EHRs), March 1, 2015, through September 30, 2017; Surgical Service Report of Delayed Operations and Report of Cancellations, and other relevant documents.

During the unannounced September 27–29, 2017, site visit, the OIG inspected SPS preparation areas, office space, and the main storage area in the basement, as well as the dental,

[41] ePER User Manual – Version 5, *ePER User Guide*, December 11, 2013. The ePER is a web-based event reporting system adapted for national use. The data are collected for the purpose of improving the quality of health care and improving the utilization of healthcare resources.

gastroenterology, and genitourinary storage rooms. The OIG observed the SPS decontamination room and inspected the gastroenterology decontamination room.[42]

The OIG reviewed EHRs, ePER data, and the Facility's delayed and canceled surgery data to assess whether patients experienced adverse clinical outcomes as a result of unavailable surgical instrument sets or equipment.

[42] Gastroenterology is a branch of medicine concerned with the structure, functions, diseases, and pathology of the stomach and intestines. https://www.merriam-webster.com. (The website was accessed on January 10, 2018.); Genitourinary is relating to, affecting, or being the organs of reproduction and urination. https://www.merriam-webster.com. (The website was accessed on January 10, 2018.)

Table 1. OIG Patient Case Review Methodology for Assessing Adverse Clinical Outcomes[43]

Source	Methodology
Complaint	The OIG received a list of six patients who experienced OR delays or cancellations during April and May 2017 that allegedly had an adverse impact on their care. Of these six patients, only five were identifiable based upon the information provided. An OIG physician reviewed the remaining five patient EHRs.
ePERs	The OIG obtained 101 ePERs completed between March 2015 and August 2017. An OIG team (nurses and a physician) reviewed the reports and identified patient safety occurrences that involved supplies, instrument sets, or equipment. The team's analysis yielded 25 unique patients for further review to determine whether adverse clinical outcomes had occurred.
Delayed Surgical Procedures	The OIG reviewed all delayed surgical procedures occurring between March 1, 2015, and September 30, 2017,* in which the Facility recorded unavailable sterile instruments sets or equipment as the reason for the delay. OIG nurses reviewed 157 patient procedures in which the delay potentially resulted from unavailable sterile instruments or equipment, identified 16 with issues that could have led to adverse clinical outcomes, and referred them to an OIG physician. The OIG physician conducted an in-depth review of the 16 patient EHRs to evaluate whether a surgical procedure delay was related to an adverse clinical outcome.
Canceled Surgical Procedures	The OIG reviewed all canceled surgical procedures occurring between March 1, 2015, and September 30, 2017,** in which the Facility recorded unavailable sterile instrument sets or equipment as the reason for the cancellation. OIG nurses reviewed 40 patient procedures cases in which the cancellation potentially resulted from unavailable sterile instruments or equipment, identified 11 canceled surgical procedures that could have been related to clinically concerning issues, and referred them to an OIG physician. The OIG physician conducted an in-depth review of the 11 patient EHRs to evaluate whether a surgical procedure cancellation was related to an adverse clinical outcome.
Interviews	The OIG identified an additional surgical procedure during interviews that could not proceed at the Facility due to unavailable instruments. The patient case was referred to the OIG physician to conduct an in-depth review to evaluate for adverse clinical outcomes related to the unavailable instruments.

Source: VA OIG analysis of VHA data and documents
**The Facility provided the OIG a list of 2,981 delayed procedures. OIG reviewed the list and identified delays in 157 (5.3 percent) procedures related to unavailable sterile instruments and equipment.*
***The Facility provided the OIG a list of 936 canceled procedures. OIG reviewed the list and identified cancellations of 11 (1.2 percent) procedures related to unavailable sterile instruments and equipment.*

From the five categories listed in Table 1, 58 patients were referred for further review by an OIG physician to determine if adverse clinical outcomes occurred due to unavailable or incomplete

[43] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in the course of treatment/diagnosis, or a significant change in the patient's level of care. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays and cancellations associated with the deficiencies discussed in this report may impact the convenience and quality of care received by veterans, some of whom travel long distances to seek care from a VA hospital. The OIG was unable to quantify the frustration, confusion, or disturbances in a veteran's activities of daily living that may have resulted from these deficiencies and focused our evaluation of patient harm in terms of adverse clinical outcomes.

sterile instrument sets. The OIG physician determined that although none of the 58 patients had adverse clinical outcomes, there was an increased risk for adverse clinical outcomes for three patients related to delayed or canceled surgeries (see Issue 3).

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(s).

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 substantiate an allegation when the available evidence is insufficient to determine whether or not an alleged event or action took place.

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.

Inspection Results

Issue 1: Alleged Tampering with SPS Equipment Processes

The Facility conducted an AIB in 2015 that concluded tampering with SPS equipment processes had occurred in FY 2015. The then-Facility Director did not take action on the finding as he reportedly did not consider the supporting evidence conclusive. To evaluate whether tampering had occurred since 2015, the OIG conducted an unannounced site visit, interviewed Facility staff, and reviewed pertinent Facility documents and meeting minutes. The OIG did not substantiate that tampering with equipment was occurring in SPS.

The OIG reviewed the 2015 AIB report that addressed an allegation that SPS staff tampered with equipment processes.[44] During AIB testimony, a witness described an instance of tampering of an assembled tray:

> [the person] would pop the seal and the arrow, which is a tamper proof arrow, take items out of the tray, reclose the lid and put a new arrow in it, as if it was ready to be sterilized and it should be all good to go...[45]

The AIB substantiated the tampering allegation and recommended appropriate disciplinary action. A staff member confirmed that disciplinary action related to the tampering was not taken because, despite the AIB findings, the Facility Director determined the evidence that tampering had occurred was not conclusive.

VHA policy requires that once sterilized, medical equipment and sterile sets are to be stored in a designated area. During an unannounced site visit, the OIG team inspected the main SPS storage room where sterile sets were stored prior to transport to the OR and outpatient surgery clinics. Visual inspection of sterile sets showed no visible compromise of package integrity. No reports of SPS-related tampering were found.

Issue 2: Sterile Sets were Allegedly Missing Instruments, Incorrectly Stored, or Damaged

Upon physical inspection, the OIG substantiated that 38 of the 356 SPS sterile sets were missing instruments. OIG did not substantiate that sterile sets were incorrectly stored or damaged. Although damaged sets were not observed, the OIG noted that Facility staff had reported incidences of damaged sterile sets and instruments to Patient Safety Services.

[44] Additional concerns, not related to the tampering of equipment processes, were also addressed during the AIB.

[45] The arrow indicates that a tray is ready for sterilization and is designed to be tamper-proof, thus requiring a new arrow-label if the seal is broken.

VHA policy outlines the requirements for sterile set integrity, handling, verification, and storage to ensure they are ready for use by the end users.[46] The policy also outlines the requirements for proper distribution: "[h]andle and store items so that they do not become crushed, bent, compressed, or punctured. Bundling of clean/sterile packaged items shall never be done by using rubber bands, paper clips, tape, or any means which may cause damage to the packaging."[47]

Missing Instruments

The OIG evaluated 59 sterile sets in the OR storage area and found 9 sterile sets (15 percent) with orange stickers indicating they were missing instruments. Of the nine sterile sets, seven did not include a description of the missing instruments. The OIG evaluated 297 sterile sets in the SPS storage area and found 29 sterile (10 percent) sets with orange stickers indicating they were missing instruments. Of the 29 sterile sets, 10 did not contain the description of the missing instruments.

Accurate instrument descriptions and inventories are essential to ensuring that all necessary equipment and instruments are present before a procedure is initiated. A description of missing instruments on the outside of the sterile set allows clinical staff to determine whether the missing instruments are critical or necessary for the planned surgical procedure and request the needed item. If SPS is unable to supply the needed item in a timely fashion, the surgical procedure may be delayed or canceled.

Incorrectly Stored/Damaged Sets

During the inspection of the main storage area located in the basement and three satellite storage rooms, the OIG team did not observe incorrectly stored or damaged sterile sets. The OIG team did not observe crushed, bent, compressed, or punctured sterile sets.[48]

Incidental Finding—Mislabeled Laparotomy Set[49]

While damaged sets were not identified during the OIG's on-site inspection, the seal of a sterile set was inadvertently broken during the physical inspection in SPS which allowed the OIG to examine the contents of that sterile set.

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[46] Items deemed to be of compromised integrity would include surgical tools which appear to have broken seals or tears in the protective wrap used to protect sterilized instruments.

[47] VHA Directive 1761 (1), Appendix J, J-1, number 2.

[48] VHA Directive 1761 (1), Appendix J, J-1, number 1.

[49] Laparotomy is a surgical incision into the abdominal wall. https://www.merriam-webster.com/dictionary/laparotomy. (The website was accessed on July 6, 2018.)

The label on the outside of the sterile set indicated that it was a laparotomy set that should have contained 99 instruments. An instrument count sheet[50] that was on the inside of the set identified the set as a *minor* laparotomy set that contained 93 items. The set was in fact a *minor* laparotomy set. Had this mislabeled sterile set been opened in the OR in preparation for a planned surgery, the lack of the required instruments may have delayed or canceled the surgical procedure. Facility staff were unable to explain the mislabeling of the sterile set.

Incidental Finding—Patient Safety Event Reporting of Sterile Set Issues

VHA policy states that, "when an adverse event or close call occurs, VA personnel may use any available or locally accepted method to notify the Patient Safety Manager and begin the [Facility's] consideration of the event."[51] VHA policy also requires reporting and documentation of patient safety adverse events or "close calls" to the National Center for Patient Safety using a software application called WebSPOT.[52]

At the Facility level, the Patient Safety Manager is responsible for analyzing and reporting relevant data to the National Center for Patient Safety using WebSPOT.[53] Facility policy requires that the first staff member who becomes aware of a patient safety event report the event to the immediate supervisor and enter the event in the ePERs system.[54,55] The Patient Safety Manager will review, assess, track, and trend all finalized ePERs. The National Center for Patient Safety analyzes data reported from all facilities to identify emerging trends with the potential to compromise patient safety in multiple facilities.

The OIG reviewed Facility ePERs, and WebSPOT for reports related to sterile set issues and compared reports entered into the ePER with the WebSPOT system to ensure that applicable events were reported to VHA NCPS as required by VHA policy.[56]

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[50] VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016, p. 39 requires that sterile sets include an instrument count sheet to identify each item included in the set. To ensure completeness, functionality, and cleanliness of the sterile set, two SPS staff (the staff member who assembled the set and a second SPS staff member) must check the contents of the set and sign the instrument count sheet. Sterile sets must also be visibly inspected for integrity prior to distribution and prior to patient use.

[51] VHA Handbook, 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

[52] VHA Handbook, 1050.01.

[53] VHA Handbook, 1050.01.

[54] Facility policy also identifies an anonymous system of reporting through a telephone message system.

[55] New Mexico VA Health Care System Memorandum 003-20, *Patient Event Reporting*, October 18, 2016.

[56] VHA Handbook, 1050.01.

Not all Facility-reported events were captured in WebSPOT. The OIG concluded that the identification of emerging trends related to these sterile set issues could not be fully identified and remedied.

Issue 3: Delayed or Canceled Surgical Procedures

The OIG substantiated that surgical procedures were delayed or canceled due to unavailable sterile instruments and equipment. The OIG reviewed the Facility's March 1, 2015, through September 30, 2017 "Surgical Service Report of Delayed Operations" and "Surgical Service Report of Cancelled Operations" and identified 157 operations were delayed and 11 were canceled due to unavailable sterile instruments and equipment.[57] During interviews, the OIG was told about a patient whose surgery could not proceed at the Facility due to unavailable sterile instrument sets. The OIG included this patient in its review of delayed or canceled procedures (total of 169).

Facility policy states the Chief of SPS is responsible for ensuring a continuous flow of processed critical and semi-critical instruments to all points of use. The return of reusable soiled items to SPS must also be handled in a manner conducive to patient and staff safety, as well as efficient reprocessing for future use. The Chief of SPS is responsible for coordinating with clinical area personnel to support the management, identification, and repair of instrument sets.[58]

The Chief of Staff informed the OIG that all surgical delays and cancellations were tracked daily and discussed with surgical managers. The OIG team found limited documentation regarding delayed or canceled surgical procedures due to unavailable sterile instruments and equipment. In the few cases that were documented, the OIG found no corresponding action plans or follow-up discussions to remediate the identified concerns.

The OIG interviewed surgeons whose patients' procedures were delayed or canceled due to unavailable sterile instruments and equipment. Surgeons attributed various reasons for delays:

- The system was inefficient.
- No one takes ownership of the equipment and supplies including the restocking of carts with the right number of instruments.
- "Several trays have to be opened to obtain matching parts."

[57] The Facility provided the OIG a list of 2,981 procedures that were delayed during the specified time frame. OIG reviewed the list and identified delays in 157 (5.3 percent) procedures related to unavailable sterile instruments and equipment. The Facility provided the OIG a list of 936 procedures that were canceled during the specified time frame. OIG reviewed the list and identified cancellations of 11 (1.2 percent) procedures related to unavailable sterile instruments and equipment.

[58] New Mexico VA Health Care System Memorandum 129-2.

- Current equipment is not maintained, and broken equipment is not replaced in a timely manner.
- SPS often cannot find instruments or there is a delay in finding them.
- "The system's process is not changing or improving."
- SPS staff are totally independent of the OR.
- Basic or commonly used instruments are lacking.
- The process for requesting new or additional equipment is "a painful one."

Patient Case Reviews

OIG clinical staff reviewed the 169 EHRs of patients whose surgeries were delayed or canceled and referred patients to the OIG physician based on pre-defined criteria. The OIG physician did not identify patients with adverse clinical outcomes but determined that three patients were exposed to increased risks for adverse clinical outcomes due to unavailable or incomplete sterile instrument sets. Patient 1 had to be awakened from general anesthesia before surgery could begin. Patient 2 received spinal anesthesia before the procedure was canceled due to unavailable sterile instruments sets. Patient 3 was transferred to a non-VA facility for surgery due to unavailable sterile instruments sets.[59]

Patient 1

Patient 1, who was in his/her 80s, was evaluated as an outpatient in 2016, for hearing loss by an Ear, Nose, and Throat (ENT) surgeon.[60] The ENT surgeon planned to implant a hearing aid anchored through the skin into the temporal bone to improve the patient's hearing.

Patient 1's past medical history included coronary artery disease, diabetes mellitus, and lower urinary tract symptoms. As requested by the ENT surgeon, the primary care physician and an anesthesiologist evaluated the patient to ensure Patient 1 could safely undergo surgery. Patient 1 was cleared for surgery.

On the day of surgery, the ENT surgeon documented in the operative note that "all necessary implants are in hand...." The anesthesiologist started induction of general anesthesia. Approximately five minutes later, the ENT surgeon notified the anesthesiologist that not all surgical instruments were available, and induction was aborted. The ENT surgeon's note reflected it would take one to two hours to decontaminate another instrument set for use. Patient 1's family was informed of the delay; the family requested the surgeon proceed with

[59] General anesthesia is a combination of intravenous drugs and inhaled gases to make a patient unconscious and unable to feel pain during medical procedure; the OIG uses gender neutral language to protect patients' privacy.

[60] An ENT surgeon may also be known as an otolaryngologist.

the procedure when the instruments were available. The surgery proceeded four hours later, and Patient 1 again received general anesthesia.

The patient experienced difficulty urinating after surgery. A bladder scan demonstrated retained urine, an indicator that the patient was unable to empty his bladder. The OIG could not ascertain whether the urinary retention was due to the anesthesia or past urinary tract problems. The OIG reviewed the patient's EHR and did not identify any adverse clinical outcomes.

General anesthesia can result in serious complications, such as heart attacks, strokes, respiratory difficulties, allergic reactions, or even death. Patients may experience a variety of uncomfortable minor side effects, such as nausea and vomiting, difficulty passing urine, sore throat due to the breathing tube, and confusion. While the patient did not experience an adverse clinical outcome, the patient was exposed to increased risk by being placed under general anesthesia twice within a four-hour period for one surgical procedure.

Patient 2

Patient 2, who was in his/her 70s, was admitted to the Facility in 2017 on Day 1, for a total knee replacement for severe degenerative joint disease (arthritis) that did not respond to nonsurgical therapy. The patient had a past medical history of hypothyroidism, hypertension, obesity, and other chronic medical and mental health conditions.

Patient 2 underwent sedation, a regional block, and spinal anesthesia.[61] Prophylactic antibiotics were administered as well as medication to prevent bleeding.

Twenty-five minutes after the start of anesthesia, the procedure was canceled because an OR staff member reported a hole in the surgical wrap containing the sterile instruments needed for surgery, indicating that the sterility of the instruments may have been compromised. Other surgical sets containing these instruments were not available.

The anesthesiologist explained to Patient 2 and the family that Patient 2 should remain hospitalized after the canceled procedure because of the potential effects of the anesthetic medications. The next day, a nurse documented Patient 2 was told to wait for further instructions before standing. However, Patient 2 stood up without assistance and "began to fall." The nurse assisted Patient 2 to the floor and then staff assisted Patient 2 back to bed. A physical therapist evaluated Patient 2 and recommended continued hospitalization due to an unsafe gait and transfers.

[61] A regional block is a peripheral nerve block used for surgical anesthesia; spinal anesthesia is a type of neuraxial anesthesia; local anesthetic (LA) is injected into cerebrospinal fluid (CSF) in the lumbar spine to anesthetize nerves that exit the spinal cord. Spinal anesthesia is most commonly used for anesthesia and/or analgesia for a variety of lower extremity, lower abdominal, pelvic, and perineal procedures.

On Day 4, Patient 2 again received prophylactic antibiotics and underwent the planned knee joint replacement. Patient 2 was discharged on day 7 to a rehabilitation center for continued physical therapy. The patient was subsequently discharged home for continued physical therapy.

Due to the canceled procedure, the patient had an increased length of stay, a witnessed fall, repeat anesthesia, and additional doses of antibiotics, which increased the risk for an adverse clinical outcome. While exposed to the risks of a hospital stay for an additional three days, Patient 2 did not experience an adverse clinical outcome related to the canceled surgery.

Patient 3

Patient 3, who was in his/her 70s, underwent a left hip replacement (total hip arthroplasty) for severe arthritis at the Facility in 2017. No complications were noted during the admission and the patient was discharged three days later.

Forty-four days after hip replacement surgery, a VA primary care nurse evaluated the patient for complaints related to the left hip. Patient 3 complained of swelling with tenderness and drainage at the incision of the hip replacement for one week. Documentation notes the patient was afebrile and the surgical incision was red, swollen, and warm. Patient 3 was referred to an Emergency Department. After an evaluation at a non-VA Emergency Department, Patient 3 was discharged home with an appointment for the following day at the VA orthopedic clinic.

The next day, Patient 3 was seen in the VA orthopedic clinic and was admitted to the Facility. The orthopedic surgeon described the wound as "draining serosanguinous fluid, very red and about to pop open from fluid underneath."[62] The orthopedic surgeon scheduled Patient 3 for surgery the following day to remove the infection (incision and drainage) and to possibly remove the implanted hip prosthesis and/or revise the hip arthroplasty.[63]

When interviewed by OIG inspectors, the orthopedic surgeon stated the specialized instruments necessary for the surgery had been used earlier in the week, but they had not been "processed, sterilized or available." The surgeon was told that the instruments would not be processed the day the patient was evaluated for surgery and would not be available for four days. Because the necessary surgical instruments were not available to revise the hip arthroplasty, the orthopedic surgeon canceled the surgery at the Facility and transferred Patient 3 to a non-VA facility for surgical care. The surgery was performed the next day at a

[62] Serosanguinous means containing or relating to both blood and the liquid part of blood (serum). It usually refers to fluids collected from or leaving the body. Medline Plus Medical Encyclopedia. https://medlineplus.gov. (The website was accessed on January 19, 20108.)

[63] A hip prosthesis is an artificial hip.

non-VA facility without complications, and Patient 3 was transferred back to the Facility two days later for continued care.

Although VHA policy requires that SPS support "the medical facility by ensuring a continuous flow of processed critical and semi-critical instruments,"[64] the required instruments for Patient 3 were not available and the surgeon was informed they would not be available by the next day. The surgeon assured needed and timely care by transferring Patient 3 to a non-VA facility. The OIG determined that Patient 3 did not have evidence of an adverse clinical outcome related to the canceled surgery; however, Patient 3 might have been exposed to a potential risk of complications related to infection had treatment been delayed.

Issue 4: SPS Staffing and Equipment Processing Delays

The OIG substantiated that shortages in medical supply technician (MST) staffing occurred when the SPS staffing contract with an external agency terminated. The contract was originally scheduled to terminate on March 31, 2017, but was modified to end April 30, 2017. The OIG reviewed the delays and cancellation of surgical procedures for FY 2017. The number of delays in surgery was highest in May and June. However, the OIG could not determine that equipment processing and surgical delays were related to SPS staffing.

MSTs are primarily responsible for reprocessing. In July 2015, 22.0 MST full-time equivalent employees (FTEs) were authorized for SPS. Due to recruitment and retention issues related to SPS staff, the Facility entered into a contract with an external agency to supplement SPS MST staffing on April 1, 2016.

In November 2016, the Facility Director authorized an increase in the number of MST FTEs to 30.0 and an overall total number of 40.0 SPS FTEs.[65] (See Figure 1.) While Facility managers provided the OIG team a March 2015 Staffing Analysis tool, the analysis was not repeated in 2016 or 2017.

The authorized 2016 SPS FTEs included the Chief and Assistant Chief, RME Coordinator, Quality Assurance, and Secretary, as well as Supervisory and Lead MSTs. In May and June 2017, the Chief of SPS position was vacant. According to the documents provided by the Facility, the Assistant Chief, Quality Assurance, Supervisory MSTs, and Lead MSTs demonstrated competency to reprocess specific instruments during the time at issue. (See discussion of competency requirements on the next page.)

[64] VHA Directive 1116(2).

[65] FTE refers to the equivalent of one full-time employee. One FTE can be filled by multiple part-time staff. (For example, two employees working 20 hours per week each would equal one full-time employee.)

Figure 1: New Mexico Health Care System organizational chart
Source: VA OIG representation of SPS organizational chart

The Facility continued to face challenges with recruitment of MST staff after the November 2016 increase in the number of MST FTEs.[66] In spring 2017, the contract lapsed in part because of a lack of oversight related to changes in SPS leadership when permanent staff could not be recruited. This led to a decrease in the number of available contracted MSTs for two months beginning in May 2017.

The OIG reviewed the surgical procedure delays and cancellations for May and June 2017, after the expiration of the contract. Those months saw an increase in the number of delays. (See Figure 2.) The OIG reviewed the EHRs of the 20 patients whose surgeries were delayed during this time frame. Three of the 20 delays were related to vendors' failures to provide instruments. For the remaining cases, eight occurred in May, and nine in June. Four delays were greater than one hour, ranging from 120–284 minutes. The OIG did not find increased risks for, or actual adverse clinical outcomes related to those delays.

[66] During interviews, Facility and NPOSP leaders attributed SPS' recruitment and retention struggles to low salaries being offered to MSTs, particularly when taking into consideration the complexity of the work. The OIG was told that recruitment became increasingly difficult due to the low pay grade and a nation-wide pay downgrade associated with the SPS MST job classification.

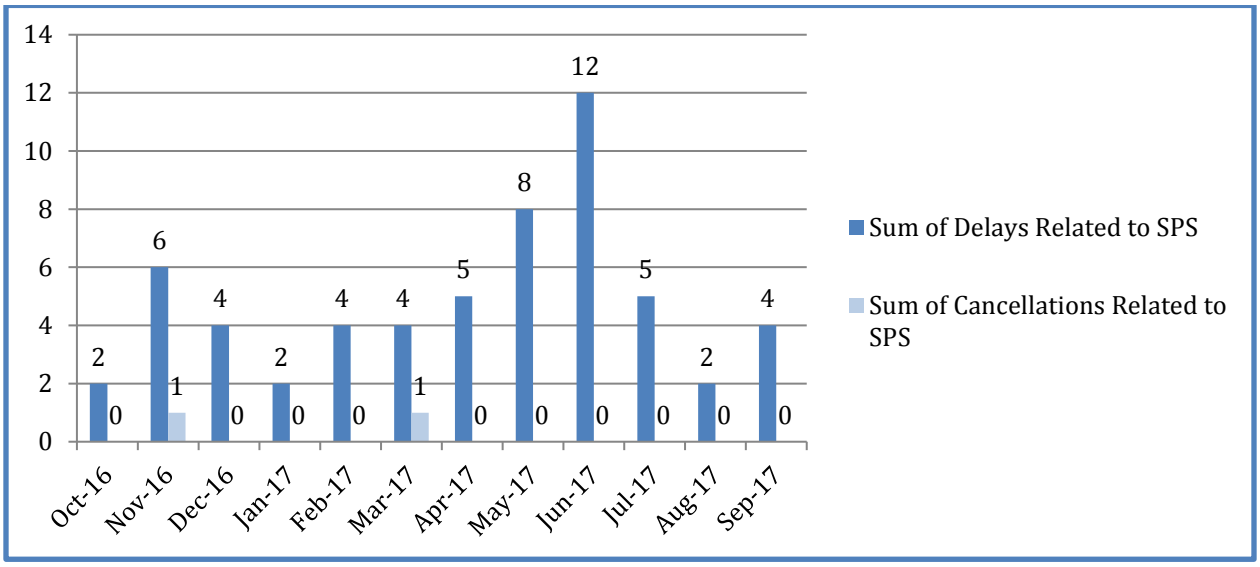

Figure 2. Delays and cancellations related to SPS instrument issues FY2017
Source: VA OIG representation of Facility delays and cancellations data

At the time of the OIG's unannounced inspection in September 2017, the SPS Chief and seven MST positions were vacant. A contract was in effect that allowed for 10 contract MSTs (three more than the number of vacant positions); however, only five contract staff were available to perform reprocessing duties, which left two unfilled positions.

Issue 5: SPS Staff Training and Competencies

The OIG substantiated that documentation of SPS staff required training and competencies was incomplete or missing. The OIG also determined that attendance at required monthly SPS in-service education sessions was low.

Training

Following the implementation of a VHA policy outlining SPS procedures on March 23, 2016, all new SPS employees were required to complete the SPS Level 1 training program within 90 days of hire (initial training). Level 2 certification by a recognized accrediting body was encouraged for SPS employees who had completed orientation and all Level 1 requirements.[67]

The OIG reviewed all SPS (29) and contract staff (5) training records. The OIG found that 13 of the 29 Facility staff were assigned to SPS after March 23, 2016. Four of the 13 Facility employees (31 percent) did not have the required Level 1 training.

[67] VHA Directive 1116(2). During initial orientation, all new SPS employees must complete the SPS Level 1 training program within 90 days of hire.

When questioned about the contract SPS technicians' training, the QSV Chief provided the OIG with the Deputy Chief of NPOSP's December 5, 2017, communication to the Facility Nurse Executive stating that VHA Directive 1116(2) training requirements were "not intended for contract staff." According to the Deputy Chief of NPOSP, "[c]ontract staff requirements are covered by the statement of work found in the contractual agreement between the vendor and VA Medical Center with guidance/oversight by the Contract Officer's Technical Representative." The Deputy Chief of NPOSP further stated that contracted staff will hold certifications which are "equal to our VA Level 2 Certification as outlined in the VHA Directive 1116(2)."

The OIG reviewed the Facility's 2016 and 2017 contract for SPS non-VA staff. The Statements of Work indicated that

> Contract SPS Technicians shall be Sterile Processing Technicians and/or Surgical Technologists certified by the Certification Board for Sterile Processing and Distribution (CBSPD), Certified Registered Central Service Technician (CRCST), Certified Surgical Technologist (CST), or comparable to military training identified on the technician's DD214.

Directive 1116(2) requires Level 1 training, encourages Level 2 certification for SPS staff after completing Level 1 training, and is silent about comparable military training. The OIG requested certification documentation for the five contracted MST staff who were working at the Facility at the time of the unannounced inspection in September 2017. The Facility provided certificates for four of the five contractors awarded from the Certification Board for Sterile Processing and Distribution.[68]

Annual Training Plan

VHA policy requires that in-service education sessions be held at least once per month and focus on the technical aspects of SPS.[69] An annual training plan must be developed to include these in-service education opportunities.[70] The OIG reviewed the FY 2017 Continuing Education Plan and found that in-service education sessions were not provided during the months of November, December, or June.

[68] VHA Directive 1116(2), p. 12 (m) indicating the certification by this Board (CBSPD) satisfies VHA Level 2 requirement. See: "***NOTE:*** *Level 2 training or certification (IAHCSMM or CBSPD) for all employees should be the goal of the employee development program."*

[69] VHA Directive 1116(2).

[70] VHA Directive 1116(2).

The OIG reviewed the documentation associated with in-service education sessions provided during FY 2017. Documentation showed 18 in-service education sessions occurred over the remaining nine months and none documented all three of the required elements:

- Attendance roster
- Objectives
- Brief description of the content to be covered[71]

The OIG reviewed the attendance rosters for the FY 2017 in-service education sessions to assess participation of SPS employees. The OIG did not find consistent participation for the in-service education sessions provided. Documentation indicated that three of 18 in-service education sessions were attended by 81–75 percent, 10 were attended by 74–50 percent, and 5 were attended by 49–13 percent of the SPS employees. (See Figure 3.) During interviews, a staff member confirmed that training was an issue. VHA policy requires SPS employees to participate in the continuing education program.[72]

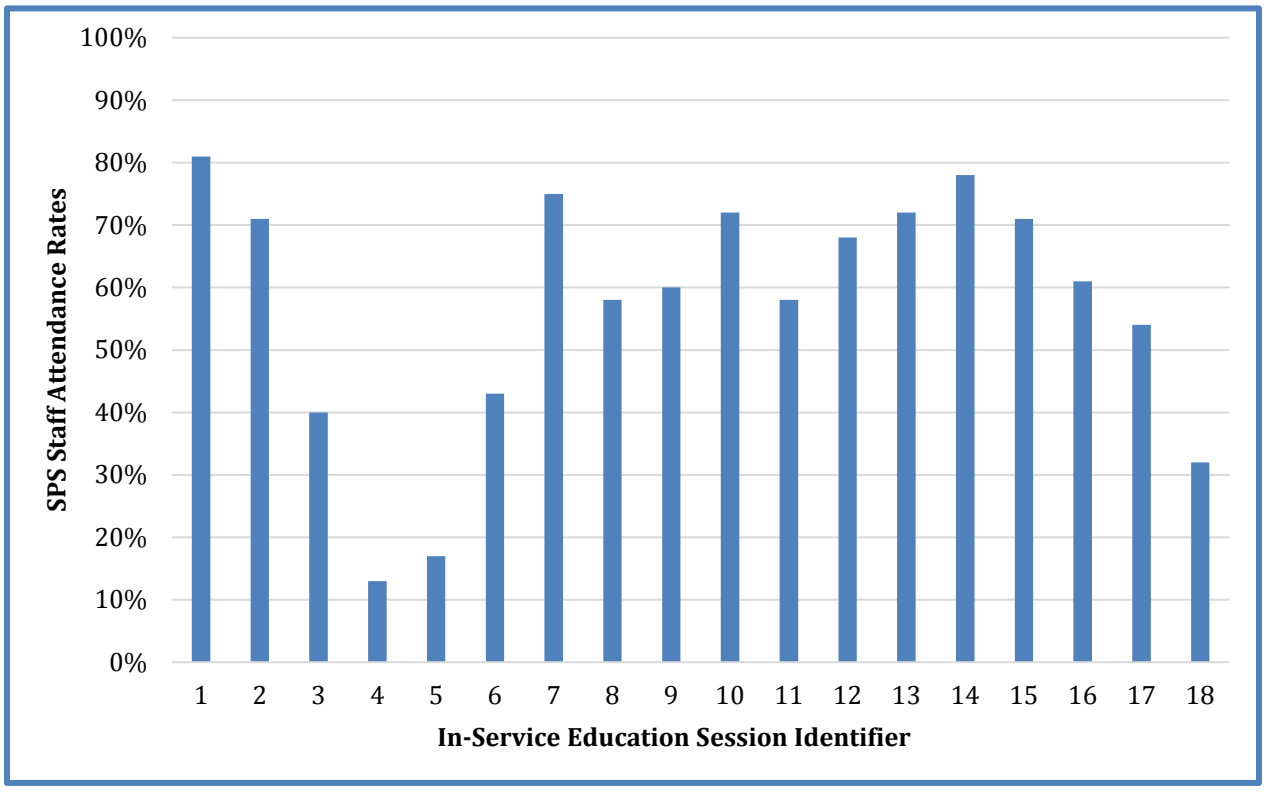

Figure 3. SPS attendance for 18 in-service education sessions for nine months in FY 2017
Source: VA OIG graphical representation of SPS staff in-service education attendance

[71] VHA Directive 1116(2).
[72] VHA Directive 1116(2).

Competencies

The OIG reviewed the 2017 Facility's SPS risk analysis (RA) that was erroneously dated September 22, 2016. VHA policy requires an SPS RA be performed annually to identify potential problems or process failures that could occur in SPS.[73] The RME Coordinator informed the OIG that the 2016 date was an error and the plan was completed on September 22, 2017.

An SPS RA should include a risk assessment that determines potential sources of a process failure, estimates the likelihood that such a failure will occur, and evaluates the consequences if that failure does occur and how prepared the Facility is to manage the failure.[74] The RA should also include risk management strategies that propose actions that can be taken to mitigate risks and control for potential process failures.[75] Conducting competency assessments of SPS staff is a strategy that mitigates risks related to the improper cleaning of equipment and instruments. Competency assessments that are identified on the RA should be performed and documented annually.[76]

The OIG reviewed the SPS RA and found two endoscopes were not identified as high-risk RME and not scheduled for annual competency assessments.[77] An April 2017 DUSHOM memorandum provided guidance regarding areas identified by the RA to be "high risk, problem prone, [or] low usage [that] must have competency assessments conducted and documented annually.[78] Examples of problematic RME/instruments include but are not limited to lumened instruments, take-apart instruments, endoscopes, robotics orthopedic systems, [and] implants trays."[79]

The RME Coordinator informed the OIG team that a review and observation was conducted of the high-level disinfection process for the two endoscopes at issue and the decision was made to change the competency assessment interval from every year to every three years.

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[73] VHA Directive 1116(2).

[74] VHA Directive 1116(2).

[75] VHA Directive 1116(2).

[76] VHA Directive 1116(2). "Competency assessments not identified by the risk analysis must be performed and documented every 3 years or more frequently as determined by the SPS/RME Committee." Such assessments would include but not be limited to "general stainless steel instrumentation, low complexity, high-use, non-problem prone instrumentation, and reprocessing equipment."

[77] VHA Directive 1116(2) "An endoscope is a rigid or flexible device consisting of a tube with a light and a lens on the end that is inserted into a body opening or incision, typically used to examine hollow organs inside the body such as the esophagus, stomach, duodenum, colon or rectum, and is also used to take tissue from the body for testing."

[78] DUSHOM Memorandum, *Competency Assessment for Employees Reprocessing Critical and Semi-Critical Reusable Medical Equipment*, April 11, 2017.

[79] DUSHOM Memorandum, April 11, 2017.

RME Processing and SOPs

Processing of RME includes the functions of decontamination, preparation, sterilization (or high-level disinfection for endoscopes), and storage. (See Figure 4.)[80]

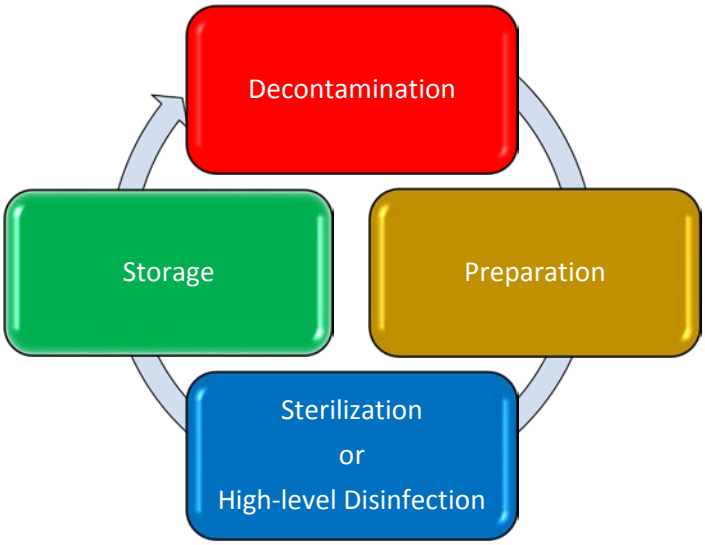

Figure 4. Cycle of RME processing
Source: OIG graphical representation of RME processing

Each item of RME must have a specific SOP for processing and corresponding competency assessments to assess an SPS employee's ability to perform processing independently. Facility policy requires training and documentation of the training when manufacturers' instructions for use manuals are changed significantly and whenever new or different equipment is used.[81] Employees in SPS must receive ongoing training and verification of the adequacy of that training to properly clean equipment. As these employees serve a vital role in the realm of patient safety, it is crucial that they are knowledgeable and well trained, so that only properly cleaned instruments touch the patient. To that end, the importance of adhering to the specific cleaning instructions of various equipment necessitates that training is adequate and up-to-date.

Documentation of competency assessments requires a utilization of a two-verification method to validate and measure the proficiency of an individual for a specific task.[82] Competency

[80]VHA Directive 1116(2). Decontamination is the cleaning of soiled or contaminated RME items. Preparation is the assembling, wrapping, and packaging of articles, trays, and basins prior to sterilization. Sterilization is the process of completely devoid of all living microorganisms. Storage is the process of storing clean and sterile supplies/instruments and to protect them from contamination.

[81] New Mexico VA Health Care System Memorandum 129-2, 2014 and 2017.

[82] VHA Directive 1116(2). Competency verification methods can include return demonstrations, observation, and verbalization.

verification methods can include return demonstrations, observation, verbalization, and simulations.[83] Those assessing competence must be familiar with the process. These assessments can be performed by the SPS Chief, Assistant Chief, SPS supervisors, educators, or other designated staff members.[84]

To determine if SPS staff had documented competencies to perform job duties, the OIG selected 14 specific items of RME and reviewed the corresponding SOPs and competency assessments. The OIG found that 5 of 14 (36 percent) selected items of RME did not have a corresponding SOP. (See Table 2.)

Table 2. RME Items and Corresponding SOPs

RME Item Number	RME Item Name	Date SOP Reviewed
OR #3508	Richard Wolf Eragon Laparoscope Tray	April 25, 2016
OR #3525	Rultract Retractor	September 15, 2016
OR #3535	Edwards Aortic Valve	April 25, 2016
OR #3538	Medtronic Mosiac Valve Set	No SOP
GU #3702	Flexible Cystoscope 11272 & 11274 series	No SOP
GU #3703	KS Uteroscope	No SOP
GU #3704	Richard Wolf Flexible Ureterorenoscopes	No SOP
OPT #3801	General Optical stainless steel instruments	No SOP
OPT #3802	Ocular Instrument Lens	May 1, 2017
ENT #3301	Pentax VNL-1190STK Updated	May 4, 2016
ENT #3303	Karl Storz Flexible Scope 1101VN	May 1, 2017
GI #3601	Olympus GIF HQ190, CF HQ190L Update	May 1, 2017
GI #3602	Olympus TJF Q180V	November 3, 2016
GI #3607	Pilling Esophageal Bougie	November 3, 2016

Source: VA OIG analysis of SOPs

The OIG reviewed the SPS staff competency assessments for the nine RME items that had corresponding SOPs. (See results in Table 3.)

[83] VHA Directive 1116(2); DUSHOM Memorandum, April 2017.

[84] VHA Directive 1116(2).

Table 3. RME Items and SPS Staff Corresponding Competency Assessments

RME Item Number	RME Item Name	Completed Staff Competency Assessments
OR #3508	Richard Wolf Eragon Laparoscope Tray	3
OR #3525	Rultract Retractor	0
OR #3535	Edwards Aortic Valve	0
OPT #3802	Ocular Instrument Lens	0
ENT #3301	Pentax VNL-1190STK Updated	6
ENT #3303	Karl Storz Flexible Scope 1101VN	7
GI #3601	Olympus GIF HQ190, CF HQ190L Update	8
GI #3602	Olympus TJF Q180V	11
GI #3607	Pilling Esophageal Bougie	0

Source: VA OIG analysis of SPS staff competency assessment documentation

For four of the nine RME items, there were no competency assessments documented. For the remaining five RME items, less than half of the 33 SPS staff members had documented competency assessments.

Issue 6: Leadership

The OIG substantiated that VISN[85] and Facility leaders were aware of the quality of care concerns in SPS and determined that the VISN did not provide effective oversight and the Facility did not effectively implement proposed action plans, as evidenced by the number of recurring and ongoing findings. (See Table 4.)

[85] In October 2016, the Facility, which had previously been aligned with VISN 18, was re-aligned with VISN 22. VISN 18 conducted an SPS review in 2015, and VISN 22 conducted an SPS review in 2016. (See Table 4.)

Table 4. Facility SPS Inspections, October 2014–May 2017

Reviewing Body	Dates	Total Findings[86]
NPOSP	October 21–23, 2014	23
NPOSP	March 31–April 2, 2015	16
VISN 18	June 3–5, 2015	22
Office of Medical Inspector	August 3–6, 2015	14
NPOSP	August 11–14, 2015	69
VISN 22	April 5–8, 2016	139
NPOSP	June 28–30, 2016	57
VISN 22	October 4–7, 2016	40
NPOSP	May 2–4, 2017	70

Source: VA OIG representation of Facility SPS inspections

VISN and Facility leaders were notified of the findings of reports from the nine site inspections performed from October 2014 through May 2017. The nine reports identified 450 findings that were presented to Facility leaders for remediation. The highest number of findings was in the SPS administrative and gastroenterology categories. The SPS administrative findings included a lack of policies and procedures, staff training and competencies, and instrument tracking. The VHA's Office of the Medical Inspector concluded in its 2015 report the Facility had "violations of policies and multiple issues that have the potential of being a substantial and specific danger to public health."

The Facility was re-aligned from VISN 18 to VISN 22 in October 2016. VISN 22 staff told the OIG that VISN leaders relied on Facility leaders and staff to review the action plan items and provide evidence of compliance. While VISN leaders monitored the plans, they did not take additional actions. Due to the number of findings, the OIG team determined that VISN leaders should have had a higher level of concern and taken action (for example, conferred with a subject matter expert or conduct additional inspections).

The VISN 22 SPS staff member (SPS Lead) who had SPS Level 1 training and reported to the VISN 22 Quality Management Officer told the OIG

> I depend on leadership of that medical center to ensure that the action plans are being developed and worked through the leadership team at that medical center for their review. And then it comes to me. When I receive an action plan that recommends an item be closed, I review it. In my mind, it has already been reviewed by leadership at that medical center, their supporting closure, and the

[86] A finding is an item or action that is not in compliance with VHA policies.

> documentation is there that issue is closed. I document it and then I "reaction" it back to that medical center. I give them 30 days for any updates. I track it until all actions have been complete.

The VISN 22 Quality Management Officer confirmed the VISN 22 SPS action plan review process stating

> The Facility provides the evidence. It might be an audit report, an SOP, or an updated competency. They provide evidence of compliance to whatever the action item was and then the verification piece would come when someone actually physically visits the Facility. During our annual VISN inspections it would be whomever has "boots on the ground." It is expected that the Facility provide them with evidence of sustained compliance. If they are not compliant then the issue is put back onto another action plan.

The VISN 22 Quality Management Officer further stated SPS action plan items "…submitted generally [do not] require a subject matter expertise to confirm that the Facility has met the particular requirements."

The Facility Director has overall responsibility for ensuring "facility compliance…and compliance of affiliated sites…with critical and semi-critical RME processes."[87]

The QSV Chief provided documents to the OIG related to Facility action plans associated with the external inspections' findings. The documentation did not clearly delineate what findings were related to each action plan and the number of closed action plans. The QSV Chief informed the OIG that "some of the action plan tracking documents were lost" due to SharePoint issues and that frequently, items could not be closed out, and therefore were rolled up into the next action plan. The QSV Chief further stated one clean action plan tracker with all items closed on all the action plans was not available.

Lack of Consistent Leadership in SPS

From July 2015 through September 2017, eight different individuals were assigned to the Acting Chief of SPS position. (See Table 5.) The Nurse Executive stated that the "lack of consistent leadership in SPS has challenged the [Facility] since the summer of 2015." The number of Acting Chiefs of SPS most likely contributed to the lack of rapid resolution of the quality of care concerns in SPS; most acting Chiefs were in place for only 120 days. The Chief of SPS has "responsibility over SPS staff members who perform the functions of decontamination, [high level disinfection] and sterilization of all critical and semi-critical

[87] VHA Directive 1116(2).

RME."[88] For a seven-month period from April 2016 through December 2016, the Facility had a permanent Chief of SPS who was reassigned to a different role within the Facility.

The Nurse Executive reported recruitment efforts for the Chief of SPS position "7–8 times over [the] past 18 months, no selections [were made] related to lack of experience in SPS/RME and management."

Table 5. Acting Facility Chiefs of SPS from July 2015–September 2017

Individuals Acting as Facility Chief of SPS	Dates
Individual 1	July 2015–October 2015
Individual 2	October 2015–January 2016
Individual 3	January 2016–May 2016
Individual 4	December 2016–February 2017
Individual 5	February 2017–May 2017
Individual 6	May 2017–September 2017
Individual 7	September 2017
Individual 8	September 2017–Present

Source: VA OIG representation of Acting Facility Chiefs of SPS

Lack of Senior Leader Oversight of SPS

Eighteen different senior leaders assumed key roles from January 2015, through September 2017. (See Figure 5.) The OIG concluded that frequent management turnover was likely a factor in failing to ensure that the goal that "clear lines of responsibility and accountability [are] established to ensure a standardized process for proper reprocessing and maintenance of RME within VA medical facilities" as articulated in VHA Directive 1116(2).[89]

[88] VHA Directive 1116(2).

[89] VHA Directive 1116(2).

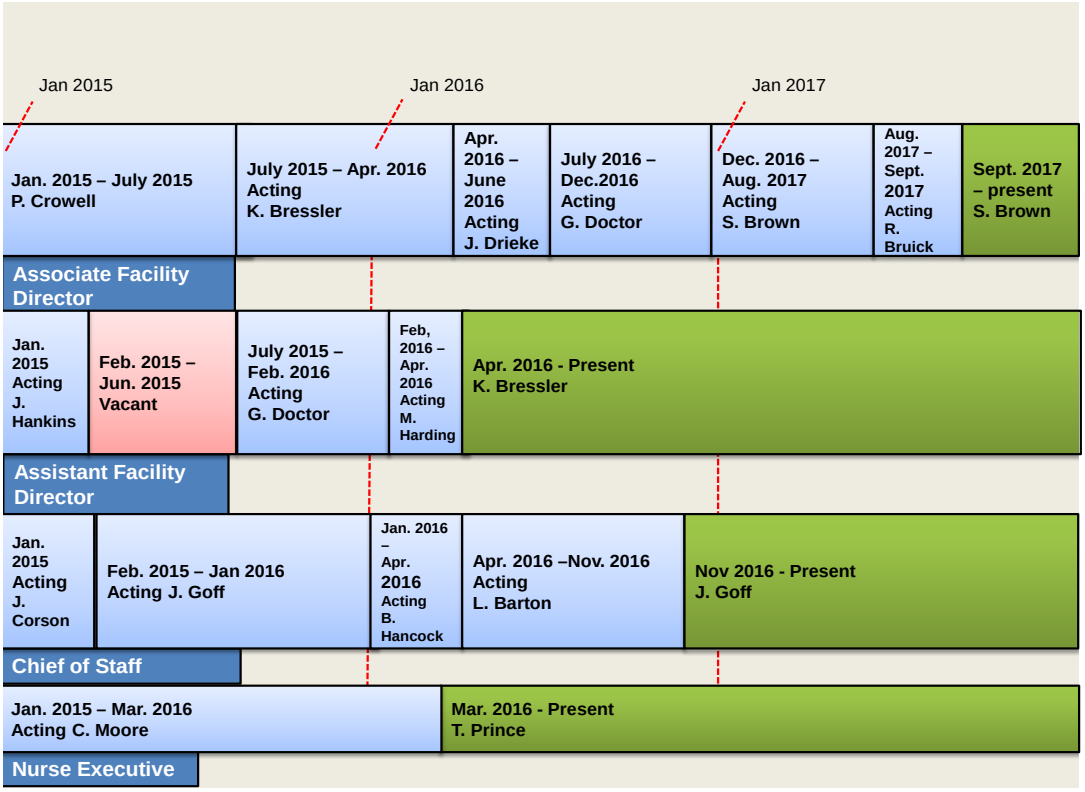

Figure 5. Changes in Facility senior leaders under the current Director, January 2015–September 2017[90]
Source: VA OIG graphical representation of Facility senior leaders' tenure

SPS and Facility senior leaders relied on face-to-face communication and workgroup meeting minutes to discuss SPS items. The Facility hosted three committees that discussed SPS and RME items: the Surgical Working Group, the Clinical Executive Board, and the Infection Control Committee. OIG inspectors reviewed the committees' meeting minutes to evaluate Facility actions and oversight of SPS issues.

The Chief of Staff (or Acting Chief of Staff) was present at 100 percent of the Facility Surgical Workgroup meetings from October 2015 through September 2017 when SPS related issues were discussed.

From January 2015 through September 2017, the Clinical Executive Board meeting minutes included five discussions of SPS related issues. The Chief of Staff (or Acting Chief of Staff), who chaired the committee, and the Nurse Executive (or Acting Nurse Executive) attended 100 percent of the meetings in which SPS related issues were discussed. SPS leaders attended

[90] Facility senior leaders include the Director, Associate Director, Assistant Director, Chief of Staff, and the Nurse Executive.

25 percent of the Clinical Executive Board meetings in 2015, 83 percent in 2016, and zero percent from January through July 2017.

The Infection Control Committee discussed SPS sterilization and RME equipment policy 19 times from January 2015 through September 2017.[91]

SPS leaders attended 25 percent of Environmental Infection Control Committee meetings in FY 2015 and FY 2016, and 50 percent through February 2017. The VISN 22 SPS Lead provided the OIG documentation that showed Facility attendance at two of three VISN 22 SPS Management Board meetings held in FY 2016; however, the documentation did not include discussion regarding Facility action plans for remediation of identified SPS issues. No meeting minutes were provided to the OIG for FY 2017.[92]

According to VHA policy, SPS is organizationally aligned under the Nurse Executive. The Facility Nurse Executive, assigned March 2016, confirmed knowledge of SPS issues when she arrived. The Nurse Executive is tasked with "providing oversight, organizational responsibility, and leadership of the local SPS operations" and is responsible for "[ensuring] that proper critical and semi-critical RME processes are in place in all clinical areas."[93] Four of the nine reports listed above were completed after March 2016. According to the Nurse Executive, the inability to recruit and maintain competent SPS leaders and staff impacted her ability to improve SPS processes.

Acting Chiefs of SPS told the OIG they communicated their concerns about the quality of care issues in SPS to the former or current Nurse Executive such as

- Lack of urgency, compassion, or understanding among the staff,
- Old, broken, and incomplete equipment,
- Non-etched instruments,[94]
- Unwillingness of SPS staff to change old habits,
- Lack of leadership ability to lead, and
- Management level issues for the SPS.

[91] The Infection Control Committee had two distinct types of meetings, the clinical Infection Control Committee and the Environmental Infection Control Committee.

[92] VISN 22 changed the title of the SPS Management Board to SPS Management Council in FY 2017.

[93] VHA Directive 1116(2).

[94] Etching is a permanent labeling method using a process called electrolysis. Infection Control Today. infectioncontroltoday.com. (The website was accessed on January 17, 2018.)

According to VHA policy, the Chief of Staff is responsible "for partnering with the Nurse Executive to ensure the proper critical and semi-critical RME processes are in place in all clinical areas."[95] Two surgeons stated they had raised their concerns regarding patient delays and lack of instrumentation to the Facility Chief of Staff and Chief of Surgery who had not addressed their concerns. When interviewed, the Chief of Staff indicated that he did not have the ability to change SPS processes as that service was not aligned under the Chief of Staff.[96] He further stated that he did not track or trend SPS action items and was unaware of any pending action items. OIG staff identified that at least 45 SPS action plans were outstanding at the time of their interview with the COS.

The Facility Director has overall responsibility for ensuring Facility compliance with SPS processes[97] When interviewed, the Facility Director was knowledgeable about the multiple inspections and findings, and identified a major outstanding issue was construction of a new SPS suite.

While the Nurse Executive and two Acting Chiefs of SPS stated that the Facility Director was supportive when they reported SPS issues, the OIG team determined that SPS issues related to training, competencies, staffing, and RME processing have persisted.

[95] VHA Directive 1116(2). As noted above, both the COS and Nurse Executive attended the Clinical Executive Board meetings where SPS related issues were discussed during the specified timeframe.

[96] The Facility organizational structure was consistent with VHA policy regarding SPS alignment. The SPS Chief reported to the Nurse Executive who reported to the Facility Director. While SPS was not aligned under the Chief of Staff at the Facility, VHA's expectation as outlined by VHA Directive 1116(2) is that the Chief of Staff "partner" with the Nurse Executive on RME processes.

[97] VHA Directive 1116(2).

Conclusion

An AIB conducted by the Facility in 2015 concluded that tampering with SPS equipment processes had occurred in FY 2015. The then-Facility Director did not take action on the finding as he reportedly did not consider the supporting evidence conclusive. The OIG conducted an unannounced site visit, interviewed Facility staff, reviewed pertinent Facility documents, and did not substantiate that tampering with equipment was occurring in SPS.

The OIG substantiated that 38 of 356 SPS sterile sets inspected were missing instruments but did not substantiate that sterile sets were incorrectly stored or damaged. The sterile sets that were missing instruments were not consistently labeled as to which instruments were missing. The OIG also identified a sterile set whose label on the outside of the package did not match the count sheet that was placed inside the package. The OIG determined that the Facility ePERS were not consistently captured in WebSPOT.

The OIG substantiated that surgical procedures were delayed or canceled due to unavailable sterile instruments and equipment. The OIG reviewed the Facility's March 1, 2015, through September 30, 2017, "Surgical Service Report of Delayed Operations" and "Surgical Service Report of Cancelled Operations" and identified 157 operations were delayed and 11 were canceled due to unavailable sterile instruments and equipment. Another patient was identified whose operation could not proceed at the Facility due to unavailable instruments. The OIG determined none of the patients experienced an adverse clinical outcome; however, three patients were placed at risk for adverse clinical outcomes related to the delayed or canceled operations.

The OIG substantiated that shortages in MST staffing occurred when the SPS staffing contract with an external agency terminated. The contract, originally scheduled to terminate on March 31, 2017, lapsed in April 30, 2017. The OIG reviewed the delays and cancellation of surgical procedures for FY 2017. The number of delays in surgery was highest in May and June. The OIG could not determine that equipment processing, or surgical delays were related to SPS staffing. A contract for MSTs was in place at the time of the September 2017 OIG site visit.

Documentation of SPS staff required training and competencies was incomplete or missing. The OIG also determined that attendance at required monthly SPS in-service education sessions was low.

The OIG substantiated that VISN and Facility leaders were aware of the quality of care concerns in SPS and did not oversee or effectively address them as evidenced by the number of recurring and ongoing findings.

The OIG made 12 recommendations.

Recommendations 1–12

1. The New Mexico VA Health Care System Director ensures that Sterile Processing Services staff adhere to the missing instrument procedures for sterile sets as required by Veterans Health Administration policy.

2. The New Mexico VA Health Care System Director ensures that Sterile Processing Services staff adhere to the requirements for verification of items in sterile sets as required by Veterans Health Administration policy.

3. The New Mexico VA Health Care System Director evaluates patient safety reporting systems to ensure that all events are captured in WebSPOT as required by Veterans Health Administration policy.

4. The New Mexico VA Health Care System Director ensures that all Sterile Processing Services staff, including contract staff, complete training as required by Veterans Health Administration Directive 1116 (2).

5. The New Mexico VA Health Care System Director verifies that Sterile Processing Services managers maintain an accurate list for reusable medical equipment and copies of manufacturers' instructions as required by Veterans Health Administration policy and the April 2017 Deputy Under Secretary for Health for Operations and Management memorandum.

6. The New Mexico VA Health Care System Director ensures that Sterile Processing Services maintain updated and readily accessible standard operating procedures for all instruments and equipment within Sterile Processing Services in accordance with Veterans Health Administration policy.

7. The New Mexico VA Health Care System Director ensures that competency assessments for all Sterile Processing Services staff, including contract staff, are conducted and documented as required by Veterans Health Administration Directive 1116 (2).

8. The New Mexico VA Health Care System Director reviews the contract related to Sterile Processing Services technicians to determine if requirements for training and certification are consistent with Veterans Health Administration Directive 1116 (2) and takes action as necessary.

9. The Veterans Integrated Service Network 22 Director ensures that the New Mexico VA Health Care System Director implements action items from previous external Sterile Processing Services inspection reviews.

10. The Veterans Integrated Service Network 22 Director oversees implementation of this report's recommendations that are directed to the New Mexico VA Health Care System Director.

11. The Veterans Integrated Service Network 22 Director reviews the New Mexico VA Health Care System's Sterile Processing Services risk assessment to determine if identified high-risk

items and areas are in alignment with guidance from the Deputy Under Secretary for Health for Operations and Management and takes action as necessary.

12. The Veterans Integrated Service Network 22 implements a process that identifies instances when independent verification by Veterans Integrated Service Network staff is necessary to ensure that the Facility implements action plans related to Sterile Processing Services recommendations.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: September 25, 2018

From: Interim Director, VA Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection— Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care System, Albuquerque, New Mexico

To: Director, Chicago Office of Healthcare Inspections (54CH)

Director, Management Review Service (VHA 10E1D MRS Action)

1. We have reviewed the Draft Report on the Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care system.
2. Please find the attached facility and VISN response to the recommendations in the report.

(Original signed by:)
Robert M. Smith, MD

Comments to OIG's Report

Recommendations 1–8 are directed to the New Mexico VA Health Care System Director.

Recommendation 9

The Veterans Integrated Service Network 22 Director ensures that the New Mexico VA Health Care System Director implements action items from previous external Sterile Processing Services inspection reviews.

Concur.

Target date for completion: March 29, 2019

Director Comments

Veterans Integrated Service Network (VISN) 22 Director will ensure the New Mexico VA Health Care System (NMHCS) Director implements action items from external Sterile Processing Services (SPS) inspection reviews. The VISN has a process in place for tracking facilities action items, ensuring implementation, and completion of actions from inspection reviews.

Recommendation 10

The Veterans Integrated Service Network 22 Director oversees implementation of this report's recommendations that are directed to the New Mexico VA Health Care System Director.

Concur.

Target date for completion: March 29, 2019

Director Comments

Veterans Integrated Service Network 22 Director will oversee implementation and completion of this report's recommendations to NMHCS.

Recommendation 11

The Veterans Integrated Service Network 22 Director reviews the New Mexico VA Health Care System's Sterile Processing Services risk assessment to determine if identified high-risk items and areas are in alignment with guidance from the Deputy Under Secretary for Health for Operations and Management and takes action as necessary.

Concur.

Target date for completion: February 28, 2019

Director Comments

Veterans Integrated Service Network 22 Director has reviewed the NMHCS SPS risk assessment and identified high-risk areas. An action plan is in process to ensure alignment with guidance from the Deputy Under Secretary for Health, Operations, and Management. The VISN will ensure the action plan is completed.

Recommendation 12

The Veterans Integrated Service Network 22 Director implements a process that identifies instances when independent verification by Veterans Integrated Service Network staff is necessary to ensure that the Facility implements action plans related to Sterile Processing Services recommendations.

Concur.

Target date for completion: January 31, 2019

Director Comments

The VISN has a process in place that identifies areas or concerns to ensure that VISN 22 facilities implement action plans related to SPS recommendations.

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: September 24, 2018

From: Director, New Mexico VA Health Care System (501/00)

Subj: Healthcare Inspection— Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care System, Albuquerque, New Mexico

To: Director, VA Desert Pacific Healthcare Network (10N22)

We appreciate the Office of Inspector General's review of alleged concerns in the Sterile Processing Service (SPS). The facility has already worked on many of the recommendations based on the understanding of the issues at the time of the site visit. The facility has implemented daily reporting by SPS at the Director's High Reliability Morning Report and a weekly report on the status of pending action items. Executive Leadership oversight continues to evolve based on outcomes tracking. The Network has also provided attention and support for SPS issues.

(Original signed by:)
Andrew M. Welch, FACHE

Comments to OIG's Report

Recommendations 9–12 are directed to the Veterans Integrated Service Network 22 Director.

Recommendation 1

The New Mexico VA Health Care System Director ensures that Sterile Processing Services staff adhere to the missing instrument procedures for sterile sets as required by Veterans Health Administration policy.

Concur.

Target date for completion: January 1, 2019

Director Comments

Staff education and process improvement was initiated to improve staff adherence to missing instrument procedures after the site visit in September 2017. Starting in October 2018, SPS will provide a monthly report to the Reusable Medical Equipment (RME) Committee that tracks all missing items including the description of the item, the impact of it being missing (e.g. case delayed, cancelled, changed, no impact), if a Joint Patient Safety Report (JPSR) was indicated and completed and the action plan to ensure the item is not missing again and/or that impact is minimized (e.g. extra items available and ready for use). The RME Committee will address any non-compliance with requirements. The Patient safety representative will confirm if a JPSR was indicated and if it was completed. Monthly reporting will be tracked for two quarters to ensure a reliable process is in place.

Recommendation 2

The New Mexico VA Health Care System Director ensures that Sterile Processing Services staff adhere to the requirements for verification of items in sterile sets as required by Veterans Health Administration policy.

Concur.

Target date for completion: January 1, 2019

Director Comments

Signature verification of all sterile sets by a SPS supervisor or lead was implemented immediately following the September 2017 site visit. Starting in October 2018, SPS will provide a monthly report to the RME Committee that includes data on compliance with two-person verification, the accuracy rate of instruments per the double check and the rate of defective set returns that show that the verification system failed. The RME Committee will track and determine appropriate actions on all non-compliance with two-person verification, when the

double check identifies an issue and all instances where a double check failed to identify a defective set. Monthly reporting will be tracked for two quarters to ensure a reliable process is in place.

Recommendation 3

The New Mexico VA Health Care System Director evaluates patient safety reporting systems to ensure that all events are captured in WebSPOT as required by Veterans Health Administration policy.

Concur.

Target date for completion: Completed and Recommend Closure

Director Comments

In April 2018 the facility implemented the required Joint Patient Safety Report (JPSR) system. The Network and National Center for Patient Safety (NCPS) have immediate access to all events entered into JPSR by anyone and entry into WebSPOT by Patient Safety is no longer required. With full access to all JPSRs, the NCPS can easily identify any emerging trends. The facility requests closure of this recommendation.

OIG Comment

The OIG considers this recommendation open in order to allow time for the Facility to provide supporting documentation.

Recommendation 4

The New Mexico VA Health Care System Director ensures that all Sterile Processing Services staff, including contract staff, complete training as required by Veterans Health Administration Directive 1116 (2).

Concur.

Target date for completion: January 1, 2019

Director Comments

Starting in October 2018, SPS will submit reports to the RME Committee to include an intermittent report on contract staff certifications (with all new SPS contracted staff) and a quarterly report of SPS staff list with enter on duty date and the date of Level 1 training to ensure compliance within 90 days. In addition, SPS Educator will submit to the RME Committee on a quarterly basis the Education Plan that includes monthly topic, educational objectives for each session, brief description of content for each session, copies of handouts and attendance roster for educational sessions that occurred in the previous quarter. Make-up sessions will be provided

when necessary. The Training Report will be tracked for two quarters to ensure a reliable process is in place.

Recommendation 5

The New Mexico VA Health Care System Director verifies that Sterile Processing Services managers maintain an accurate list for reusable medical equipment and copies of manufacturers' instructions as required by Veterans Health Administration policy and the April 2017 Deputy Under Secretary for Health for Operations and Management memorandum.

Concur.

Target date for completion: November 30, 2018

Director Comments

Since the OIG Site Visit in September 2017, NMVAHCS SPS staff have continued work on the master list of RME, ensuring it is accurate and that copies of the manufacturer's instructions are available. It has been recognized that it is a complex multidisciplinary process to ensure that new RME is added to the master list, that retired RME is removed and that loaner RME is designated as such. SPS is currently drafting a Medical Center Memorandum (MCM) that outlines management of the master list, that clearly defines responsibilities and that includes a method of validation that the master list is accurate. The review and publication of the MCM will be expediated and is anticipated by October 31, 2018. A validated master list will be approved by the RME Committee by November 30, 2018.

Recommendation 6

The New Mexico VA Health Care System Director ensures that Sterile Processing Services maintain updated and readily accessible standard operating procedures for all instruments and equipment within Sterile Processing Services in accordance with Veterans Health Administration policy.

Concur.

Target date for completion: January 1, 2019

Director Comments

Since the OIG Site Visit in September 2017, NMVAHCS SPS staff have continued work on ensuring up-to-date RME SOPs are available. A SOP is in place for the five RME items that were missing a SOP during the site visit. Once the master list is validated, SPS will provide validation that appropriate SOPs are in place for all RME.

Recommendation 7

The New Mexico VA Health Care System Director ensures that competency assessments for all Sterile Processing Services staff, including contract staff, are conducted and documented as required by Veterans Health Administration Directive 1116 (2).

Concur.

Target date for completion: March 31, 2019

Director Comments

Since the OIG Site Visit in September 2017, NMVAHCS SPS staff have continued work on maintaining staff competency, including contract staff. The master competency tracker is now updated daily. A SPS Educator was hired to assist with competencies and multiple competency fairs have been held. Staff are reminded regularly to not reprocess any RME that they are not competent to reprocess. Once the master list is validated, SPS will report the master competency tracker to the RME Committee on a regular basis. The tracker will validate that all SOPs have a corresponding competency, that an updated risk assessment has been completed to determine frequency of competency, all endoscopes have a risk designation of high-risk requiring annual competency and that competencies are tracked for all SPS technicians. The Competency Report will be tracked for two quarters to ensure a reliable process is in place.

Recommendation 8

The New Mexico VA Health Care System Director reviews the contract related to Sterile Processing Services technicians to determine if requirements for training and certification are consistent with Veterans Health Administration Directive 1116 (2) and takes action as necessary.

Concur.

Target date for completion: Completed and Recommend Closure

Director Comments

A new contract for SPS Technician staff has recently been awarded through the VISN 22 Network Contracting Office. The contract does include certification/training that is not deemed equivalent to VA Level 2 Training (e.g. graduation from nationally recognized Operating Room Technician program, graduation from a US military program for Surgical Technicians).

The Contract allows for the facility to review and approve each prospective contract staff and the Contractor has been notified that the NMVAHCS will only accept staff that are certified as Certified Registered Central Service Technician (CRCST) or higher by International Association

of Healthcare Central Service Material Management (IAHCSMN), graduation from a nationally recognized CRCST training program or VA Level 2 Certification

OIG Comment

The OIG considers this recommendation open in order to allow time for the Facility to provide supporting documentation.

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