DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Inspection of Sterile Processing Services at the Carl T. Hayden VA Medical Center in Phoenix, Arizona

HEALTHCARE INSPECTION | REPORT #21-02489-69 | JANUARY 26, 2022

MISSION

The mission of the Office of Inspector General is to serve veterans and the public by conducting meaningful independent oversight of the Department of Veterans Affairs.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

Report suspected wrongdoing in VA programs and operations to the VA OIG Hotline:

www.va.gov/oig/hotline

1-800-488-8244

Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations concerning Sterile Processing Services (SPS) at the Carl T. Hayden VA Medical Center (facility) in Phoenix, Arizona. Specifically, the complainant alleged that SPS staff (1) do not follow personal protective equipment (PPE) requirements in SPS decontamination areas; (2) falsified Resi-Tests for endoscopes from October through December 2020 by documenting the same lot number, and did not follow validation testing requirements for biological indicators and Bowie-Dick tests for sterilizers; (3) did not follow requirements for reprocessing endoscopes, da Vinci Surgical System instrumentation, or dental cassettes, and did not have adequate supplies; (4) reprocessed and included floor grade instruments in surgical trays; (5) did not check manufacturers' instructions for use resulting in loaner trays being reprocessed at incorrect sterilization parameters; (6) lacked documentation for instrumentation reprocessed at another VA facility; and (7) supervisors were unaware of Association for the Advancement of Medical Instrumentation and Association of periOperative Registered Nurses standards.[1]

The OIG substantiated that SPS staff failed to don PPE in SPS decontamination areas as required by the Veterans Health Administration in order to minimize exposure to hazards that may cause workplace illnesses and injuries. The OIG observed multiple staff entering the SPS decontamination areas without the required PPE. The OIG found that SPS leaders issued verbal warnings and corrective actions to address non-compliant SPS staff. The Chief of SPS informed the OIG that SPS staff put on PPE inside the decontamination area, as opposed to prior to entering as required, due to lack of space. Facility leaders acknowledged space limitations caused this to occur and reported that a plan was in place for the construction of a new SPS building in order to alleviate space constraints. However, the leaders did not have a start date, and a facility engineer indicated a construction contract had not been established.

[1] The OIG inspected the following decontamination areas: Operating Room/Same Day Surgery; SPS; gastroenterology; and ear, nose, and throat. STERIS, Verify Resi-Test Cleaning Indicators, "How Verify Resi-Test Cleaning Indicators Work," accessed August 17, 2021, https://www.steris.com/healthcare/products/endoscope-reprocessing/verify-resi-test-cleaning-indicators. 3M Attest Rapid 5 Steam-Plus Test Pack 41382/41382F, "Product Description," accessed August 26, 2021, https://multimedia.3m.com/mws/media/497746O/attest-rapid-5-steam-plus-test-41382-package-insert-english.pdf. Biological indicators are used to validate and monitor steam sterilization. An indicator that had not been processed through a steam sterilization cycle changes color to indicate the presence of bacteria. If the steam sterilization cycle is successful, the biological indicator that was processed will not change color. STERIS, "Verify Bowie-Dick test pack technical data," accessed on August 26, 2021, https://ww1.steris.com/onbDocs/V419/1298/688105.pdf. Bowie-Dick tests are used to verify that a steam sterilizer effectively removes all the air in the chamber and replaces it with steam. Each day, prior to being used, sterilizers must pass a Bowie-Dick test. VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016. Floor grade instruments contain a shiny finish and will rust after reprocessing. Floor grade instruments are not intended for repeated use in surgical environments and are disposable. For the purposes of this report, the OIG uses floor grade instruments and single-use items interchangeably. Loaner trays are borrowed instrument trays provided by outside vendors. SPS is responsible to reprocess loaner instrument trays in the decontamination area.

The OIG and the Assistant Chief of SPS observed that a rack designated for PPE items prior to entering the SPS decontamination area was insufficiently supplied, containing only gowns. Upon reinspection the following day, the OIG found that the PPE supply rack had been replenished with other PPE items such as head, hair, and shoe coverings.

The OIG did not substantiate that SPS staff falsified Resi-Tests by documenting the same lot number for endoscopes. During the unannounced site visit, the OIG found that multiple Resi-Test kits contained the same lot number and that having the same lot number for Resi-Test results was not an indication that SPS staff falsified documents. The OIG identified a related concern during the inspection—missing documentation of Resi-Test results from October through December 2020.

The OIG found that SPS staff received varying instructions related to the required documentation of Resi-Test results, including a September 2020 email from the former CensiTrac Coordinator directing SPS staff to discontinue documentation of Resi-Tests on paper logs but to document in CensiTrac.[2] An SPS leader explained that SPS staff were uncertain of the guidance and most staff stopped performing Resi-Tests. Additionally, an SPS leader further explained that some Resi-Test documents were displaced during a relocation of the files. In January 2021, a former SPS supervisor directed SPS staff to resume Resi-Tests on every scope and to document results in CensiTrac and on paper logs. Based on review of subsequent documentation, direct observations, and interviews, the OIG concluded that SPS staff completed Resi-Tests in accordance with policy and, therefore, made no recommendation on this topic.

SPS staff followed requirements for reprocessing endoscopes. Although the da Vinci arm instrumentation and dental cassettes were not being processed during the site visit, SPS staff were able to verbalize the steps to reprocess these instruments. The OIG did not identify supply issues.

Based on documentation review and interviews, the OIG did not substantiate that SPS staff reprocessed floor grade instrumentation, reprocessed loaner trays at incorrect parameters, or lacked documentation for instruments sterilized at another VA facility.

SPS supervisors were knowledgeable of Association for the Advancement of Medical Instrumentation and Association of periOperative Registered Nurses standards. The OIG determined SPS supervisors incorporated these standards into SPS practices.

The OIG made a recommendation to the Facility Director related to staff donning required PPE prior to entry into decontamination areas.

[2] VA Technical Reference Model, "CensiTrac InstrumenTrac," accessed June 2, 2021, https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=8145. CensiTrac is an "electronic tracking and data management system for surgical instruments."

Comments

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Contents

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AORN	Association of periOperative Registered Nurses
IFU	instructions for use
OIG	Office of Inspector General
PPE	personal protective equipment
RME	reusable medical equipment
SOP	standard operating procedure
SPS	Sterile Processing Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations concerning Sterile Processing Services (SPS) at the Carl T. Hayden VA Medical Center (facility) in Phoenix, Arizona.

Background

Sterile Processing Services

In VA facilities, SPS has the primary responsibility to decontaminate or sterilize reusable medical equipment (RME) and instrumentation.[1] Centers for Disease Control and Prevention guidelines emphasize that the sterilization of medical instruments is essential in preventing the transmission of infectious pathogens to patients. Failure to properly disinfect or sterilize equipment carries significant risk for person-to-person transmission of infectious diseases.[2] Reprocessing is a term used to describe the steps involved in making a contaminated item reusable, including cleaning, testing, disinfecting, or sterilizing.[3] Staff responsible for reprocessing RME must be trained according to device-specific instructions for use (IFUs) and establish competency by demonstrating the proper reprocessing procedure for each item.[4]

Personal Protective Equipment

Personal protective equipment (PPE) is worn to reduce exposure to hazards that may cause injuries or illnesses in the workplace. These injuries and illnesses may result from contact with physical, chemical, radiological, or other workplace hazards.[5] PPE is often used in health care settings to provide a layer of protection between infectious materials and workers. This barrier

[1] VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016. RME is "intended for repeated use on different patients with appropriate decontamination and other processing between uses."

[2] Centers for Disease Control and Prevention, "*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008,"* updated May 2019, accessed June 6, 2021, https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

[3] VHA Directive 1116(2).

[4] VHA Directive 1116(2). Facility MCP 118S-01, *Critical and Semi-Critical Reusable Medical Equipment (RME)*, October 15, 2017. This policy was in effect for a portion of the time frame of the events discussed in this report. It was rescinded and replaced by Facility MCP 118S-01, *Critical and Semi-Critical Reusable Medical Equipment (RME)*, December 30, 2020. The two policies contain the same or similar language related to critical and semi-critical RME.

[5] Occupational Safety and Health Administration, *Personal Protective Equipment*, accessed August 26, 2021, https://www.osha.gov/personal-protective-equipment.

may block transmission of contaminants from body fluids, such as respiratory secretions or blood. When used properly, PPE minimizes the spread of infection from person-to-person.[6]

Facility Operations

The facility is part of the Phoenix VA Health Care System within Veterans Integrated Service Network (VISN) 22 and includes ten community care clinics. The Veterans Health Administration (VHA) classifies the facility as level 1a, highest complexity. The facility provides acute medical, surgical, and psychiatric inpatient care, as well as rehabilitation medicine and neurological care.[7] From October 1, 2020, through September 30, 2021, the facility served 111,222 patients, had 166 operating hospital beds, and had 104 community living center beds. A program manager reported that the facility has five primary decontamination areas where RME reprocessing occurs, including one in SPS; one in the Ear, Nose, and Throat Department; and three in the Gastroenterology Department.[8]

Prior OIG Report

In May 2019, the OIG published a report, *Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona*. The OIG found that SPS did not have sufficient space, sterilizers, or equipment to manage the volume of work associated with orthopedic surgical cases to include lack of an electronic system to track loaner instruments. Additionally, the OIG determined that the facility's infrastructure and partnerships required to support a surgery complexity and efficiency were not at a level needed to achieve optimal results in perioperative care. The OIG made 12 recommendations that have been closed.[9]

Allegations and Related Concern

On February 9, 2021, the OIG received a complaint alleging that SPS staff were not following policies and procedures. During an interview, the OIG clarified the allegations with the complainant:

---

[6] Food and Drug Administration, *Personal Protective Equipment for Infection Control,* accessed August 26, 2021, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control.

[7] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex. "Facility Complexity Model," VHA Office of Productivity, Efficiency and Staffing.

[8] Occupational Safety and Health Administration, "Decontamination," accessed August 11, 2021. https://www.osha.gov/hazardous-waste/decontamination. "The process of removing or neutralizing contaminants that have accumulated on personnel and equipment."

[9] VA OIG, *Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona,* Report No. 18-02493-122, May 7, 2019, https://www.va.gov/oig/pubs/VAOIG-18-02493-122.pdf.

- SPS staff did not follow PPE requirements in decontamination areas.
- SPS staff falsified Resi-Tests for endoscopes from October through December 2020 by documenting the same lot number and did not follow validation testing requirements for biological indicators and Bowie-Dick tests for sterilizers.[10]
- SPS staff did not follow requirements for reprocessing endoscopes, da Vinci Surgical System instrumentation, dental cassettes, and did not have adequate supplies.
- SPS staff reprocessed and included floor grade instruments in surgical trays.[11]
- SPS staff did not check IFUs resulting in loaner trays being reprocessed at incorrect sterilization parameters.[12]
- SPS staff lacked documentation for instrumentation reprocessed at another VA facility.
- SPS supervisors were unaware of Association for the Advancement of Medical Instrumentation (AAMI) and Association of periOperative Registered Nurses (AORN) standards (practice standards).

During the inspection, the OIG identified a related concern regarding missing documentation of Resi-Test results.

[10] STERIS, Verify Resi-Test Cleaning Indicators, "How Verify Resi-Test Cleaning Indicators Work," accessed August 17, 2021, https://www.steris.com/healthcare/products/endoscope-reprocessing/verify-resi-test-cleaning-indicators. 3M Attest Rapid 5 Steam-Plus Test Pack 41382/41382F, "Product Description," accessed August 26, 2021, https://multimedia.3m.com/mws/media/497746O/attest-rapid-5-steam-plus-test-41382-package-insert-english.pdf. Biological indicators are used to validate and monitor steam sterilization. An indicator that had not been processed through a steam sterilization cycle changes color to indicate the presence of bacteria. If the steam sterilization cycle is successful, the biological indicator that was processed will not change color; STERIS, "Verify Bowie-Dick test pack technical data," accessed on August 26, 2021, https://ww1.steris.com/onbDocs/V419/1298/688105.pdf. Bowie-Dick tests are used to verify that a steam sterilizer effectively removes all the air in the chamber and replaces it with steam. Each day, prior to being used, sterilizers must pass a Bowie-Dick test.

[11] VHA Directive 1116(2). Floor grade instruments contain a shiny finish and will rust after reprocessing. Floor grade instruments are not intended for repeated use in surgical environments and are disposable. For the purposes of this report, the OIG uses floor grade instruments and single-use items interchangeably.

[12] VHA Directive 1116(2). Loaner trays are borrowed instrument trays provided by outside vendors to the facility for use. SPS is responsible to reprocess loaner instrument trays received in the decontamination area.

Scope and Methodology

The OIG initiated the inspection on May 27, 2021, clarified allegations with the complainant on June 8, 2021, and conducted an unannounced site visit June 29–30, 2021. The OIG conducted additional interviews June 30–July 20, 2021.

The OIG interviewed the Facility Director, Associate Director for Patient Care Services, Operating Room Nurse Manager, and the Chief of Infectious Disease. The OIG also interviewed the current and former SPS chiefs as well as SPS supervisors and staff.

The OIG reviewed relevant VHA directives as well as facility policies; standard operating procedures (SOPs); IFUs; meeting minutes of the RME, Infection Prevention and Control, and Surgical Work Group committees; SPS in-service trainings; Human Resources and personnel documents; CensiTrac reports, issue briefs, and quality assurance reports; internal and external quality reviews; SPS staff training records; and infection control data.[13] The OIG did not independently verify VHA data for accuracy or completeness. The OIG also reviewed relevant external standards.

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 determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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.

[13] VA Technical Reference Model, "CensiTrac InstrumenTrac," accessed June 2, 2021, https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=8145. CensiTrac is an "electronic tracking and data management system for surgical instruments."

Inspection Results

1. Personal Protective Equipment

The OIG substantiated that SPS staff failed to don PPE in SPS decontamination areas.[14] The OIG observed SPS and other facility staff in decontamination areas without required PPE.

VHA policy requires that individuals entering a decontamination area wear required PPE such as long-sleeved gowns, head and hair coverings, full-length face shields, heavy duty impervious decontamination gloves, and impervious knee-length shoe covers.[15] The facility also requires entrants to don powered air purifying respirators in decontamination areas.[16]

During an unannounced inspection of the SPS decontamination area, OIG team members observed an SPS leader and two repairmen enter the area without the required PPE. Specifically, the SPS leader and one of the repairmen did not don any of the required PPE, while the second repairman did not wear a face shield or powered air purifying respirators.

The OIG also observed SPS staff enter directly from the hallway into the Gastroenterology, and Ear, Nose, and Throat decontamination areas without PPE and don PPE inside the endoscope reprocessing area. According to an SPS staff member, staff typically don PPE within the decontamination areas due to a lack of dedicated space between the hallway and door leading to each decontamination area.

During interviews, SPS leaders reported previously addressing SPS staff non-compliance with PPE requirements and following up with verbal warnings and corrective actions. The OIG reviewed documentation confirming that SPS leaders addressed staff non-compliance with entering decontamination areas without PPE on October 24, 2019, and January 14, 2021. Despite the follow-up, SPS leaders informed the OIG that staff and visitors donning PPE on a bench inside of the decontamination area was common practice. The Chief of SPS elaborated that this practice was due to a lack of space prior to entering into the SPS decontamination area. See figure 1.

[14] The OIG inspected the following decontamination areas: Operating room/Same Day Surgery; SPS; Gastroenterology; and Ear, Nose, and Throat.

[15] VHA Directive 1116(2).

[16] Facility SOP VHA-V22-644-SPS-SOP-2005, *Reprocessing/Use SOP and Competency Honeywell PA700 Primair PAPR*, June 27, 2020.

Figure 1. *SPS hallway before entrance into the SPS decontamination area.*
Source: Facility; Phoenix, Arizona; November 23, 2021.

During interviews, the Facility Director acknowledged space constraints in SPS and reported prior attempts to resolve these constraints by devoting additional storage space for scopes. Facility leaders explained that, at the time of the inspection, a plan was in place for constructing a new SPS building to alleviate the issue of space constraints but did not have a start date for the project. Additionally, a facility engineer indicated a construction contract had not been established.

In the hallway leading to the decontamination area, the OIG observed a rack designated for PPE items that was insufficiently supplied, containing only gowns. The Assistant Chief of SPS escorted OIG team members to another location where the bulk of PPE supplies were stored. The Assistant Chief of SPS reportedly restocked the rack late in the previous week and indicated that restocking the supply rack is a team effort, informing the OIG team that staff who use the last of PPE were encouraged to restock the rack. Upon reinspection the following day, the OIG team found that the PPE supply rack had been replenished.

The OIG found that staff failed to enter decontamination areas with the required PPE. Failure to wear proper PPE could expose individuals to infectious diseases.

2. Validation Testing

Resi-Tests

The OIG did not substantiate that SPS staff falsified Resi-Tests by documenting the same lot number for endoscopes. During the inspection, the OIG found that some Resi-Test kits had the

same lot numbers but that was not an indication of falsified tests. The OIG identified a related concern during the inspection—missing documentation of Resi-Test results from October through December 2020. However, based on review of subsequent documentation, direct observations, and interviews, the OIG concluded that SPS staff completed Resi-Tests in accordance with policy and, therefore, made no recommendation.

VHA policy requires that after manual cleaning of flexible endoscopes, each model of endoscope is tested to ensure bioburden has been removed.[17] At a minimum, 10 percent of reprocessed endoscopes must be tested.[18] The facility has an SOP and competency checklist regarding verification of Resi-Tests for reprocessing endoscopes and requires documentation of results on a log sheet.[19]

Both a current and former SPS supervisor informed the OIG that SPS staff received varying instructions related to the required documentation of Resi-Test results. According to the Assistant Chief of SPS, SPS staff were uncertain of the guidance to follow. The OIG discovered that the former CensiTrac Coordinator instructed SPS staff by email in September 2020 to discontinue the Resi-Test logs and continue to document results using CensiTrac. The Assistant Chief of SPS informed the OIG that staff reported being told not to do Resi-Tests. Most staff stopped performing Resi-Tests, which contributed to the gap in documentation. An SPS leader explained the gap in documentation by reporting that some of the documented Resi-Test files contained in a storage unit were misplaced during a relocation. As a result, facility staff were unable to provide documentation of completed Resi-Tests from October through December 2020. In January 2021, a former SPS supervisor directed SPS staff by email to resume Resi-Tests on every scope and to document in CensiTrac and on paper logs.

During the inspection, the OIG observed that SPS staff documented the completed Resi-Tests in CensiTrac and on paper logs, following the reprocessing of three endoscopes in three separate decontamination areas. The SPS supervisor and a staff member informed the OIG that the Resi-Test results are turned in at the end of the day. During observations, the OIG noted the Resi-Test packages for endoscopes contained multiple items with the same lot number.

Although the OIG did not substantiate the falsification of Resi-Tests, the OIG learned that documentation was missing from October through December 2020. Prior to the OIG inspection, SPS supervisors clarified the information provided to SPS staff that contributed to the missing documentation. During interviews and observations, the OIG determined that SPS staff were following the current procedure to document Resi-Test results on at least 10 percent of

[17] VHA Directive 1116(2). Bioburden is the amount of bacteria on a contaminated item.

[18] VHA Directive 1116(2).

[19] Facility SOP VHA-V22-644-SPS-SOP-4141, *Verify Endo Resi-Test Reprocessing SOP and Competency,* April 10, 2021.

reprocessed endoscopes in accordance with VHA policy; therefore, the OIG made no recommendations.

Biological Indicators and Bowie-Dick Tests

The OIG did not substantiate that SPS staff did not follow validation testing requirements for biological indicators and Bowie-Dick tests for sterilizers. The OIG also found no infection concerns associated with inadequate reprocessing of equipment.

VHA policy requires that the Chief of SPS has IFUs and SOPs related to the handling, reading, and documenting of biological indicators available in SPS work areas.[20] VHA policy recommends that biological indicators be run with every sterilizer load; however, the minimum requirements are at least once each day a sterilizer is used.[21] VHA policy also requires that any time a new sterilizer is installed, three consecutive biological indicators and Bowie-Dick tests must be run in an empty sterilizer chamber and found to be acceptable.[22] VHA policy requires facility directors to establish a process that involves all stakeholders, including a representative from Infection Prevention and Control, to decide which medical instruments and equipment are used in the facility.[23]

SPS leaders and staff articulated the steps involved in the use of biological indicators and Bowie-Dick tests to ensure sterilizers were tested at recommended intervals. In January 2021, the facility's SPS received two new sterilizers and two single-chamber washers. The Assistant Chief of SPS informed the OIG that three biological indicators and three Bowie-Dick tests were run on the two new sterilizer machines. The OIG reviewed the corresponding CensiTrac reports and confirmed that the tests were completed after the new sterilizer machines were installed. In addition, the OIG found that SPS staff completed biological indicator tests multiple times per day. The Chief of SPS confirmed that biological indicators were completed on every load processed, thus exceeding the requirement established by VHA policy.

The OIG interviewed the Chief of Infectious Disease and reviewed facility documents to assess whether a correlation existed between inadequate reprocessing of RME and infectious diseases. During an interview with the OIG, the Chief of Infectious Disease reported no concerns related to infections from inadequate reprocessing of equipment. The OIG reviewed infection control data contained within the Surgical Work Group/Infection Control Committee meeting minutes and did not identify a correlation to inadequate reprocessing of equipment.

[20] VHA Directive 1116(2).
[21] VHA Directive 1116(2).
[22] VHA Directive 1116(2).
[23] VHA Directive 1116(2).

The OIG found that SPS staff followed validation testing requirements for biological indicators and Bowie-Dick tests for sterilizers. The OIG identified no infection concerns related to SPS equipment reprocessing.

3. Reprocessing Requirements and Supplies

The OIG did not substantiate that SPS staff did not follow requirements for reprocessing endoscopes, dental cassettes, and da Vinci arm instrumentation. The OIG found that SPS staff followed reprocessing steps according to SOPs and IFUs. The OIG also did not substantiate that SPS staff did not have adequate reprocessing supplies. The OIG found that SPS staff had supplies available to reprocess instruments.

VHA policy requires the Chief of SPS to develop SOPs and competency assessments for all critical and semi-critical RME according to IFUs.[24] SOPs must always be accessible to SPS staff and followed where decontamination and sterilization processes occur. VHA and facility policies require individuals assigned to reprocessing duties to be trained and competent.[25]

Endoscopes

The OIG did not substantiate that SPS staff failed to follow reprocessing requirements for endoscopes.

During the unannounced inspection, the OIG observed SPS staff reprocess an endoscope in three decontamination areas. The OIG found that in each decontamination area, SPS staff readily retrieved the SOP and IFU for reprocessing the endoscopes. The OIG found that SPS staff had the required supplies available to reprocess the endoscopes. During interviews, SPS staff reported having access to adequate supplies for reprocessing and conveyed how to obtain additional supplies, if needed. The OIG also reviewed the competency files of the SPS staff who reprocessed the endoscopes and found all files up to date.

The OIG concluded that SPS staff reprocessed endoscopes in accordance with SOPs and IFUs and had adequate supplies available for reprocessing RME.

Dental Cassettes and the da Vinci Arm Instrumentation

The OIG did not substantiate that SPS staff failed to follow established requirements for reprocessing dental cassettes and da Vinci arm instrumentation.

[24] VHA Directive 1116(2). Critical items "are instruments or objects introduced directly into the bloodstream or other normally sterile body areas." Semi-critical items "are those that come in contact with non-intact skin or mucous membranes." In the case of loaner trays, facility staff follow IFUs to reprocess equipment.

[25] VHA Directive 1116(2). Facility SOP VHA-V22-644-SPS-SOP-3004, *Reprocessing of Reusable Medical Equipment/Devices/Instruments SOP and Competency*, January 31, 2019.

The OIG reviewed the facility SOPs for dental cassettes and da Vinci arm instrumentation and noted for both instruments reprocessing steps included, but were not limited to, brushing, soaking, and processing instruments through a washer. The OIG attempted to observe the reprocessing of the dental cassettes and da Vinci arm instrumentation, but these instruments were not being reprocessed during that time. However, during inspection of the SPS decontamination area, the OIG observed an SPS staff member retrieving the IFUs and SOPs for a different piece of instrumentation that was being reprocessed. While onsite and during interviews, SPS staff demonstrated and verbalized the ability to locate SOPs and IFUs, electronically and from three-ring binders. SPS staff generally articulated the reprocessing steps for the dental cassette and da Vinci arm instruments. Although SPS staff are required to reprocess numerous pieces of instrumentation, the OIG interviewed SPS staff and found that each provided a general understanding of how to reprocess the instruments without reviewing the IFUs or SOPs in advance. The OIG reviewed the competencies of SPS staff who reprocess the RME and found that each had current competencies for both instruments. During interviews, SPS staff verbalized having brushes, cleaning solutions, and other supplies needed to clean instrumentation.

The OIG concluded that SPS staff demonstrated access to SOPs and IFUs and articulated general steps to reprocess dental cassettes and the da Vinci arm. Additionally, supplies were available for cleaning of instruments.

4. Floor Grade Instruments

The OIG did not substantiate that SPS reprocessed and included floor grade instruments in surgical trays. The OIG found that floor grade instruments received in decontamination were discarded and not reprocessed.

According to VHA policy, floor grade instruments contain a shiny finish and will rust after reprocessing.[26] Single use instruments are disposable and not cleaned, sterilized, or reused on multiple patients.[27]

The Operating Room Nurse Manager, who oversees the Surgical Department and is an end-user of surgical trays processed by SPS, described a process for documenting issues with sterile equipment using quality assurance forms. The OIG was told the quality assurance forms are returned to SPS leaders then reported to surgical and facility leaders. The OIG reviewed quality assurance forms provided by the Operating Room Nurse Manager for the period June 2020 through June 2021 and found no concerns related to reprocessed floor grade instruments.

During the onsite inspection and subsequent interviews, SPS staff articulated how to identify floor grade instruments. An SPS staff member described floor grade instrumentation as shiny and

[26] VHA Directive 1116(2).
[27] VHA Directive 1116(2).

cheap looking. During interviews, SPS staff described the process for identifying, removing, and discarding floor grade instruments that are mistakenly returned to SPS for reprocessing. Another SPS staff member indicated that floor grade instrumentation may have a marking to note that the item is for single use. Multiple SPS staff reported discarding floor grade instruments that were mistakenly returned to SPS.

The OIG did not find that SPS staff used floor grade instruments in surgical trays. The OIG concluded that SPS staff were knowledgeable of the process for identification and proper disposal of floor grade instrumentation.

5. Loaner Trays

The OIG did not substantiate that SPS staff reprocessed loaner trays at incorrect sterilization parameters due to not checking IFUs. The OIG found that SPS staff sterilized loaner trays at the correct parameters during the inspection. Additionally, the OIG found that SPS staff verbalized the correct procedures to check IFUs when loaner trays were received.

VHA policy requires that the SPS decontamination area receive loaner instrument trays with corresponding IFUs at least 48 hours prior to use to allow for adequate reprocessing time.[28] Facility policy requires vendors to deliver instrument trays with reprocessing instructions 72 hours prior to scheduled use.[29]

The OIG conducted a physical inspection of SPS. The OIG observed loaner trays pending reprocessing. Attached to each loaner tray, the OIG found a tag that indicated the sterilization parameters. The OIG compared the tag-indicated sterilization parameters with the associated IFU and found that the sterilization parameters aligned with the requirements for each associated IFU. Additionally, the OIG reviewed the documentation for the loaner trays and found that each one was sterilized at the correct parameters.

SPS staff explained to the OIG that loaner trays arrived at the facility with accompanying IFUs, which included the tray's sterilization parameters. SPS staff added that loaner trays submitted to SPS without IFUs were returned to the vendor.

The OIG found that SPS staff reviewed IFUs for loaner trays upon receipt at the facility. The OIG determined that the loaner trays reviewed were reprocessed at the correct parameters in accordance with the IFUs.

6. Off-site Reprocessing

The OIG did not substantiate that SPS staff failed to receive documentation for instruments sterilized at another VA facility. The OIG found that the documentation included elements

[28] VHA Directive 1116(2).

[29] Facility MCP 118S-07, *Management of Loaner Instrumentation*, March 20, 2020.

required by VHA policy. Instruments reprocessed at the facility or in another location outside the facility followed the same requirements to ensure proper sterilization occurred for safe use.

VHA policy requires that sterilizers have an automatic recording device. The sterilizer operator must check the recording after each cycle for the date and time the cycle started, the time sterilization began, sterilization temperature, pressure achieved during steam sterilization phase, and the length of sterilizing cycle at desired temperature.[30] The recording must be examined for correct parameters and signed by the sterilizer operator. SPS must maintain a record of the load content and information for a period of no less than three years for loads sterilized.[31]

In January 2021, SPS received two new sterilizers and two washers for RME. During interviews, the OIG learned that during installation of the new machines, instruments were sent to another VA facility for reprocessing. According to the Assistant Chief of SPS, records for instruments reprocessed at another location were recorded on paper, returned to the facility SPS, and maintained. Further, the Assistant Chief of SPS explained that during the installation of the new sterilizers, the only items that needed reprocessing at another facility were dental because the operating rooms shut down during that time. SPS staff maintained reprocessing documentation for items that were sent outside the facility and items that were returned. During an interview, an SPS staff member described that in the event instruments required reprocessing at another location, the facility process was followed.

The OIG found that facility SPS staff maintained documentation of the instruments reprocessed at another VA facility. Additionally, the OIG determined that the documentation included information required by VHA policy.

7. SPS Leaders Awareness of AAMI and AORN Standards

The OIG did not substantiate that SPS supervisors were unaware of the AAMI and AORN standards (practice standards). The OIG found that SPS supervisors understood the practice standards and described how the practice standards guide policy and practice for SPS.

VHA policy requires the application of AAMI standards to critical and semi-critical RME management and that VHA facilities incorporate the AAMI standards in areas where sterile processing occurs.[32] According to VHA Directive 1116(2), AORN "publishes standards and recommended practices to ensure safe patient care and a safe work environment in all settings where surgical and other invasive procedures are performed."

[30] VHA Directive 1116(2).

[31] VHA Directive 1116(2).

[32] VHA Directive 1116(2). "What are Standards," AAMI, accessed August 10, 2021, https://www.aami.org/standards/committee-contacts/what-are-standards. AAMI develops standards "to enhance the safety and efficacy of the use and management of medical devices." A standard "may provide clinical users with guidelines for the use, care, evaluation, or processing of medical devices."

The OIG conducted interviews with SPS leaders and a former SPS supervisor; each of whom articulated awareness of the practice standards. The Chief of SPS described VHA Directive 1116(2), which incorporates the practice standards for SPS, as the "gold standard" that the VA follows. In addition, the practice standards were used to develop SOPs. The Assistant Chief of SPS discussed the application of the AAMI standards to sterilization and described the AORN standards as additional guidance for SPS. Further, the Assistant Chief of SPS described assisting the Chief of SPS with writing the policies. A former SPS supervisor explained that the practice standards were used in conjunction with IFUs to develop SOPs. A current SPS supervisor explained that the purpose of the SOPs and IFUs is to ensure processes and procedures are done in accordance with the practice standards for patient safety. The OIG reviewed the facility policy for critical and semi-critical RME and found that the practice standards were cited as references.[33]

The OIG concluded that SPS leaders were knowledgeable of the practice standards. Facility documents confirmed that the practice standards were referenced in the service level policies and incorporated into SPS practices.

[33] Facility MCP 118S-01, *Critical and Semi-Critical Reusable Medical Equipment (RME*), October 15, 2017. Facility MCP 118S-01, *Critical and Semi-Critical Reusable Medical Equipment (RME),* December 30, 2020.

Conclusion

The OIG substantiated that SPS staff failed to don PPE in SPS decontamination areas. The OIG observed SPS and other facility staff enter decontamination areas without required PPE.

The OIG did not substantiate that SPS staff falsified Resi-Tests by documenting the same lot number for endoscopes. During the inspection, the OIG found that some Resi-Test kits had the same lot numbers but that was not an indication of falsified tests. The OIG identified a related concern during the inspection—missing documentation of Resi-Test results from October through December 2020. In January 2021, a former SPS supervisor directed SPS staff by email to resume Resi-Tests on every scope and to document in CensiTrac and on paper logs. Based on review of subsequent documentation, direct observations, and interviews, the OIG concluded that SPS staff completed Resi-Tests in accordance with policy and, therefore, made no recommendation.

The OIG did not substantiate the remaining allegations:

- SPS staff followed validation testing requirements for biological indicators and Bowie-Dick tests for sterilizers. There were no infection concerns associated with inadequate reprocessing of equipment.
- SPS staff followed requirements for reprocessing endoscopes, da Vinci arm instrumentation, and dental cassettes. SPS staff followed reprocessing steps according to SOPs and IFUs; supplies were available to reprocess instrumentation.
- If floor grade instruments were received in decontamination areas, SPS staff identified and disposed of the instruments. SPS staff did not reprocess floor grade instruments.
- SPS staff reviewed IFUs, reprocessed loaner trays at correct sterilization parameters, and verbalized the correct procedures to check IFUs when loaner trays were received.
- SPS staff maintained documentation of instrumentation sterilized at another VA facility, which included elements required by VHA policy.
- SPS supervisors were aware and understood the practice standards. The practice standards were incorporated into SPS policies and SOPs.

Recommendation

The Carl T. Hayden VA Medical Center Director ensures that staff comply with requirements for donning required personal protective equipment prior to entry into decontamination areas.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 28, 2021

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

Subj: Facility Response to OIG Draft Report Inspection of Sterile Processing Services at the Carl T. Hayden VA Medical Center in Phoenix, Arizona

To: Director, Office of the Inspector General, Office of Healthcare Inspections (54HL04)

1. Thank you for the opportunity to review and respond to the draft report, *Inspection of Sterile Processing Services at the Carl T. Hayden VA Medical Center in Phoenix, Arizona.*
2. I have reviewed the draft report and concur with the recommendation. I have reviewed and concur with the Phoenix VA Health Care System action plan underway to address the recommendation.
3. If you have any additional questions, you may contact the Chief of Quality, Safety, and Improvement.

(*Original signed by*:)

MICHAEL W. FISHER

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 28, 2021

From: Director, Phoenix VA Health Care System (644/00)

Subj: Facility Response to OIG Draft Report Inspection of Sterile Processing Services at the Carl T. Hayden VA Medical Center in Phoenix, Arizona

To: Director, Office of the Inspector General, Office of Healthcare Inspections (54HL04)

1. Thank you for the opportunity to review and respond to the draft report, *Inspection of Sterile Processing Services at the Carl T. Hayden VA Medical Center in Phoenix, Arizona.*
2. I have reviewed the draft report and concur with the recommendation. The PVAHCS has already begun to take actions to address the recommendation.
3. To address the recommendation, current sterile processing service (SPS) employees completed re-training regarding the protective personal equipment (PPE) requirements for the decontamination areas of SPS, and scope reprocessing areas for Gastroenterology (GI) and Ear, Nose and Throat (ENT) in December 2021. This training includes the requirement to don PPE prior to entry into the decontamination areas. New employees will be trained as part of orientation. In addition, SPS employees are receiving education to ensure anyone entering the decontamination areas of SPS, GI or ENT scope reprocessing has donned the required PPE. The education reinforces their duty to speak up, a key high reliability organization (HRO) value.
4. The availability of PPE remains a priority and in December 2021 the SPS PPE storage area was reorganized for easier access and to ensure the required PPE is available prior to entering the decontamination areas of SPS, and scope reprocessing areas for GI and ENT. The supervisory checklist has been modified to include an assessment of PPE availability in the SPS areas. In addition to the staff education and supervisory assessment of PPE availability, signage indicating the required PPE has been posted at the entry points for the SPS department and entry is restricted. The monitoring plan will be completed for 3 consecutive months.
5. If you have any additional questions, you may contact the Chief of Quality, Safety, and Improvement.

(*Original signed by*:)

ALYSHIA SMITH, DNP, RN

Facility Director Response

Recommendation

The Carl T. Hayden VA Medical Center Director ensures that staff comply with requirements for donning required personal protective equipment prior to entry into decontamination areas.

Concur.

Target date for completion: March 31, 2022

Director Comments

Action Plan: Sterile Processing Service (SPS) staff will be re-trained in personal protective equipment (PPE) requirements for the SPS areas to include the decontamination areas of the SPS department and the scope reprocessing areas. SPS staff will also be educated to stop the line for non-compliance with PPE requirements in the decontamination areas of the SPS department and scope reprocessing areas. New employees will be trained as part of orientation. Action completed.

Monitoring: a) 100% of current staff has completed PPE re-training. b) 30 observations monthly will be completed within the decontamination areas of the SPS department, GI and ENT scope reprocessing areas to assess compliance with PPE requirements prior to entering these areas. This will be monitored monthly for 3 consecutive months with compliance $\geq$ 90%.

Action Plan: The area for PPE storage has been reorganized to ensure all necessary PPE is available prior to entering SPS Decontamination area, as well as reprocessing areas within GI and ENT. Action completed.

Monitoring: Observation of the PPE area and availability of necessary items has been added to the supervisory checklist. The availability of PPE will be monitored for 3 consecutive months with compliance $\geq$ 90%.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Clarissa Reynolds, MBA, NHA, Director Marlene DeMaio, MD Christopher Dong, JD Kevin Hosey, MBA, LCSW Dannette Johnson, DO Glenn Schubert, BS, MPH Shedale Tindall, RN, MSN
Other Contributors	Lin Clegg, PhD Adam Hummel, MPPA Ping Luo, PhD Barbara Mallory-Sampat, JD, MSN Natalie Sadow, MBA April Terenzi

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, Desert Pacific Healthcare Network (10N22)
Director, Carl T. Hayden VA Medical Center (644)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate:
Mark Kelly, Kyrsten Sinema
U.S. House of Representatives:
Andy Biggs, Ruben Gallego, Paul A. Gosar, Raul Grijalva, Ann Kirkpatrick, Debbie Lesko, Tom O'Halleran, David Schweikert, Greg Stanton

OIG reports are available at www.va.gov/oig.