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VETERANS HEALTH ADMINISTRATION

Deficiencies in Documentation of Reusable Medical Device Reprocessing and Failures in VISN 22 Oversight of Sterile Processing Service at the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Raymond G. Murphy VA Medical Center (facility) in Albuquerque, New Mexico, to assess allegations regarding deficiencies in the reprocessing of reusable medical devices (RMDs) and quality control procedures.[1] The OIG also reviewed Veterans Integrated Service Network (VISN) 22 oversight of the facility Sterile Processing Service (SPS) leaders' management of RMD reprocessing.

The OIG reviewed the facility and VISN leaders' response to the allegations and concerns in the context of High Reliability Organization (HRO) principles and values related to patient safety, process improvement, and communication. Specifically, VISN leaders did not clearly communicate with facility leaders regarding the results of the 2022 VISN audit. HRO principles and values include (1) *Sensitivity to Operations,* in which leaders focus on frontline staff, and processes and systems with potential to impact care; (2) *Preoccupation with Failure*, in which leaders anticipate and eliminate risks to patient care before they happen; and (3) *Clear Communications*, in which leaders provide clear and timely communication to improve patient safety.[2]

Reprocessing is the term used to describe the steps involved in making contaminated RMD ready for reuse. The Food and Drug Administration, which regulates RMD, outlines reprocessing completion to exact standards "to avoid any risk of infection," which "is vital to protecting patient safety."[3] For some RMDs, such as endoscopes and anal manometers that are commonly used to examine the gastrointestinal (GI) tract, high-level disinfection (HLD) is a required

[1] Reusable medical devices are instruments or equipment healthcare providers use on multiple patients. "Reprocessing of Reusable Medical Devices," Food and Drug Administration, accessed August 11, 2023, https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-reusable-medical-devices.

[2] "VHA High Reliability Organization (HRO) Reference Guide," VHA, https://dvagov.sharepoint.com/sites/VHAPugNU/PrimaryCare/Shared%20Documents/Forms/AllItems.asp. (This web page is not publicly accessible.)

[3] "Reprocessing of Reusable Medical Devices," Food and Drug Administration; "How are Reusable Medical Devices Reprocessed?," Food and Drug Administration, accessed January 10, 2024, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/how-are-reusable-medical-devices-reprocessed.

reprocessing step to remove microorganisms, including bacteria and viruses.[4] HLD involves a medical supply technician manually cleaning and submerging the devices in a chemical solution, and documenting completion.[5] To ensure patient safety and minimize risk of infection, Veterans Health Administration (VHA) requires SPS to use an instrument tracking system that establishes an electronic record of documentation for each RMD, verifying completion of all reprocessing steps.[6]

On April 5, 2023, the OIG received a complaint alleging that the chief of SPS failed to ensure required RMD reprocessing, maintain disinfection records, and perform quality assurance activities for RMDs as required by VHA. Specifically, the complainant alleged 24 instances in which endoscopes lacked HLD documentation in the instrument tracking system (scope list) confirming reprocessing, and three patients underwent a GI procedure with endoscopes for which HLD documentation could not be located.[7] The complainant further alleged that insufficient record keeping and quality assurance for HLD documentation persisted, even after being identified in a May 2022 VISN audit.[8]

[4] "A Rational Approach to Disinfection and Sterilization," Centers for Disease Control and Prevention, accessed September 7, 2023, https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html; "What is Microbiology?," Microbiology Society, accessed September 7, 2023, https://microbiologysociety.org/why-microbiology-matters/what-is-microbiology.html; "Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation," Food and Drug Administration, accessed September 5, 2023, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation; "Endoscopy," Cleveland Clinic, accessed September 7, 2023, https://my.clevelandclinic.org/health/diagnostics/25126-endoscopy. Endoscopes are devices usually with small cameras to internally examine organs in the gastrointestinal tract; "Anorectal Manometry," Cleveland Clinic, accessed September 7, 2023, https://my.clevelandclinic.org/health/diagnostics/12760-anorectal-manometry. Anal manometers measure how well muscles in the digestive system are functioning.

[5] Facility SPS Standard Operating Procedure (SOP) 3604, *Medtronic™ ManoScan ESO (Esophageal) and AR (Anorectal) Catheters*, June 20, 2023; Facility SPS SOP 2501, *Cidex™ OPA and Test Strips*, September 10, 2021.

[6] Deputy Under Secretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services," memorandum to VISN Network Directors, January 1, 2019; VA Office of Cyber Security, "ARM Security Policy Product Review CensiTrac™," May 21, 2018; VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016. This directive was in effect at the time of the events discussed in this report until rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. SPS are responsible for the reprocessing of RMDs. The two policies contain similar language to the responsibilities of SPS.

[7] In the instrument tracking system, endoscopes are identified by a unique serial number and associated with specific dates of patient care. The complainant provided Joint Patient Safety Reporting system reports for the three patients and upon further review, the OIG found the scope numbers associated with the patients' care were included in the scope list.

[8] Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum to VISN Directors, Chief Medical Officers, Chief Nursing Officers, Quality Management Officers, VISN Chief Sterile Processing Officers, and Medical Directors, October 31, 2021.

The complaint also contained allegations that the chief of SPS prohibited staff from reporting concerns to the OIG regarding RMD reprocessing because the issues could be addressed within the facility; and facility SPS leaders submitted an action plan to the VISN on March 6, 2023, with "false information."

Deficiencies in Documentation of HLD

The OIG reviewed relevant instrument tracking system records, Joint Patient Safety Reports, and electronic health records (EHRs) for patient safety concerns to determine if adverse clinical outcomes occurred due to RMD reprocessing errors.[9] The OIG

- substantiated that documentation verifying completion of HLD for endoscope reprocessing was missing in 4 of 24 instances, identified in the scope list—the 4 instances were associated with the care of four unique patients;
- found three additional patients underwent GI procedures with anal manometers where documentation of completed HLD processes could not be produced; and
- determined deficiencies in HLD documentation occurred due to medical supply technicians missing required documentation steps, such as not scanning reprocessor receipts or associating reprocessor receipts to the incorrect RMDs.

The OIG reviewed the EHRs and did not find adverse clinical outcomes for the seven unique patients who underwent a GI procedure with RMDs for which SPS leaders could not produce documentation to confirm HLD completion. The OIG could not determine if any of the RMDs were improperly cleaned prior to reuse.

Deficiencies in HLD Quality Assurance Reviews

The OIG substantiated deficiencies in HLD quality assurance processes persisted into March 2023, despite facility leaders' awareness of HLD findings from the May 2022 annual VISN audit.[10]

The May 2022 VISN audit found that (1) HLD records were unreadable, (2) hard copies of HLD records were not organized or retained for review, and (3) quality assurance reviews of HLD

[9] For the purpose of this report, the OIG defines adverse clinical outcomes as an iatrogenic infection resulting from the use of cross-contaminated RMD. Iatrogenic infections may occur while receiving medical treatment or undergoing a procedure. *Merriam-Webster.com Dictionary*, "iatrogenic," accessed July 27, 2023, https://www.merriam-webster.com/dictionary/iatrogenic.

[10] VHA requires VISNs complete annual audits of all facility SPS programs using an audit tool provided annually by VHA's Office of Sterile Processing. Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum.

records were not being performed.[11] In response to the findings, the chief of SPS only addressed the readability of reprocessor receipts, believing this resolved all aspects of the findings. The chief of SPS told the OIG of assuming supervisors were performing daily quality assurance reviews as required and reported unawareness of lapses until a March 2023 quality nurse specialist review. Since March 2023, SPS leaders implemented supervisor and staff training and a new oversight process to ensure completion of daily quality assurance reviews.[12] Had SPS leaders upheld the HRO principles and values, specifically *Sensitivity to Operations* and *Preoccupation with Failure*, to focus on these deficiencies upon first knowledge almost a year before, errors may have been identified and corrected earlier to minimize risks to patient safety.

Risk of Infection and Lack of Communication Regarding Patient Safety Risks

The OIG substantiated that where there was no documentation of required RMD reprocessing, patients were at risk for infection if the RMD used during subsequent procedures was, in fact, not cleaned per requirements. The OIG could not determine if any of the RMDs were improperly cleaned prior to use but found no adverse clinical outcomes.

According to the American National Standards Institute/Association for the Advancement of Medical Instrumentation standards, SPS leaders should communicate safety concerns regarding RMD reprocessing to stakeholders.[13] Furthermore, VHA expects that facility services work together "to anticipate risk and prevent patient harm."[14] While the chief of SPS reported that "due diligence" of the SPS quality assurance process includes communicating RMD reprocessing concerns to the associated clinical services, the OIG determined SPS leaders did not inform the GI Service upon first awareness (in March 2023) of missing HLD documentation. When the OIG asked the chief of SPS why the GI Service was not notified of missing HLD documentation, as identified in the scope list, the chief of SPS said "there was so much going on." This lack of notification and concern for patient safety precluded clinical staff from evaluating at-risk patients for adverse clinical outcomes.[15]

Additionally, when asked if GI clinicians considered clinical disclosures during the review, the GI nurse manager reported, "no clinical disclosures were made to any of the patients." If actual

[11] For this report, the OIG uses "HLD findings" when referring, collectively, to the three aspects of the 2022 VISN audit findings related to HLD documentation—readability of HLD documentation (in the instrument tracking system), organizations of HLD records, and quality assurance of HLD documentation.

[12] Facility SPS SOP 1128, *Quality Assurance (QA)* v3, August 24, 2023.

[13] American National Standards Institute/Association for the Advancement of Medical Instrumentation, *American National Standard*, ST90:2017, accessed October 26, 2017.

[14] VHA High Reliability Organization (HRO), "HRO Principle: Sensitivity to Operations" (fact sheet).

[15] The OIG requested that facility clinical staff review the EHRs of the seven patients who underwent GI procedures with RMDs that lacked HLD documentation, and on August 25, 2023, the GI nurse manager confirmed that GI clinicians reviewed the EHRs and found no indications of infection associated with the RMDs.

or potential patient harm occurs during care, VHA considers it an obligation for clinicians to inform the patient or the patient's personal representative "that a harmful or potentially harmful adverse event has occurred during the patient's care" through clinical disclosure. In consideration of a clinical disclosure, the "decision needs to be based on the risks and benefits of disclosure relative to the probability of serious future health consequences.[16] On December 12, 2023, the OIG requested the chief of GI review the care provided to the seven patients and determine if disclosure was appropriate, and upon review, the chief of GI informed the OIG "clinical disclosure is not indicated."

Alleged Discouragement of OIG Reporting and Submission of False Information to the VISN

The OIG did not substantiate that the chief of SPS prohibited staff from reporting RMD reprocessing concerns to the OIG. The complainant had no direct knowledge of any prohibitions regarding OIG reporting, and SPS staff interviewed by the OIG denied any prohibitions on reporting concerns.

The OIG did not substantiate that facility leaders submitted false information in the action plan for the 2022 VISN audit. The OIG determined a lack of clear communication regarding roles and responsibilities related to action plans led to the quality nurse specialist's belief that the information was false. Improved communication between facility leaders and the quality nurse specialist would have likely alleviated the concern that the action plan contained false information.

VISN Failed to Provide SPS Oversight

The OIG determined VISN oversight of facility SPS operations was deficient, failing to ensure timely and sustainable actions to address the May 2022 VISN audit findings.

VHA requires an annual VISN-led audit for all facility RMD programs to identify opportunities for SPS process improvement. For the 2022 audit process, VISN Chief Sterile Processing Officers were required to report audit findings within 45 days of audit completion and track action plans through resolution. Additionally, VISN leaders were required to review audit results through a VISN level RMD management board.[17]

[16] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

[17] Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum; Deputy Under Secretary for Health for Operations and Management, "Information and Instructions for Sterile Processing Accountability Tool (SPAT)," memorandum to Network Directors, Chief Medical Officers, Quality Management Officers, and VISN Sterile Processing Service (SPS) Leads, November 4, 2019.

A former acting VISN Chief Sterile Processing Officer reported that completion of the facility action plan was delayed because the Office of Sterile Processing did not distribute a final report with the audit findings.[18] However, the OIG found that the former acting VISN Chief Sterile Processing Officer was aware of the audit findings in May 2022, but did not communicate them to VISN leaders or require a facility action plan. A VISN leader told the OIG that the position was a collateral duty and acknowledged that having an acting VISN Chief Sterile Processing Officer with collateral duties created gaps in oversight. The OIG also found that VISN leaders did not review audit findings through the VISN RMD management board.

The OIG determined that the lack of a full-time VISN Chief Sterile Processing Officer most likely contributed to the deficiencies in oversight. The current full-time VISN Chief Sterile Processing Officer, appointed in December 2022, ensured a facility action plan was developed and required sustainable and corrective actions. However, VISN leaders' failure to uphold HRO principles and values of leadership commitment and clear communication prior to the full-time appointment of the VISN Chief Sterile Processing Officer delayed mitigation of risks to patient safety.[19]

The OIG made three recommendations to the VISN Director related to timely communication of audit findings as required. The OIG also made four recommendations to the Facility Director related to completion and oversight of daily quality assurance reviews; identification and resolution of HLD documentation errors as they occur and communication to associated clinical services when HLD documentation cannot be located; and SPS leaders' communication to staff regarding roles and responsibilities.

VA Comments and OIG Response

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

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Assistant Inspector General
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[18] The Office of Sterile Processing later issued the VISN a final report with audit findings in February 2023.

[19] "VHA High Reliability Organization (HRO) Reference Guide," VHA. Patients' safety is at risk when leaders do not commit to participation in processes that impact patient care and VHA expects leaders provide clear and timely communication, such as setting expectations, to improve patient safety.

Contents

Abbreviations

EHR	electronic health record
GI	gastrointestinal
HLD	high-level disinfection
HRO	High Reliability Organization
OIG	Office of Inspector General
RMD	reusable medical device
SPS	Sterile Processing Service
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to determine the validity of allegations made regarding the reprocessing of reusable medical devices (RMDs) and quality control procedures at the Raymond G. Murphy VA Medical Center (facility) in Albuquerque, New Mexico.[1] The OIG also reviewed Veterans Integrated Service Network (VISN) 22 oversight of the facility Sterile Processing Service (SPS) leaders' management of RMD reprocessing.

Background

VISN 22, also known as the VA Desert Pacific Healthcare Network, includes eight VA health care systems and 65 community clinics in Arizona, New Mexico, and Southern California.[2] The VA New Mexico Health Care System, part of VISN 22, includes the facility and 13 community-based outpatient clinics. The Veterans Health Administration (VHA) classifies the facility as a level 1b, high complexity.[3] The facility has 167 hospital beds, 36 community living center beds, and 70 domiciliary beds. From October 1, 2021, through September 30, 2022, the facility served 65,247 patients.

The facility's Medicine Service includes Gastroenterology Service to study and treat diseases of the gastrointestinal (GI) tract.[4] Providers use various methods to assess GI health, including the

[1] "Reprocessing of Reusable Medical Devices," Food and Drug Administration, accessed August 11, 2023, https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-reusable-medical-devices. Reusable medical devices are instruments or equipment healthcare providers use and re-use, on multiple patients, to provide patient care. Reprocessing is the "detailed, multistep process to clean and then disinfect or sterilize" reusable medical devices.

[2] "About the VA Desert Pacific Healthcare Network," VA Desert Pacific Healthcare Network, accessed November 2, 2023, https://www.desertpacific.va.gov/DESERTPACIFIC/about/index.asp.

[3] VHA Office of Productivity, Efficiency, and Staffing, "Facility Complexity Model Fact Sheet," approved January 28, 2021. The VHA Facility Complexity Model classifies medical facilities at levels 1a, 1b, 1c, 2, or 3, with level 1a being the most complex and level 3 being the least complex. A level 1b facility has "medium-high volume, high risk patients, many complex clinical programs, and medium-large research and teaching programs."

[4] "What is a Gastroenterologist?," American College of Gastroenterology, accessed September 5, 2023. https://gi.org/patients/gi-health-and-disease/what-is-a-gastroenterologist/#:~:text=What%%2020is%20Gastroenterology%20%3F,gallbladder%2C%20bile%20ducts%20and%20liver."Gastroenterology is the study of the normal function and diseases of the esophagus, stomach, small intestine, colon and rectum, pancreas, gallbladder, bile ducts and liver." Gastroenterologists receive training in the use of RMD to view internal organs, interpret findings, and make treatment recommendations. The abbreviation 'GI' is an informal term, widely used in medicine, referring to the staff and activities of the gastroenterology section to include tests, procedures, and treatments relating to the digestive system.

use of devices or instruments with cameras to internally view organs, and other tools to measure how the GI tract is functioning.[5]

Sterile Processing Service

VHA SPS staff are responsible for decontamination of RMDs, such as scopes, used to view internal organs; and instrumentation, which includes surgical instruments such as forceps and clamps.[6] After health care providers use RMDs and instruments in the care of a patient, the devices and instruments must undergo reprocessing before they are used in subsequent patient care. *Reprocessing* is a term used to describe the steps involved in making contaminated RMDs ready for reuse, which includes cleaning, disinfecting, or sterilizing.[7] The Centers for Disease Control and Prevention evidence-based recommendations emphasize that "disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients."[8] To minimize risk of infection, VHA requires SPS to have detailed procedures for handling and storage of RMDs, as well as for documenting confirmation of reprocessing.[9]

The Office of Sterile Processing provides oversight for all VHA SPS and RMD operations, and the VISN Director appoints a VISN SPS Management Board and VISN Chief Sterile Processing Officer to oversee reprocessing at all VHA facilities within the VISN. VISN oversight of facility SPS includes ensuring training is provided to SPS chiefs and that a quality assurance program is

[5] "Health Services," VA New Mexico Healthcare System, accessed September 8, 2023, https://www.va.gov/new-mexico-health-care/health-services/#other-services.

[6] VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016. This directive was in effect at the time of the events discussed in this report until rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. The two policies contain similar language to the responsibilities of SPS; "What are Reusable Medical Devices?," Food and Drug Administration, accessed September 15, 2023, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/what-are-reusable-medical-devices.

[7] "Reprocessing of Reusable Medical Devices," Food and Drug Administration.

[8] Centers for Disease Control and Prevention, "*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008,"* updated May 2019, accessed November 8, 2021, https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

[9] VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same or similar language related to SPS and requirements for RMD procedures.

in place.[10] At the facility level, the Associate Director for Patient Care Services is responsible for oversight of SPS operations.[11]

RMD Used in GI Procedures

Examples of RMDs used in GI procedures include endoscopes, which are devices, usually with small cameras, to internally examine organs in the GI tract; and anal manometers, which measure how well muscles in the digestive system are functioning.[12] Endoscopes and anal manometers require high-level disinfection (HLD) during reprocessing to remove microorganisms, such as bacteria and viruses, to "mitigate the risk of patient infection."[13]

Reprocessing of a contaminated endoscope begins with precleaning by the Gastroenterology Service, which involves immediate removal of microorganisms by flushing the inside and wiping the outside of the scope with a chemical solution.[14] The endoscope is then transported to SPS, where a medical supply technician inspects the device to ensure there are no leaks. The medical supply technician performs manual cleaning of the endoscope, which includes submerging the scope in a chemical solution and brushing all internal openings.[15] The technician then runs the endoscope through an automated endoscope reprocessor (reprocessor), specifically designed to

[10] "Office of Sterile Processing Services (OSP)," VHA Office of Patient Care Services, accessed September 25, 2023, https://www.patientcare.va.gov/Office_Sterile_Processing/index.asp; VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same or similar language related to the VISN Director's responsibility to appoint a VISN SPS Management Board. The 2016 policy does not include the appointment of a VISN Chief Sterile Processing Officer as the 2023 policy does. The VISN Chief Nursing Officer reported that VISN 22 had a Chief Sterile Processing Officer position established as of 2019.

[11] VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same or similar language related to Associate Director for Patient Care Services oversight of SPS.

[12] "Endoscopy," Cleveland Clinic, accessed September 7, 2023, https://my.clevelandclinic.org/health/diagnostics/25126-endoscopy; "Anorectal Manometry," Cleveland Clinic, accessed September 7, 2023, https://my.clevelandclinic.org/health/diagnostics/12760-anorectal-manometry.

[13] "A Rational Approach to Disinfection and Sterilization," Centers for Disease Control and Prevention, accessed September 7, 2023, https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html; "What is Microbiology?," Microbiology Society, accessed September 7, 2023, https://microbiologysociety.org/why-microbiology-matters/what-is-microbiology.html; "Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation," Food and Drug Administration, accessed September 5, 2023, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation.

[14] American National Standards Institute/Association for the Advancement of Medical Instrumentation, *American National Standard*, ST91:2021, December 21, 2021. "Flexible and semi-rigid endoscope processing in health care facilities."

[15] *American National Standard*, ST91:2021.

perform HLD.[16] The endoscope is then dried, tagged with the date of reprocessing to indicate the time frame for safe patient use, and transported back to the Gastroenterology Service for reuse.

Instrument Tracking Systems

An instrument tracking system is a software program that establishes an electronic record system for RMDs. The instrument tracking system provides the facility with the ability to verify completion of all reprocessing steps, which improves patient safety and infection control.[17] All VHA facilities that conduct RMD reprocessing, such as HLD, are required to use an instrument tracking system.[18] Facility policy states medical supply technicians are responsible for reprocessing RMDs and must document all steps in the instrument tracking system so the device can be traced and completion of HLD verified in accordance with VHA requirements.[19] See figure 1 for more details on the HLD process and required instrument tracking system documentation.

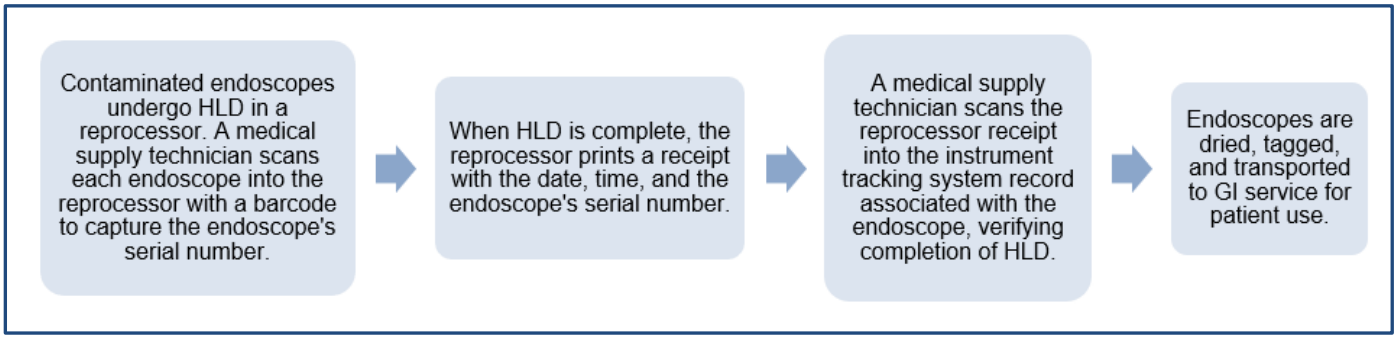

Figure 1. *HLD documentation process for endoscopes in the instrument tracking system.*
Source: OIG analysis from the facility SPS' visual aid for HLD documentation process and information received during interview with the chief of SPS.
Note: Per facility policy, documentation of HLD for anal manometers is also required in the instrument tracking system.[20]

[16] "Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation," Food and Drug Administration; Facility SPS Standard Operating Procedure (SOP) 3604, *Medtronic™ ManoScan ESO (Esophageal) and AR (Anorectal) Catheters*, June 20, 2023; Facility SPS SOP 2501, *Cidex™ OPA and Test Strips*, September 10, 2021.

[17] Deputy Under Secretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services," memorandum to VISN Network Directors, January 1, 2019; VA Office of Cyber Security, "ARM Security Policy Product Review CensiTrac™," May 21, 2018.

[18] Deputy Under Secretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services," memorandum.

[19] Facility SPS SOP 1101, *Censitrac™*, April 26, 2022; VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same, or similar language related to record keeping for traceability of RMD. The old directive used the term "look back investigation" while the new directive uses the term "traceability".

[20] Facility SPS SOP 2501; Facility SPS SOP 3604.

High Reliability Organization and Patient Safety

In 2018, the National Center for Patient Safety introduced VHA's "Journey to High Reliability," which provides a framework for effective leadership, prevention of harm, and continuous process improvement. The goal is to transform workplace culture and empower "dedicated, compassionate VA employees" to provide high quality and safe patient care.[21]

VHA established the High Reliability Organization (HRO) Steering Committee to "define the vision, principles, and values of VHA's Journey to High Reliability." The committee leads HRO practices enterprise-wide, which begin with leaders who engage staff at all levels of the organization.[22] VHA's National Center for Patient Safety recognizes leaders' communication and actions as vital in creating a culture of patient safety as "poor communication has been proven to put patients in jeopardy."[23] VHA considers the commitment of leaders as one of the most critical elements to change, and requires "participation of highly visible and vocal leaders to promote and demonstrate their sustained commitment to HRO transformation through their actions."[24] VHA's HRO principles are the foundation to help guide performance improvement and VHA expects leaders to model HRO principles and values, such as

- *Sensitivity to Operations*, in which leaders focus on frontline staff, processes, and systems with potential to impact care;
- *Preoccupation with Failure*, in which leaders anticipate and eliminate risks to patients before they happen; and
- *Clear Communications*, in which leaders provide "clear and timely communication through collaborative team work" to improve patient safety.[25]

The OIG reviewed the facility and VISN leaders' response to the allegations and concerns in the context of HRO principles and values related to patient safety, process improvement, and communication.

Prior OIG Report

In an October 2018 report, the OIG found deficiencies in required facility SPS risk assessments. Specifically, risk assessments did not include all high-risk RMDs to fully address potential

[21] "VHA High Reliability Organization (HRO) Reference Guide," VHA, https://dvagov.sharepoint.com/sites/VHAPugNU/PrimaryCare/Shared%20Documents/Forms/AllItems.asp. (This web page is not publicly accessible.)

[22] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

[23] Joe Murphy, "Developing a Culture of Safety," *Federal Practitioner* E3, (January 2013), p.1; Gary Sculli and Robin Hemphill, "Culture of Safety and Just Culture," *UT Health San Antonio,* accessed January 17, 2024, https://uthscsa.edu/medicine/sites/medicine/files/2023-08.

[24] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

[25] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

process failures or facility preparation plans to manage failures. The OIG also 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. The OIG made 12 recommendations, all of which are closed.[26]

Allegations and Related Concerns

On April 5, 2023, the OIG received a complaint from a facility staff member alleging that the chief of SPS failed to ensure instrument reprocessing, maintain disinfection records, and perform quality assurance activities for RMDs as required by VHA. Specifically, the complainant alleged:

- A quality assurance review of endoscopes used for GI procedures from January through March 2023 revealed several deficiencies in HLD documentation including,
    - 24 instances in which endoscopes lacked HLD documentation in the instrument tracking system (scope list) confirming reprocessing, and[27]
    - three patients underwent a GI procedure with endoscopes for which HLD documentation could not be located.[28]
- Improperly cleaned scopes placed patients at risk for infection.
- Insufficient record keeping and quality assurance for HLD documentation was a finding in a May 2022 VISN audit but "[quality assurance] review of HLD records [was] still not being done."[29]
- The chief of SPS prohibited staff from reporting concerns to the OIG regarding RMD reprocessing because the issues could be addressed within the facility.

[26] VA OIG, *Alleged Concerns in Sterile Processing Services at the New Mexico VA Health System Albuquerque, New Mexico*, Report No. 17-04593-10, October 31, 2018.

[27] The scope list identified 24 instances in which endoscopes lacked HLD documentation. Some endoscopes appeared on the list more than once if the endoscopes were used in different episodes of care. The endoscopes are identified by a serial number and associated with specific episodes of care.

[28] The complainant provided Joint Patient Safety Reporting system reports for the three patients. Upon further review, the OIG found the three patients were also included in the scope list of 24 instances in which endoscopes lacked HLD documentation.

[29] VHA policy requires VISNs complete annual audits of all facility SPS programs using an audit tool provided annually by VHA's Office of Sterile Processing. Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum to VISN Directors, Chief Medical Officers, Chief Nursing Officers, Quality Management Officers, VISN Chief Sterile Processing Officers, and Medical Center Directors, October 31, 2021.

- Facility leaders submitted an action plan to the VISN on March 6, 2023, with "false information. . .so it appears that [it] has been addressed even when no real action has been taken."

On May 11, 2023, the OIG opened a hotline inspection to review the above allegations and assess the facility leaders' response to deficiencies identified through the 2022 VISN audit and evaluate the VISN's oversight of facility SPS leaders' management of RMD procedures.

Scope and Methodology

The OIG initiated the inspection on May 11, 2023, and conducted a virtual site visit from June 21, 2023, through July 10, 2023. The OIG interviewed the complainant; VISN Chief Nursing Officer and Chief Sterile Processing Officers; facility Associate Director for Patient Care Services and chief nurse perioperative; chief of and nurse manager of GI studies (GI nurse manager); SPS staff including the chief of SPS, the assistant chief of SPS, the RMD quality nurse specialist (quality nurse specialist), an RMD coordinator, the RMD educator, a medical supply technician supervisor, a lead medical supply technician, and an administrative officer; and a patient safety manager.[30]

The OIG reviewed relevant VHA directives, handbooks, VISN 22 audits of facility SPS processes, facility policies and standard operating procedures related to SPS, safety in the use of RMD, patient safety, and guidance related to high reliability organizations from May 1, 2022, through May 31, 2023. The OIG also reviewed Joint Patient Safety Reports and meeting minutes for the VISN Sterile Processing Advisory Board and facility RMD committee, as well as facility SPS training documents.[31] Additionally, the OIG reviewed electronic health records (EHRs) for seven patients who underwent a GI procedure with RMDs that lacked HLD documentation.

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

[30] "Perioperative Nurse," Mayo Clinic College of Medicine and Science, accessed October 5, 2023, https://college.mayo.edu/academics/explore-health-care-careers/careers-a-z/perioperative-nurse/. A perioperative nurse is a registered nurse who specializes in patient care before, during, and after surgery.

[31] VISN Charter C2022-002, *Sterile Processing Service Advisory Board*, September 30, 2022. The VISN 22 Sterile Processing Advisory Board is an "oversight committee of Sterile Processing Service (SPS)" chaired by the VISN Chief Nursing Officer and co-chaired by the VISN Chief Sterile Processing Officer with membership of various SPS stakeholders such as the VISN Quality Management Officer, facility chiefs of SPS, facility RMD coordinators, and facility Infection and Prevention Control nurses. Although the OIG requested Joint Patient Safety Reports from May 2022 through May 2023, there were no entries of Joint Patient Safety Reports related to GI RMD reprocessing until March 2023.

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, as amended, 5 U.S.C. §§ 401–424. 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.

Inspection Results

1. Deficiencies in Documentation of HLD

The OIG substantiated that documentation verifying completion of HLD for endoscope reprocessing was missing in 4 of the 24 instances identified by the complainant. The 4 instances represented four unique patients who underwent a GI procedure with an endoscope that lacked HLD documentation.[32]

The OIG reviewed 17 Joint Patient Safety Reports related to RMD reprocessing errors and the corresponding EHRs. During review of the EHRs, the OIG found three additional patients who underwent GI procedures with RMD (other than endoscopes) where completion of HLD processes could not be verified. Through review of EHRs, the OIG determined the RMDs used during these procedures were anal manometers. The OIG ultimately found a total of seven unique patients who underwent a GI procedure with an RMD for which SPS leaders could not produce documentation to confirm HLD completion (see table 1).

Table 1. Seven Unique Patients Who Underwent a GI Procedure with an RMD Lacking HLD Documentation

Unique Patient	RMD Type	Identification Source
Patient 1	Endoscope	Scope List, Complainant, and OIG Review
Patient 2	Endoscope	Scope List
Patient 3	Endoscope	Scope List

[32] Patients 1–4 included one of the three patients specifically identified by the complainant. The OIG determined there was HLD documentation to verify reprocessing for the endoscopes associated with the other two patients specifically identified by the complainant.

Unique Patient	RMD Type	Identification Source
Patient 4	Endoscope	Scope List
Patient 5	Anal Manometer	OIG Review
Patient 6	Anal Manometer	OIG Review
Patient 7	Anal Manometer	OIG Review

Source: OIG analysis of original complaint, scope list, and OIG patient care reviews.
Note: The episodes of care occurred in January, February, March, and April 2023.

The OIG found that deficiencies in documentation occurred because SPS medical supply technicians missed required documentation steps to verify RMDs underwent HLD. The OIG could not determine if any of the RMDs were improperly cleaned prior to use but did not find adverse clinical outcomes related to the episodes of care for the seven identified patients.[33]

GI Procedures Performed with RMDs Lacking Required Documentation of HLD

The Food and Drug Administration, which regulates RMDs, outlines reprocessing completion to exact standards "to avoid any risk of infection," which "is vital to protecting patient safety."[34] American National Standards Institute/Association for the Advancement of Medical Instrumentation standards require facilities maintain RMD reprocessing records so that each device can be tracked to validate completion of all reprocessing steps.[35]

Facility medical supply technicians are required to document all RMD reprocessing steps in the instrument tracking system, including directly scanning RMDs, and are not permitted to use

[33] For the purpose of this report, the OIG defines adverse clinical outcomes as an iatrogenic infection resulting from the use of cross-contaminated RMD. Iatrogenic infections may occur while receiving medical treatment or undergoing a procedure. *Merriam-Webster.com Dictionary*, "iatrogenic," accessed July 27, 2023, https://www.merriam-webster.com/dictionary/iatrogenic.

[34] "Reprocessing of Reusable Medical Devices," Food and Drug Administration; "How are Reusable Medical Devices Reprocessed?," Food and Drug Administration, accessed January 10, 2024, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/how-are-reusable-medical-devices-reprocessed.

[35] American National Standards Institute/Association for the Advancement of Medical Instrumentation, *American National Standard*, ST90:2017, accessed October 26, 2017. "Processing of health care products—Quality management systems for processing in health care facilities." The American National Standards Institute facilitates oversight for the development of voluntary standards in the United States including the Association for the Advancement of Medical Instrumentation, which specifically provides the standards for medical devices; "About ANSI," American National Standards Institute, accessed September 5, 2023, https://www.ansi.org/about/introduction; "About AAMI," Association for the Advancement of Medical Instrumentation, accessed September 5, 2023, https://www.aami.org/about-aami/about-aami. VHA requires application of the American National Standards Institute/Advancement of Medical Instrumentation (ANSI/AAMI) standards to RMD management; VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same, or similar language related to ANSI/AAMI standards.

workarounds, which could lead to inaccurate documentation.[36] VHA requires facility SPS leaders to conduct quality assurance of RMD reprocessing records to ensure traceability of RMDs.[37] Documentation of all reprocessing steps, including HLD, must be maintained to provide a record demonstrating contaminated devices are safe for use in subsequent patient care.[38]

In March 2023, a quality nurse specialist conducted a review of HLD records in the facility's instrument tracking system from January through March 2023, and found multiple documentation errors.[39] Specifically, the quality nurse specialist identified a total of 24 instances in which endoscopes lacked HLD documentation (scope list) confirming reprocessing. The quality nurse specialist told the OIG of conducting the review because the facility received new reprocessors in March 2023 and believed a review was not only required but would identify any HLD errors.

In a March 2023 SPS meeting, the quality nurse specialist shared the HLD review findings with SPS leaders. Based on the information, SPS leaders documented a plan to

- continue HLD documentation reviews to assess for errors,
- provide training for medical supply technician supervisors on quality assurance to ensure receipts in the instrument tracking system are associated with the correct scope serial number, and
- have the RMD educator review the HLD documentation errors with staff.

On June 12, 2023, the OIG requested SPS leaders provide documentation to verify HLD completion for the RMDs on the scope list. The OIG found that SPS leaders could not provide documentation to verify HLD completion for 4 of the 24 instances. The 4 instances represented four unique patients and included one of the three patients (Patient 1) specifically identified in the complaint. To determine risks to patient safety, the OIG reviewed EHRs for the four patients associated with the missing HLD documentation and found no adverse clinical outcomes.[40]

To better understand the reasons for lack of HLD documentation, the OIG interviewed SPS leaders, who reported that although documentation errors occurred, medical supply technicians

[36] Facility SPS SOP 1101, Censitrac™; Deputy Under Secretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services," memorandum.

[37] VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same, or similar language related to record keeping for traceability of RMD. The old directive used the term "look back investigation" while new directive uses the term "traceability".

[38] *American National Standard*, ST90:2017.

[39] The OIG learned of the HLD record reviews during an interview with the quality nurse specialist.

[40] The OIG reviewed the EHRs of the three patients identified by the complainant. Although only one patient (Patient 1) underwent a GI procedure with an endoscope that lacked HLD documentation, the OIG reviewed all three patient EHRs and identified no adverse clinical outcomes associated with the GI procedures.

appropriately reprocessed RMDs.[41] SPS staff reported that the reasons for documentation errors were multifactorial and that medical supply technicians

- omitted reprocessor receipts;
- manually entered information into the instrument tracking system instead of scanning endoscopes directly; and
- ran multiple reprocessor loads simultaneously, and medical supply technicians mixed up reprocessor receipts and subsequently scanned them into the incorrect instrument tracking system record (thereby matching to the wrong endoscope).[42]

SPS leaders told the OIG that RMDs were reprocessed appropriately despite the documentation errors; however, the OIG ultimately found a total of four unique patients who underwent a GI procedure with RMDs for which SPS leaders could not produce documentation to confirm HLD completion. The OIG found no adverse clinical outcomes for the four patients where documentation could not be produced.

Additional Patients Who Underwent Procedures with Missing HLD Documentation

In addition to the four unique patients with missing HLD documentation, the OIG reviewed Joint Patient Safety Reports and corresponding EHRs. In reviewing those EHRs, the OIG found three patients who underwent GI procedures with RMDs (other than endoscopes) where the OIG could not verify completion of HLD processes. Through review of EHRs, the OIG determined the RMDs used during these procedures were anal manometers.

To determine risks to patient safety, the OIG requested all Joint Patient Safety Reports related to RMD reprocessing for devices used in GI procedures from May 1, 2022, through May 31, 2023. The facility patient safety manager provided 17 Joint Patient Safety Reports related to RMD reprocessing errors from January 11, through May 22, 2023. Notably there were no Joint Patient Safety Reports entered prior to March 2023 for RMD reprocessing errors related to GI procedures.[43] The OIG reviewed the 17 corresponding EHRs and found SPS staff were unable to provide additional information that verified RMD reprocessing for three patients who underwent

[41] SPS leaders included the assistant chief of SPS and a medical supply technician supervisor. Additionally, the facility's SPS RMD educator told the OIG that "[medical supply technicians] know those processes."

[42] SPS staff included the assistant chief of SPS, the quality nurse specialist, and a lead medical supply technician.

[43] A facility patient safety manager and the VISN Chief Sterile Processing Officer told the OIG that entry of Joint Patient Safety Reports related to GI RMD reprocessing were believed to begin around March 2023, which the OIG determined is likely due to the March 2023 quality nurse specialist review of HLD documentation.

GI procedures.[44] The OIG reviewed EHRs for the three patients and did not identify adverse clinical outcomes related to these procedures.

In April 2023, to address HLD documentation errors, the RMD educator provided all medical supply technicians with training on documentation steps for GI endoscopes in the instrument tracking system.[45] A lead medical supply technician told the OIG that medical supply technicians are no longer running multiple loads, and to reduce scanning errors, medical supply technicians are scanning receipts into the instrument tracking system as soon as the reprocessor receipt is printed. Additionally, the chief of SPS told the OIG that the service has been approved to hire three medical supply technician trainers, who will provide training to and shadow medical supply technicians, as well as perform medical supply technician duties if SPS is short-staffed.[46] The chief of SPS further told the OIG that, moving forward, SPS staff will reprocess any endoscope that lacks HLD documentation.

2. Risk of Infection and Lack of Communication Regarding Patient Safety Risks

The OIG substantiated that in instances where there was no documentation of required reprocessing of RMDs, patients were at risk for infection if an RMD used during subsequent procedures, was in fact, not cleaned per requirements. However, the OIG could not determine if any of the RMDs were improperly cleaned prior to use. Further, the OIG found no adverse clinical outcomes.

The OIG requested that facility clinical staff review the EHRs of the seven patients for whom the RMD lacked documentation of HLD. On August 25, 2023, the GI nurse manager confirmed that GI clinicians reviewed the EHRs of the seven unique patients and did not find indications of infection associated with the RMDs. The chief of GI reported having no concerns about infection related to the reprocessing of GI RMDs. Additionally, the facility's infection prevention and control team told the OIG there were no ongoing concerns found during monthly rounds of SPS.

According to the American National Standards Institute/Association for the Advancement of Medical Instrumentation standards, SPS leaders should communicate safety concerns regarding RMD reprocessing to stakeholders.[47] VHA expects that facility service staff work together "to anticipate risk and prevent patient harm" to uphold the HRO principle *Sensitivity to*

[44] For the remaining Joint Patient Safety Reports, the OIG found that either RMD was not used in patient care or HLD processes were completed.

[45] During an interview, the OIG learned the training was to address HLD documentation errors.

[46] The facility approved SPS to convert three vacant medical supply technician positions to medical supply technician trainers on May 9, 2023. As of October 17, 2023, the acting chief of Quality and Patient Safety confirmed that SPS leaders have selected candidates for two of the three positions, and the third position has not yet posted.

[47] *American National Standard*, ST90:2017.

Operations.[48] Furthermore, if actual or potential patient harm occurs during care, VHA considers it an obligation for clinicians to inform patients through clinical disclosure. In consideration of a disclosure, the "decision needs to be based on the risks and benefits of disclosure relative to the probability of serious future health consequences."[49]

When asked if GI clinicians considered clinical disclosures during the review, the GI nurse manager told the OIG, "no clinical disclosures were made to any of the patients." On December 12, 2023, the OIG requested the chief of GI review the care provided to the seven patients and determine if disclosure was appropriate. The chief of GI responded that reviews "showed no evidence of adverse events" and "clinical disclosure is not indicated."

The OIG determined SPS leaders did not inform the GI Service when HLD documentation was missing. This lack of notification and concern for patient safety precluded clinical staff from evaluating patients at risk for adverse clinical outcomes.

During an interview with the OIG, the chief of SPS reported "due diligence" of the SPS quality assurance process includes communicating RMD reprocessing concerns to the associated clinical services. However, the GI nurse manager reported that SPS leaders did not inform the GI Service when HLD documentation could not be located. When the OIG asked the chief of SPS why the GI Service did not receive notice of missing HLD documentation as identified in the scope list, the chief of SPS said "there was so much going on." Additionally, the chief of GI and the GI nurse manager reported that if notified that an RMD lacking HLD documentation was used in patient care, the GI Service would have conducted a clinical review and considered disclosure if appropriate. The OIG expects SPS leaders to collaborate with the GI Service upon awareness that HLD could not be verified, to ensure risks to patient safety could be immediately addressed.

3. Deficiencies in Quality Assurance of HLD Documentation

The OIG substantiated deficiencies in HLD quality assurance processes persisted into March 2023, although facility leaders were aware of the VISN audit findings in May 2022. Specifically, SPS supervisors did not consistently follow facility procedures to complete daily quality assurance reviews of HLD documentation.[50]

[48] VHA High Reliability Organization (HRO), "HRO Principle: Sensitivity to Operations" (fact sheet).

[49] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The directive further defines clinical disclosure as "a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care."

[50] During interviews, SPS leaders referred to facility procedures regarding daily quality assurance reviews as *daily checks*. For the purpose of this report, the OIG will use the term *quality assurance reviews* in lieu of *daily checks*.

VHA requires the facility chief of SPS ensure "a quality management program is in place," verifying completion of all RMD reprocessing steps through review of HLD documentation.[51] Facility policy states SPS supervisors are responsible for daily quality assurance reviews.[52]

In May 2022, an annual VISN audit found that HLD records were (1) unreadable in the instrument tracking system, (2) hard copies of these records were not organized or retained for review, and (3) quality assurance of HLD records was not being performed.[53] During an interview with the OIG, the chief of SPS recalled awareness of the 2022 VISN audit findings and that, in response to the audit, the reprocessor printer cartridge and scanners were replaced, ensuring HLD receipts were legible for supervisors to continue completion of the daily quality assurance reviews. The chief of SPS believed that legible receipts resolved all aspects of the HLD findings, including quality assurance of HLD documentation. In early March 2023, as evidence of this belief, the chief of SPS submitted an action plan to the VISN, in which the only corrective action required was that HLD receipts demonstrate legibility in the instrument tracking system.[54]

Later in March 2023, the quality nurse specialist told the OIG of discovering, through the review of HLD records, multiple documentation errors and that daily quality assurance reviews were still not being completed as required.

The OIG learned that SPS leaders relied on a specific SPS staff member, an instrument tracking system supervisor, to keep SPS leaders informed of findings from the quality assurance reviews.[55] The assistant chief of SPS reported the instrument tracking system supervisor left the facility in February 2022, and the chief of SPS told the OIG of believing that the remaining supervisors were performing the reviews as required. However, the assistant chief of SPS admitted that with the vacancy of the instrument tracking system supervisor, SPS supervisory staff "missed a beat" and there were gaps in completion of daily quality assurance reviews. When the OIG asked how completion of the quality assurance reviews was ensured, the chief of SPS responded, "my impression is that [supervisors are] doing their tasks."

As a result of the quality nurse specialist's review in March 2023, the OIG found that facility SPS leaders took steps to improve HLD quality assurance and documentation processes. During

[51] VHA Directive 1116(2); VHA Directive 1116. The two policies contain the same or similar language related to record keeping for traceability of RMD. The old directive used the term *look back investigation* while the new directive uses the term *traceability*.

[52] Facility SPS SOP 1128, *Quality Audits and Quality Control*, September 2, 2020.

[53] For this report, the OIG uses "HLD findings" when referring, collectively, to the three aspects of the 2022 VISN audit findings related to HLD documentation—readability of HLD documentation (in the instrument tracking system), organizations of HLD records, and quality assurance of HLD documentation.

[54] The VISN did not require facility leaders submit an action plan until March 2023 for the reasons further discussed below in *Related Concern: VISN Failed to Provide SPS Oversight*.

[55] SPS leaders included the chief and the assistant chief of SPS.

an interview the complainant reported the improvements as sustainable. SPS leaders implemented improvements of the SPS supervisors' daily quality assurance reviews, including

- verifying that scope numbers listed in the instrument tracking system matched scope numbers of scanned reprocessor receipts; and
- having discussions with medical supply technicians during shift reports and huddles to address incorrect HLD documentation, when indicated.

Additionally, the assistant chief of SPS and a medical supply technician supervisor told the OIG that the quality nurse specialist provided supervisors with training on how to correctly complete the quality assurance reviews.[56] During an interview, a medical supply technician supervisor reported that since receiving the training, the steps to complete the reviews were more clearly defined, and the various VHA requirements and roles were clarified. The OIG also learned from the chief of SPS that a new process to ensure supervisors complete quality assurance reviews has been developed. The process requires that SPS supervisors perform daily quality assurance reviews, the quality nurse specialist audits the supervisors' review, and the chief of SPS receives daily results of any findings.[57]

Facility and SPS Leaders' Response to HLD Documentation Issues

The OIG determined facility and SPS leaders failed to uphold the VHA HRO principles of *Sensitivity to Operations* and *Preoccupation with Failure*, and the value of *Clear Communications.* The OIG found SPS leaders did not focus on the frontline processes of HLD documentation and daily quality assurance reviews; these lapses persisted into March 2023, approximately 10 months following SPS leaders' first awareness of the 2022 VISN audit findings. Additionally, the OIG found a lack of clear communication regarding the role of the quality nurse specialist delayed improvement in these processes.

VHA HRO principles expect leaders to show *Sensitivity to Operations* by focusing on frontline staff and processes with the potential to affect patient care, such as RMD reprocessing, and *Preoccupation with Failure*, in which leaders anticipate and correct risks to patient care before they occur. VHA also expects leaders to provide clear and collaborative communication to improve patient safety.[58] Additionally, the nursing service assigns the goal of achieving "a systematic process for continuous improvement . . . related to RM[D]" to the quality nurse specialist. [59]

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[56] The OIG reviewed training documentation from the facility confirming medical supply technician supervisors received training regarding quality assurance in late spring and early summer of 2023.

[57] Facility SPS- SOP 1128, *Quality Assurance (QA)* v3, August 24, 2023.

[58] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

[59] Facility Nursing Services Position Description, "Position Specific Duties Quality Control and Monitoring Program," September 23, 2021.

The quality nurse specialist told the OIG that "there's been some confusion and lack of clarity in the past" regarding the role of the quality nurse specialist and that there were delays in utilizing this position. However, once assigned the task to complete an SPS risk assessment in December 2022, the quality nurse specialist recalled the direction from the VISN "pretty much laid out everything [regarding] quality [assurance reviews]." The quality nurse specialist further explained that the risk assessment provides a checklist that "guides . . . my work," which led to the review of HLD documentation. When the OIG asked why SPS had not utilized the quality nurse specialist role earlier to assist with the HLD findings from the 2022 VISN audit, the Associate Director for Patient Care Services reported the chief nurse perioperative and chief of SPS encountered challenges in using the quality nurse specialist position, including unclear communication regarding roles and expectations.[60]

The OIG found the facility leaders failed to uphold the HRO values of *Clear Communications* and *Sensitivity to Operations*, by failing to

- define the role of a critical position in quality assurance, that of the quality nurse specialist;
- communicate patient safety concerns with the GI Service, which precluded clinicians from timely evaluating patients for adverse clinical outcomes; and
- ensure SPS roles and responsibilities, including quality assurance and oversight, were clearly defined.

Furthermore, had SPS leaders upheld HRO principles and values to focus on these deficiencies upon first knowledge, and leveraged the role of the quality nurse specialist, errors may have been identified and corrected almost a year earlier to minimize risks to patient safety.

4. Alleged Discouragement of Reporting Concerns to the OIG

The OIG did not substantiate that the chief of SPS prohibited staff from reporting RMD reprocessing concerns to the OIG.

VHA expects leaders throughout the organization to promote just culture, and that employees are responsible for reporting patient safety risks.[61] Additionally, VHA expects leaders to "listen and

[60] The OIG learned from the Associate Director for Patient Care Services that the quality nurse specialist's supervisor is the chief nurse perioperative; however, the quality nurse specialist is tasked work from the chief of SPS. Additionally, the Associate Director for Patient Care Services noted this arrangement is not typical in other SPS services within the VISN, in which the SPS nurses report directly to the chief of SPS.

[61] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011; VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain similar language regarding expectations to establish a culture of safety and report concerns with patient safety. VHA Directive 1050.01. VHA defines just culture as "an atmosphere of trust in which people are expected to provide essential safety related information" and "trust they will not be held accountable for system failures."

respond to the concerns staff members raise" when exhibiting the HRO value "Duty to Speak Up."[62]

During an interview, the complainant told the OIG that former SPS staff, from "a couple of years ago," expressed that the chief of SPS prohibited staff from reporting to the OIG. The complainant further explained, "I didn't hear it, but many people told me." However, all interviewed SPS staff listed as witnesses to the alleged prohibition of OIG reporting denied the allegation.

The OIG learned from an RMD coordinator and the assistant chief of SPS that although SPS leaders prefer staff report concerns directly to SPS leaders to address any issues, staff may make reports in alternative ways, such as through a Joint Patient Safety Report. The assistant chief of SPS stated, "if [staff] don't want to talk to us, [they] don't have to" but SPS leaders encourage medical supply technicians to "stop the line" when something is wrong. The assistant chief of SPS also clarified, "[staff] have the right to report to OIG . . . but we love to be the first one to know what the problem is."

The OIG concluded that SPS staff were not prohibited from reporting concerns regarding RMD reprocessing to the OIG and SPS leaders encourage SPS staff to immediately catch and correct errors or potential errors.

5. Alleged Submission of False Information to the VISN

The OIG did not substantiate that facility leaders submitted false information in the March 6, 2023, action plan for the 2022 VISN audit. However, the OIG determined a lack of clear communication led to the quality nurse specialist's belief that the information was false.

VHA's Code of Integrity requires VHA employees "[a]dhere to the highest professional standards," exhibiting behaviors and actions that instill trust "without the intent or effect of being false."[63] Additionally, VHA HRO values include clear and collaborative communication to achieve process improvement for safe patient care.[64]

The OIG reviewed the March 6, 2023, action plan for the 2022 VISN audit and found the statement "[quality] nurse [specialist] reviewed scans Feb 2023" listed as an action that facility SPS leaders completed to address the HLD findings. The quality nurse specialist told the OIG that upon seeing this statement in the action plan, believed the wording was false and did not represent action taken because the review of HLD documentation was not completed until March 2023. However, when the OIG asked the chief of SPS, who was responsible for the submission

[62] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

[63] "Code of Integrity," VHA Office of Oversight, Risk and Ethics, accessed August 2, 2023, https://www.va.gov/VHAoversight/integrity-compliance/index.asp.

[64] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

of the action plan, what "[quality] nurse [specialist] reviewed scans Feb 2023" meant, the chief of SPS clarified that the statement addressed the readability of the reprocessor receipts and was not in reference to the quality nurse specialist's review of HLD documentation.[65]

The OIG found a lack of clear communication about the quality nurse specialist's responsibilities regarding action plans. Specifically, the quality nurse specialist noted that the position included participation in action plans and responding to the Office of Sterile Processing but after "several meetings in the past" with the chief of SPS and chief nurse perioperative to clarify roles and responsibilities, the quality nurse specialist remained unclear. Upon review of the quality nurse specialist position description, the OIG did not find participation in action plans as a specified role; however, the position description outlined the duty to document quality assurance records and data, including actions taken as a result of reviews. The quality nurse specialist told the OIG that the VISN Chief Sterile Processing Officer has since provided clarity on the roles and expectations of the SPS quality nurse specialist.

The OIG concluded the facility action plan for the HLD findings was not false, but incomplete and unclear without the additional context of the reprocessor receipts as supporting documentation to the listed action plan. The OIG concluded that had clear communication between facility leaders and the quality nurse specialist been present, more likely than not, the belief that the facility action plan contained false information may not have taken hold.

6. Related Concern: VISN Failed to Provide SPS Oversight

In review of VISN oversight to ensure the facility implemented timely and sustainable actions to address the 2022 VISN audit findings, the OIG determined VISN oversight of facility SPS operations was deficient and found VISN leaders did not uphold the HRO objectives of leadership commitment and clear communication.

2022 VISN Audit

The OIG found the VISN failed to timely issue the HLD findings from the 2022 VISN audit to ensure facility leaders' completion of action plans. The OIG also found the former acting VISN Chief Sterile Processing Officer did not communicate audit findings to VISN leaders as required.

VHA requires an annual VISN-led audit for all facility RMD programs "to serve as a quality assurance program indicator and to determine opportunities for process improvement, and sustainability."[66] For the 2022 audit process, VHA required VISN Chief Sterile Processing

[65] Upon further review of the action plan and the documentation to demonstrate the facility action, the OIG learned that the chief of SPS submitted four receipts to the VISN from the months of May, August, and November 2022 to demonstrate legible reprocessor receipts.

[66] Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum.

Officers to enter audit results in the Sterile Processing Accountability Tool within 45 days of audit completion, to provide visibility of findings to VISN leaders for continued oversight of a facility's process improvement.[67] VISN Chief Sterile Processing Officers were also required to ensure facility action plans demonstrated sustainable corrective actions to address audit findings and track these action plans from implementation through resolution. Furthermore, VISN leaders must review audit results through a VISN level management board responsible for RMD oversight, such as the Sterile Processing Advisory Board.[68]

The 2022 VISN audit of the facility's SPS was conducted on May 17–19, 2022, and was combined with a review by the Office of Sterile Processing.[69] On August 1, 2022, the former acting VISN Chief Sterile Processing Officer distributed a preliminary report of the 2022 VISN audit to the facility chief and assistant chief of SPS, 74 days after the completion of the audit. The OIG found that facility audit results were not entered into the Sterile Processing Accountability Tool until mid-September 2022, 121 days after completion of the audit and 76 days past the required entry time.

The new VISN Chief Sterile Processing Officer began in December 2022.[70] On February 8, 2023, the VISN Chief Sterile Processing Officer received the Office of Sterile Processing's final report. On February 9, 2023, the facility chief of SPS received the final report with the requirement to submit an action plan by March 6, 2023.

The former acting VISN Chief Sterile Processing Officer told the OIG that the VISN did not issue a final report to the facility and delayed entry of audit findings into the Sterile Processing Accountability Tool because the VISN had not received a final Office of Sterile Processing

[67] Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum. Deputy Under Secretary for Health for Operations and Management, "Information and Instructions for Sterile Processing Accountability Tool (SPAT)," memorandum. The Sterile Processing Accountability Tool also provides audit teams at the national, VISN, and facility levels with the ability to "identify and document findings, analyze data, and develop risk mitigation plans."

[68] Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer, "Information and Instructions for Veterans Integrated Service Network (VISN) Directors and Facility Reusable Medical Device (RMD) Program Audits (VIEWS 6067272)," memorandum.

[69] The Office of Sterile Processing health system specialist assigned to VISN 22 told the OIG that the facility's selection for review in 2022 was based on a risk assessment score for "potential unplanned serious clinical events" and at the request of the former acting VISN Chief Sterile Processing Officer. The former acting VISN Chief Sterile Processing Officer told the OIG of historical challenges with facility SPS processes and a lack of regular communication with the facility chief of SPS.

[70] The VISN Chief Nursing Officer provided the OIG with incumbency dates for the VISN Chief Sterile Processing Officer position.

report.[71] Despite the delayed Office of Sterile Processing report, the former acting VISN Chief Sterile Processing Officer expected facility SPS leaders to take immediate action on audit findings following the on-site exit briefing commensurate with the audit. However, in review of Sterile Processing Advisory Board meeting minutes, the OIG learned that facility SPS chiefs received instruction in November 2022, to submit action plans following the receipt of the final VISN report, which had not yet been issued. The OIG would have expected the former acting VISN Chief Sterile Processing Officer to follow up on the facility's progress toward addressing audit findings for immediate action.

In May 2023, when the OIG initiated the hotline inspection, the HLD findings remained open as the VISN Chief Sterile Processing Officer reported that the facility action plan did not demonstrate sustainable improvement to ensure completion of quality assurance reviews. The VISN Chief Sterile Processing Officer told the OIG that the HLD findings were not closed until July 13, 2023, over a year from the completion of the 2022 VISN audit.

The OIG also found the 2022 VISN audit findings were not communicated to the VISN leaders through the Sterile Processing Advisory Board. In review of monthly Sterile Processing Advisory Board meeting minutes, the OIG found no description of the findings. A former acting VISN Chief Sterile Processing Officer believed that audit results were shared with the Sterile Processing Advisory Board but could not provide the OIG with confirmation. Additionally, the VISN Chief Nursing Officer told the OIG of having no recollection that the former acting VISN Chief Sterile Processing Officer reported "actionable items" associated with the 2022 VISN audit.

The OIG found that a lack of a full-time VISN Chief Sterile Processing Officer most likely contributed to the deficiencies in oversight of the 2022 VISN audit process. The VISN Chief Nursing Officer reported that the VISN did not have a full-time Chief Sterile Processing Officer from July 2019 to December 2022, when the VISN Chief Sterile Processing Officer assumed the position. The former acting VISN Chief Sterile Processing Officer reported being in the role for approximately three years while also fulfilling duties as the chief of SPS at another facility in the VISN. During an interview, the VISN Chief Nursing Officer expressed the belief that the former acting VISN Chief Sterile Processing Officer's collateral duties restricted their ability to satisfy the substantial responsibility associated with the role. The former acting VISN Chief Sterile Processing Officer reported "I did the best I could" to cover the VISN responsibilities and stated, "I was pretty well stretched." The VISN Chief Nursing Officer acknowledged that having an

[71] The Office of Sterile Processing health system specialist assigned to VISN 22 told the OIG that facilities typically receive Office of Sterile Processing site review reports within 30 days; however, the Office of Sterile Processing was revising the report writing and distribution processes during the time frame of the facility's review, resulting in the delayed 2022 audit report.

acting VISN Chief Sterile Processing Officer with collateral duties created gaps in oversight, adding "you can't have collateral coverage in this role."[72]

The OIG concluded the lack of VISN oversight to hold the facility accountable to a timely and formal action plan resulted in delayed implementation of sustainable, corrective action, which did not occur for over a year from the original audit findings. The OIG also determined the delayed entry of 2022 audit results into the Sterile Processing Accountability Tool and lack of communication to the Sterile Processing Advisory Board further limited VISN leaders' visibility to ensure oversight.

VISN Leaders Failed to Uphold HRO Values

The OIG determined VISN leaders did not uphold the HRO objectives of leadership commitment and clear communication while conducting oversight of facility SPS operations. Specifically, VISN leaders did not clearly communicate with facility leaders regarding the results of the 2022 VISN audit. However, the OIG found since the full-time appointment of the VISN Chief Sterile Processing Officer in December 2022, VISN leaders have displayed the HRO principle of Commitment to Resilience.[73]

A pillar of VHA HRO is leadership commitment, in which leaders provide support to staff within the organization and participate in staffs' HRO activities, such as oversight of process improvements to address audit findings. Furthermore, patients' safety is at risk when leaders do not commit to participation in processes that may impact patient care, such as focusing on catching errors before they occur. VHA leaders are also expected to provide clear and timely communication, and set expectations, to improve patient safety.[74]

The OIG determined the former acting VISN Chief Sterile Processing Officer did not require an action plan from facility SPS leaders, which was needed to oversee implementation of process improvement to address the 2022 VISN audit findings. The former acting VISN Chief Sterile Processing Officer also failed to communicate audit findings to VISN leaders, as required in VISN oversight of facility SPS operations. The VISN Chief Nursing Officer recalled that although the former acting VISN Chief Sterile Processing Officer was waiting for the final report from the Office of Sterile Processing, the former acting VISN Chief Sterile Processing Officer

[72] VHA Directive 1116. VHA's updated SPS policy "requires each VISN to have a dedicated [Chief Sterile Processing Officer] with no collateral duties" by January 2024. Additionally, the OIG learned of improvements in the VISN's oversight of facility SPS processes since the hiring of the VISN Chief Sterile Processing Officer in December 2022, who is full-time. Specifically, the VISN Chief Sterile Processing Officer told the OIG of using data from the Sterile Processing Accountability Tool to demonstrate facility compliance rates and sharing with VISN leaders through the Sterile Processing Advisory Board.

[73] "VHA High Reliability Organization (HRO) Reference Guide," VHA. Leaders display the HRO principle of Commitment to Resilience by helping staff "[b]ounce back from mistakes, get back on track and prevent those mistakes from happening again."

[74] "VHA High Reliability Organization (HRO) Reference Guide," VHA.

did not raise any concerns regarding facility SPS operations. The VISN Chief Nursing Officer did not recall being "worried" about the VISN 2022 audit results. However, the current VISN Chief Sterile Processing Officer found more evidence was needed to show SPS leaders had implemented sustainable, corrective actions, despite the chief of SPS's belief that HLD findings were resolved for several months before the required action plan.

The OIG concluded that failures to uphold HRO principles and values prior to the full-time appointment of the VISN Chief Sterile Processing Officer exhibited deficient oversight, and delayed mitigation of risks to patient safety.

Conclusion

The OIG substantiated that documentation verifying completion of HLD for endoscope reprocessing was missing in 4 of the 24 instances identified by the complainant. The 4 instances were associated with four unique patients. The OIG reviewed Joint Patient Safety Reports and corresponding EHRs. During review of the EHRs, the OIG found three additional patients who underwent GI procedures with RMDs lacking HLD. The OIG learned deficiencies in HLD documentation occurred due to medical supply technicians missing required documentation steps, such as not scanning reprocessor receipts or associating reprocessor receipts to incorrect RMDs.

In the instances where there was no documentation of required RMD reprocessing, patients were at risk for infection if RMDs used during subsequent procedures, were in fact, not cleaned per requirements. While the OIG could not determine if any of the RMDs were improperly cleaned prior to use, the OIG reviewed the EHRs of the seven unique patients and found no adverse clinical outcomes. The OIG determined SPS leaders did not inform the GI Service when HLD documentation was missing and precluded facility clinical staff from ensuring risks to patient safety were immediately addressed.

Deficiencies in HLD quality assurance processes persisted into March 2023, despite facility leaders' awareness of the HLD findings from a May 2022 annual VISN audit. Specifically, SPS supervisors did not consistently follow facility procedures to complete daily quality assurance reviews of HLD documentation. Lapses in completion of quality assurance reviews were attributed to supervisory staff turnover and the chief of SPS's assumption that supervisors were performing this responsibility. Following the March 2023 review of HLD documentation, SPS leaders provided staff and supervisor training and in August 2023, issued a new policy reflecting more robust oversight procedures; however, had SPS leaders upheld HRO principles, errors may have been identified and corrected earlier to minimize risks to patient safety.

The OIG did not substantiate that the chief of SPS prohibited staff from reporting concerns to the OIG regarding RMD reprocessing. The complainant had no direct knowledge of any prohibitions, and SPS staff interviewed by the OIG denied any prohibitions on reporting

concerns to the OIG. Additionally, the OIG did not substantiate that facility leaders submitted false information in the action plan for the 2022 VISN audit. The OIG found that improved communication between facility leaders and the quality nurse specialist would have likely alleviated the concern that the action plan contained false information.

The VISN failed to timely issue the findings from the 2022 VISN audit to ensure facility leaders' completion of action plans related to the HLD findings. Although the former acting VISN Chief Sterile Processing Officer expected immediate action regarding the audit findings, no VISN leaders requested an action plan from the facility until March 2023. The lack of VISN oversight to hold the facility accountable to a timely and formal action plan resulted in delayed implementation of sustainable, corrective action, which did not occur for over a year from the original audit findings. Furthermore, the former acting VISN Chief Sterile Processing Officer did not communicate audit findings to VISN leaders as required, which limited VISN leaders' ability to ensure oversight. Although the lack of a full-time VISN Chief Sterile Processing Officer most likely contributed to the deficiencies in oversight, VISN leaders did not uphold the HRO objectives of leadership commitment and clear communication.

The OIG found that since the full-time appointment of the VISN Chief Sterile Processing Officer in December 2022, VISN leaders have improved in oversight of facility SPS operations, aligned with HRO principles, and closed the 2022 VISN audit findings in July 2023.

The OIG made seven recommendations.

Recommendations 1–7

1. The VA Desert Pacific Healthcare Network Director strengthens Sterile Processing Service oversight to ensure timely communication of audit findings with action plan expectations to facility leaders.

2. The VA Desert Pacific Healthcare Network Director ensures entry of audit results into the Sterile Processing Accountability Tool within the required time frame.

3. The VA Desert Pacific Healthcare Network Director ensures audit results are shared with the Sterile Processing Advisory Board per Veterans Health Administration requirements.

4. The VA New Mexico Health Care System Director ensures Sterile Processing Service has a process to communicate all instances when high-level disinfection documentation cannot be located to the associated clinical services when the reusable medical devices was used in patient care.

5. The VA New Mexico Health Care System Director ensures Sterile Processing Service has a formal process in place to sustain daily quality assurance reviews and monitors compliance.

6. The VA New Mexico Health Care System Director ensures Sterile Processing Service leaders demonstrate clear communication of Sterile Processing Service staff roles and responsibilities in

accordance with Veterans Health Administration High Reliability Organization principles and values.

7. The VA New Mexico Health Care System Director ensures the facility's Sterile Processing Service identifies and resolves high-level disinfection documentation errors as they occur, prior to use of associated reusable medical devices on patients.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 15, 2024

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

Subj: Healthcare Inspection—Deficiencies in Documentation of Reusable Medical Device Reprocessing and Failures in VISN 22 Oversight of Sterile Processing Service at the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico

To: Director, Office of Healthcare Inspections (54HL07)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) report, Deficiencies in Documentation of Reusable Medical Device Reprocessing and Failures in VISN 22 Oversight of Sterile Processing Service at the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico.
2. Based on the thorough review of the report by VISN 22 Leadership, I concur with the findings, recommendations and submitted VISN 22 and VA New Mexico Health Care System action plans.
3. If you have additional questions or need further information, please contact the VISN 22 Quality Management Officer.

(*Original signed by:*)

Steven E. Braverman, MD
VISN 22 Network Director

VISN Director Response

Recommendation 1

The VA Desert Pacific Healthcare Network Director strengthen Sterile Processing Service oversight to ensure timely communication of audit findings with action plan expectations to facility leaders.

_ X_Concur

____Nonconcur

Target date for completion: Completed; Closed February 16, 2023

Director Comments

The VA Desert Pacific Healthcare Network Director ensures Sterile Processing Service (SPS) oversight with timely communication of audit findings and action plan expectations to facility leaders. The auditing procedures for the Sterile Processing Service's (SPS) Reusable Medical Device (RMD) Program are conducted annually, as mandated by Assistant Under Secretary for Health for Patient Care Services (PCS)/Chief Nursing Officer Memorandum, dated October 3, 2023, and provides, Information and Instructions for Veterans Integrated Service Network (VISN) and Facility RMD Program Audits. During FY23, the VISN- led RMD Program audit for VA New Mexico Health Care (VA NMHCS) System was conducted from November 29, 2022, to December 1, 2022. This FY23 RMD Program audit was a subsequent annual audit following the FY22 RMD Program audit referenced in the OIG report. On December 30, 2022, the VISN Chief Sterile Processing Officer (CSPO) shared the preliminary report with VANMHCS Executive Leadership Team and SPS leadership. The preliminary RMD Audit report was sent for review and to provide an opportunity for any supplementary documentation to be submitted to the VISN CSPO.

On January 23, 2023, VISN CSPO shared the final FY23 RMD audit report and action plan with VANMHCS SPS leadership, with a request to submit the corresponding action plan to the VISN by February 20, 2023.The action plan comprised of various elements for the facility to complete, to include identification of the root cause or contributing factor, outline of the planned actions, assignment of responsibility, target date of completion, determination of outcome measures, status and evidence of action.

On February 16, 2023, VA NMHCS submitted their action plan for the FY23 RMD Program Audit to the VISN CSPO. Updates to the action plan were conducted every 90 days. Status of the VA NMHCS action plan are monitored during the VISN SPS Reusable Medical Device (RMD) Management Board Meetings, formerly known as the SPS Advisory Board. The FY24 VISN RMD Program Audit for VANMHCS is scheduled for April 9-11, 2024, with expected

completion of timely communication of audit findings and action plan expectations to facility leaders.

VISN 22 will continue to ensure that the VISN Chief Sterile Processing Officer provides oversight of Albuquerque SPS, communicates timely VISN 22 RMD program audit findings with action plan expectation for facility leaders and reports status to the VISN 22 Reusable Medical Device Management Board.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 2

The VA Desert Pacific Healthcare Network Director ensures entry of audit results into the Sterile Processing Accountability Tool within the required time frame.

_ X_Concur

____Nonconcur

Target date for completion: Completed; Closed December 12, 2022

Director Comments

The VA Desert Pacific Healthcare Network Director ensures entry of audit results into the Sterile Processing Accountability Tool within the required time frame. The VISN Chief Sterile Processing Officer (CSPO) ensures that the VISN Reusable Medical Device (RMD) Program Audits are recorded in the Sterile Processing Accountability Tool (SPAT) audit management application within 45 days of the audit's conclusion, in adherence to VHA Assistant Under Secretary for Health for Patient Care Services (PCS)/ Chief Nursing Officer Memorandum dated October 3, 2023.

The FY23 VISN RMD Program audit for VA New Mexico Health Care (VA NMHCS) System was conducted from November 29, 2022, to December 1, 2022. This FY23 RMD Program Audit was a subsequent annual audit following the FY22 RMD Program audit referenced in the OIG report. On December 12, 2022, the VISN CSPO entered the audit results thirteen (13) days following the start of the VISN-led RMD audit. The VISN FY24 RMD Program Audit for VA NMHCS is scheduled for April 9-11, 2024, with expected entry completion of audit results into the Sterile Processing Accountability Tool.

VISN 22 will continue to ensure that the Chief Sterile Processing Officer enters RMD Program Audit results into the Sterile Processing Accountability Tool within the required time frame and

reports status to the VISN 22 Reusable Medical Device Management Board formerly known as the VISN SPS Advisory Board.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 3

The VA Desert Pacific Healthcare Network Director ensures audit results are shared with the Sterile Processing Advisory Board per Veterans Health Administration requirements.

_ X_Concur

____Nonconcur

Target date for completion: Completed; Closed September 5, 2023

Director Comments

The VA Desert Pacific Healthcare Network Director ensures audit results are shared with the Sterile Processing Advisory Board per Veterans Health Administration requirements. The FY23 VISN Reusable Medical Device (RMD) Program audit for VA New Mexico Health Care (VA NMHCS) System was conducted from November 29, 2022, to December 1, 2022. This FY23 RMD Program Audit was a subsequent annual audit following the FY22 RMD Program audit referenced in the OIG report. On December 6, 2022, the VISN 22 RMD Board, formerly known as the VISN Sterile Processing Advisory Board was briefed about the FY23 VISN RMD Program Audit for the VA New Mexico Health Care (VANMHCS). Along with this update, the VISN RMD Management Board was also presented with a review of the previous fiscal year's (FY22) collective descriptive information and a comparison of the RMD Program Audit Results.

On September 5, 2023, the VISN Chief Sterile Processing Officer (CSPO) shared the VANMHCS FY23 RMD Program Audit results with the VISN RMD Management Board. This information utilized the Sterile Processing Accountability Tool (SPAT) Cube Reports, which was developed by the Office of Sterile Processing. These reports showed specific facility's audit results and collective audit results, including data on the VISN non-conformity/non-compliance rate, program audit completion rate, and a question breakdown of audit results. The SPAT Cube Report is readily available to all members of the VISN 22 RMD Management Board via the VISN RMD SharePoint site. For FY24, the RMD Program VISN Audit for VANMHCS is scheduled for April 9-11, 2024, with expected completion of shared audit results with the VISN 22 Reusable Medical Device Management Board.

VISN 22 will continue to ensure that the Chief Sterile Processing Officer shares SPS audit results with the VISN 22 Reusable Medical Device Management Board per Veterans Health Administration requirements.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 13, 2024

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

Subj: Healthcare Inspection—Deficiencies in Documentation of Reusable Medical Device Reprocessing and Failures in VISN 22 Oversight of Sterile Processing Service at the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico

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

1. Thank you for the opportunity to review and comment on the Office of Inspector General Healthcare Inspection—Deficiencies in Documentation of Reusable Medical Device Reprocessing and Failures in VISN 22 Oversight of Sterile Processing Service at the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico. I concur with the findings and recommendations in the report.
2. VA New Mexico Healthcare System remains committed to ensuring our Veterans receive exceptional health care.

(*Original signed by*:)

Lisa M Hamilton
Interim Executive Director, VA New Mexico Healthcare System

Facility Director Response

Recommendation 4

The VA New Mexico Health Care System Director ensures Sterile Processing Service has a process to communicate all instances when high-level disinfection documentation cannot be located to the associated clinical services when the reusable medical devices was used in patient care.

_ X_Concur

____Nonconcur

Target date for completion: October 31, 2024

Director Comments

The VA New Mexico Health Care System Director evaluates and ensures Sterile Processing Service (SPS) has a process to communicate all instances when High-Level Disinfection (HLD) documentation cannot be located to the associated clinical services when the reusable medical devices was used in patient care. In June 2023, SPS developed a process to identify any potential documentation issues before reusable medical devices (RMD) are used for patient care. In August 2023, Standard Operating Procedure (SOP), SPS-SOP-ADM-1128, Quality Assurance, was developed. This SOP was developed to ensure that audits and data monitoring were being conducted in alignment to VHA Directive 1116 Management of Critical and Semi-Critical Reusable Medical Device. The role of reviewing processing documentation, to include identification of any missing High-Level Disinfection, was assigned to the SPS Quality Nurse. These quality assurance reviews are conducted daily from Monday through Friday. Weekends and holiday reviews are promptly resumed on the next business day to maintain the integrity and continuity of the quality assurance process.

The VA New Mexico Healthcare System SPS Leadership is formulating a Standard Work (SW) that will supplement the current SPS-SOP-ADM-1128. It will define rules and responsibilities, required communication via email for missing HLD documentation, and standardize follow-up actions if a reusable medical device was used for patient care. Compliance will be monitored by tracking for evidence of notification until a 90% compliance rate is sustained for six consecutive months. Compliance monitoring will be submitted monthly by SPS to the Quality Board through the governance structure.

Recommendation 5

The VA New Mexico Health Care System Director ensures Sterile Processing Service has a formal process in place to sustain daily quality assurance reviews and monitors compliance.

_ X_Concur

____Nonconcur

Target date for completion: October 31, 2024

Director Comments

VA New Mexico Healthcare System ensures that Sterile Processing Service (SPS) formally establishes a daily quality assurance review process and monitors compliance on an ongoing basis, in accordance with the Standard Operating Procedure, SPS-SOP-ADM-1128, Quality Assurance. VA New Mexico Healthcare System SPS Leadership is formulating a standard work that will supplement the current SPS-SOP-ADM-1128, to include details about the types of reviews, frequency of the reviews and notification to SPS leadership.

Upon the approval of the SW, SPS Chief, will disseminate the SW for education and training of the SPS quality nurse and staff. Compliance will be monitored by tracking the education provided to the SPS quality nurse and staff with a target of achieving a 90% compliance rate. Compliance will be monitored by tracking for daily quality assurance reviews until a 90% compliance rate is sustained for six consecutive months Compliance will be measured by evidence of 90% of daily quality assurance reviews being conducted for six consecutive months. Compliance monitoring will be submitted monthly by SPS to the Quality Board through the governance structure.

Recommendation 6

The VA New Mexico Health Care System Director ensures Sterile Processing Service leaders demonstrate clear communication of Sterile Processing Service staff roles and responsibilities in accordance with Veterans Health Administration High Reliability Organization principles and values.

_ X_Concur

____Nonconcur

Target date for completion: August 30, 2024

Director Comments

The VA New Mexico Health Care System ensures that Sterile Processing Service (SPS) leadership clearly communicates staff roles and responsibilities in accordance with the principles

and values of the Veterans Health Administration's High Reliability Organization. The SPS Chief is tasked with developing position-specific expectation documents for all roles within the SPS. The position- specific expectation documents serve as a guide for Medical Supply Techs (MSTs), who are required to review and sign their respective documents. Additionally, these documents are also used as a part of the orientation process for new hires. The position-specific expectation documents are currently being revised by SPS leadership. In addition, new expectation documents are being developed for the Assistant SPS Chief, SPS Supervisor Reusable Medical Device (RMD) Pros, CensiTrac Supervisor, MST Trainers, SPS Quality Nurse, and RMD Nurses. Every two weeks, the SPS Chief will continue to hold in-person leadership meetings, as well individual meetings with the SPS leadership team to discuss SPS staff roles and responsibilities.

Compliance will be monitored by the SPS Chief, who will ensure that 100% of position-specific documents of on-board SPS staff are signed. Compliance monitoring will be submitted monthly by SPS to the Quality Board through the governance structure.

Recommendation 7

The VA New Mexico Health Care System Director ensures the facility's Sterile Processing Service identifies and resolves high-level disinfection documentation errors as they occur, prior to use of associated reusable medical devices on patients.

_ X_Concur

____Nonconcur

Target date for completion: October 31, 2024

Director Comments

The VA New Mexico Health Care System Director ensures that Sterile Processing Service (SPS) identifies and rectifies high-level disinfection documentation errors before the associated reusable medical device (RMD) is used for patient care. The SPS Quality Nurse, or designee, is responsible for reviewing high level-disinfection documentation daily from Monday through Friday. Weekends and holiday reviews are promptly resumed on the next business day to maintain the integrity and continuity of the quality assurance process.

The daily quality assurance process includes the identification of any missing high-level disinfection documentation records. For instances of high-level disinfection documentation errors, the SPS Quality Nurse sends an email notification detailing the error, and recommended actions if applicable, to SPS leadership, including the SPS Chief, SPS Assistant Chief, Medical Supply Technician (MST Supervisor, and MST Leads).

VA New Mexico Healthcare System SPS Leadership is formulating a standard work that will supplement the current SPS-SOP-ADM-1128, to include rules and responsibilities, and required communication via email for missing HLD documentation.

Compliance will be monitored through auditing the quality assurance spreadsheet for identification and resolution of high-level disinfection documentation errors a 90% compliance rate is achieved over six consecutive months. Compliance monitoring will be submitted monthly by SPS to the Quality Board through the governance structure.

OIG Contact and Staff Acknowledgments

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