



Report to the Chairman, Committee on
Veterans' Affairs, House of
Representatives

August 2018

VA HEALTH CARE

Improved Oversight Needed for Reusable Medical Equipment

Accessible Version

GAO Highlights

Highlights of [GAO-18-474](#), a report to the Chairman, Committee on Veterans' Affairs, House of Representatives

Why GAO Did This Study

VHA operates one of the largest health care delivery systems in the nation, serving over 9 million enrolled veterans. In providing health care services to veterans, VAMCs use RME which must be reprocessed—that is, cleaned, disinfected, or sterilized—between uses. Improper reprocessing of RME can negatively affect patient care. To help ensure the safety of veterans, VHA policy establishes requirements VAMCs must follow when reprocessing RME and requires a number of related oversight efforts.

GAO was asked to review VHA's reprocessing of RME. This report examines (1) VHA's oversight of VAMCs' adherence to RME policies and (2) challenges VAMCs face in operating their Sterile Processing Services programs, and any efforts by VHA to address these challenges. GAO reviewed relevant VHA documents including RME policies and VISN inspection results for fiscal year 2017. GAO interviewed officials from VHA, all 18 VISNs, and four VAMCs, selected based on geographic variation, VAMC complexity, and data on operating room delays. GAO examined VHA's oversight in the context of federal internal control standards on communication, monitoring, and information.

What GAO Recommends

GAO is making three recommendations to VHA, including that it ensure all RME inspections are being conducted and complete results reported, and that it examine Sterile Processing Services workforce needs and make adjustments, as appropriate. VA concurred with these recommendations.

View [GAO-18-474](#). For more information, contact Sharon Silas at (202) 512-7114 or silass@gao.gov.

August 2018

VA HEALTH CARE

Improved Oversight Needed for Reusable Medical Equipment

What GAO Found

GAO found that the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) does not have reasonable assurance that VA Medical Centers (VAMC) are following policies related to reprocessing reusable medical equipment (RME). Reprocessing involves cleaning, sterilizing, and storing surgical instruments and other RME, such as endoscopes. VHA has not ensured that all VAMCs' RME inspections have been conducted because it has incomplete information from the annual inspections by Veterans Integrated Service Networks (VISN), which oversee VAMCs. For fiscal year 2017, VHA did not have 39 of the 144 VISN reports from the VISNs' inspections of their VAMCs' Sterile Processing Services departments. VISNs were able to provide GAO with evidence that they had conducted 27 of the 39 missing inspections; top areas of non-adherence in these inspections were related to quality and training, among other things. Although VHA has ultimate oversight responsibility, a VHA official told GAO that VHA had not been aware it lacked complete inspection results because it has largely relied on the VISNs to ensure complete inspection result reporting. Without analyzing and sharing complete information from inspections, VHA does not have assurance that its VAMCs are following RME policies designed to ensure that veterans receive safe care.

An endoscope is a kind of reusable medical equipment



Source: Image of endoscope reprinted with permission from Ofstead & Associates, Inc. | GAO-18-474

GAO also found that VAMCs face challenges operating their Sterile Processing Services programs—notably, addressing workforce needs. Almost all of the officials from all 18 VISNs and selected VAMCs GAO interviewed reported Sterile Processing Services workforce challenges, such as lengthy hiring timeframes and limited pay and professional growth potential. According to officials, these challenges result in programs having difficulty maintaining sufficient staffing. VHA officials told GAO that the office is considering studying Sterile Processing Services staffing at VAMCs, although VHA does not have definitive plans to do so. VHA's Sterile Processing Services workforce challenges pose a potential risk to VAMCs' ability to ensure access to sterilized medical equipment, and VHA's failure to address this risk is inconsistent with standards for internal control in the federal government. Until VHA examines these workforce needs, VHA won't know whether or to what extent the reported challenges adversely affect VAMCs' ability to effectively operate their Sterile Processing Services programs and ensure access to safe care for veterans.

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Abbreviations

RME	reusable medical equipment
SPS	Sterile Processing Service
VA	Department of Veterans Affairs
VAMC	VA medical center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

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August 3, 2018

The Honorable Phil Roe
Chairman
Committee on Veterans' Affairs
House of Representatives

Dear Mr. Chairman:

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) operates one of the largest health care delivery systems in the nation, serving over 9 million enrolled veterans. In providing health care services to veterans, VA medical centers (VAMC) use reusable medical equipment (RME), such as endoscopes and surgical instruments, which must be reprocessed—that is, cleaned, disinfected, or sterilized—between uses.¹ As medical instruments have become more complex, reprocessing has become more complicated and time consuming. For example, reprocessing an endoscope after a colonoscopy requires eight detailed cleaning steps and, on average, over 1 hour and 15 minutes of hands-on staff time.² Improper reprocessing of RME creates risks to patient safety—exposing patients to infection, for example—and can adversely affect timely access to care, such as when surgeries are delayed or canceled due to the lack of properly reprocessed medical equipment. The reprocessing of RME occurs at VAMCs within their Sterile Processing Services (SPS) programs.³ To help ensure the safety of veterans who receive care at its facilities, VHA policy establishes requirements VAMCs must follow when reprocessing RME. Further, VHA policy requires inspections to be completed each year to determine the extent to which VAMCs are following these RME requirements and that incidents involving improperly reprocessed RME are reported.

¹An endoscope is an instrument used for direct visual inspection of hollow organs or body cavities.

²See International Association of Healthcare Central Service Materiel Management Communique, *A Glimpse at the True Cost of Reprocessing Endoscopes: Results of a Pilot Project*, (Chicago, IL: January/February 2017).

³The VAMC SPS programs consist of the SPS department, which has primary responsibility for reprocessing RME, and other areas such as dental clinics, where certain reprocessing functions occur.

VHA has had ongoing challenges with RME reprocessing. For example, in 2009, two VAMCs notified about 10,000 veterans of their potential exposure to hepatitis B, hepatitis C, and HIV, because they received care using improperly reprocessed endoscopes.⁴ In 2011 we found that VHA had not provided sufficient guidance to VAMC staff operating the SPS programs to ensure that staff were reprocessing RME correctly, which posed potential safety risks to veterans.⁵ In 2016, the VHA Office of the Medical Inspector reviewed and corroborated allegations that the SPS department at a VAMC failed to provide surgeons with RME free of bioburden, debris, or both.⁶ Further, in March 2018, the VA Office of Inspector General reported on problems at a VAMC that included RME-specific issues, such as delays and cancellations of procedures due to unavailable instruments because of improper reprocessing.⁷

You asked us to review RME reprocessing within VHA. In this report, we examine:

1. VHA's oversight of VAMCs' adherence to RME policies and
2. challenges VAMCs face in operating their SPS programs, and any efforts by VHA to address these challenges.

To examine VHA's oversight, we assessed its efforts to oversee VHA's 18 Veterans Integrated Service Networks (VISN) and its efforts to directly ensure that VHA's 170 VAMCs are adhering to RME policies.⁸ We reviewed VHA Directive 1116(2), which describes RME policy requirements and instructions for how inspections of VAMCs' adherence

⁴See VA Office of Inspector General, *Healthcare Inspection: Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, (Washington, D.C.: June 16, 2009).

⁵See GAO, *VA Health Care: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety*, [GAO-11-391](#) (Washington, D.C.: May 3, 2011).

⁶Bioburden is a measure of microorganism contamination on an object. See Department of Veterans Affairs, *Department of Veterans Affairs Cincinnati Veterans Affairs Medical Center Cincinnati, Ohio, Veterans Integrated Service Network 10*, TRIM 2016-D-1082 (Washington, D.C.: May 8, 2016).

⁷See Department of Veterans Affairs, Office of Inspector General, Veterans Health Administration. *Critical Deficiencies at the Washington DC VA Medical Center*. Report #17-02644-130. (Washington, D.C.: March 7, 2018.)

⁸Each of the 18 VISNs is responsible for ensuring adherence to VHA's policies at the VAMCs within its region.

to these requirements should be conducted, and VHA's guide to issue briefs, which are reports that provide information on incidents involving improperly processed RME.⁹ We reviewed summary data from VHA on inspections of VAMCs conducted by their respective VISNs in fiscal year 2017.¹⁰ These summary data came from inspection reports submitted to VHA by the VISNs for which VHA had records as of February 2018. We also reviewed the full inspection reports that we obtained from the VISNs for inspections VISNs had conducted in fiscal year 2017, but for which VHA did not have records, which identified information about non-adherence to RME policy requirements.¹¹ Finally, we reviewed VHA's summary of issue briefs, including those related to the improper reprocessing of RME, for fiscal years 2015 through 2017.¹²

To assess the reliability of the inspection and issue brief data, we reviewed the data to identify missing information and discrepancies, and we interviewed VHA officials regarding the processes for collecting and verifying the data. Based on these efforts, we determined that VHA data on the number of VISN inspection reports for which they had records, VISN inspection reports, and VHA summary data from issue briefs were reliable for the purposes of our reporting objectives. In addition to our review of inspection and issue brief data, we interviewed VHA, VISN, and VAMC officials. Specifically, we interviewed VHA officials from the National Program Office for Sterile Processing, which is responsible for

⁹See VHA Directive 1116(2), *Sterile Processing Services (SPS)* (Washington, D.C.: March 23, 2016). See Department of Veterans Affairs, Deputy Undersecretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs* (Washington, D.C.: June 26, 2017).

¹⁰VISNs and VAMCs are each required to conduct inspections to determine the extent of VAMCs' adherence to RME policy requirements annually. According to VHA officials, VHA also inspects each VAMC triennially. We focused our review on VISN inspection results because these inspections allowed us to determine the extent of adherence to RME-related requirements for all VAMCs for the most recent fiscal year at the time of our review, and because the inspections represent a level of oversight above VAMCs' own internal reviews. We reviewed inspection results for the SPS, dental, and gastroenterology areas in the VAMCs and did not include inspection results for satellite facilities such as community-based outpatient centers and health care centers.

¹¹We also reviewed VHA's summary data for the other inspections conducted in 2017, but determined the summary data were not sufficiently reliable to report detailed information on the extent of VAMCs' non-adherence to RME policy requirements.

¹²We reviewed VISN inspection data for fiscal year 2017 because it was the most recent complete year of data available. We reviewed issue briefs for fiscal years 2015 through 2017 to ensure we had a sufficient sample.

developing RME policies and overseeing VAMCs' adherence to these policies. We also interviewed officials from the 18 VISNs and four selected VAMCs to get their views on VHA's oversight.¹³ We assessed VHA's oversight efforts in the context of federal standards for internal control for monitoring, information, and communication.¹⁴

To examine challenges VAMCs face in operating their SPS programs, we reviewed VHA's RME policy and other documents to identify the requirements VAMCs must follow in operating their SPS programs, and we interviewed officials with direct knowledge of these efforts at all 18 VISNs and the four selected VAMCs. In addition, we asked operating room nurse managers from 20 selected VAMCs to identify in writing any RME-related challenges they faced as a result of the SPS department at their VAMC, such as delays in operating room procedures due to RME issues.¹⁵ We discussed the challenges identified with officials from VHA's National Program Office for Sterile Processing and the Workforce Management and Consulting Office. We assessed VHA's efforts to address RME-related challenges in the context of federal standards for internal control for risk assessment.¹⁶

¹³We selected the four VAMCs to achieve geographic and VAMC complexity variation and the highest and lowest performance regarding operating room lag time. VHA assigns each VAMC to one of five complexity groups based on patient population served, clinical services offered, education and research complexity, and administrative complexity. Operating room lag time data captures the time elapsed from one patient leaving and the next patient entering the operating room; lag time can be attributed to RME not being available, among other factors. The four VAMCs we selected were located in Chicago, IL; Erie, PA; Fort Meade, SD; and Little Rock, AR. Within the VAMCs, we spoke with officials from the SPS department, operating room, and gastroenterology and dental clinics. We were not able to speak with the Chief of SPS at the Chicago Jesse-Brown VAMC; as such, some of our reported results are for three VAMCs.

¹⁴See GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

¹⁵We selected the 20 VAMCs based on operating room lag time data. Of the 20 VAMCs, we selected 10 VAMCs with the lowest performance based on VA's operating room lag time data and 10 VAMCs with the highest performance based on these data. The 20 VAMCs we selected are located in West Los Angeles, CA; Beckley, WV; Martinez, CA; Chicago-Jesse Brown, IL; Fort Meade, SD; Portland, OR; St. Louis, MO; New Orleans, LA; Albuquerque, NM; Vieira, FL; Little Rock, AR; Billings, MT; Lake City, FL; St. Cloud, MN; Fargo, ND; Evansville, IN; Marion, IL; Erie, PA; Grand Junction, CO; and San Juan, PR. We did not receive responses from Billings, MT and San Juan, PR.

¹⁶See [GAO-14-704G](#).

Finally, to provide a contextual understanding of RME issues across both objectives, we visited a VAMC with a large SPS program and interviewed officials outside of VHA with relevant knowledge. Specifically, we conducted an in-person site visit at the Seattle VAMC and spoke to officials involved in the SPS program, such as the SPS Chief and staff, VAMC leadership, and the Chief of Surgery and operating room Nurse Manager. Further, we spoke with officials from organizations with RME industry knowledge, such as the International Association of Healthcare Central Service Materiel Management and the Association for the Advancement of Medical Instrumentation—two professional associations that set RME reprocessing standards used by VHA and others, offer RME certification, and provide information and support regarding RME reprocessing to those working in the industry.¹⁷ We also interviewed officials from the Joint Commission and the VA Office of Inspector General who periodically review VAMCs' SPS programs and contacted three Veterans Service Organizations to obtain their views on concerns related to RME reprocessing and suggestions for addressing those concerns.¹⁸

We conducted this performance audit from April 2017 to June 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

In providing health care services to veterans, clinicians at VAMCs use RME, such as endoscopes and surgical instruments, which must be reprocessed between uses. Reprocessing covers a wide range of instruments and has become increasingly complex. VHA has developed policies that VAMCs are required to follow to help ensure that RME is

¹⁷RME certification is intended to ensure that RME professionals possess the essential knowledge and skills necessary for managing SPS tasks.

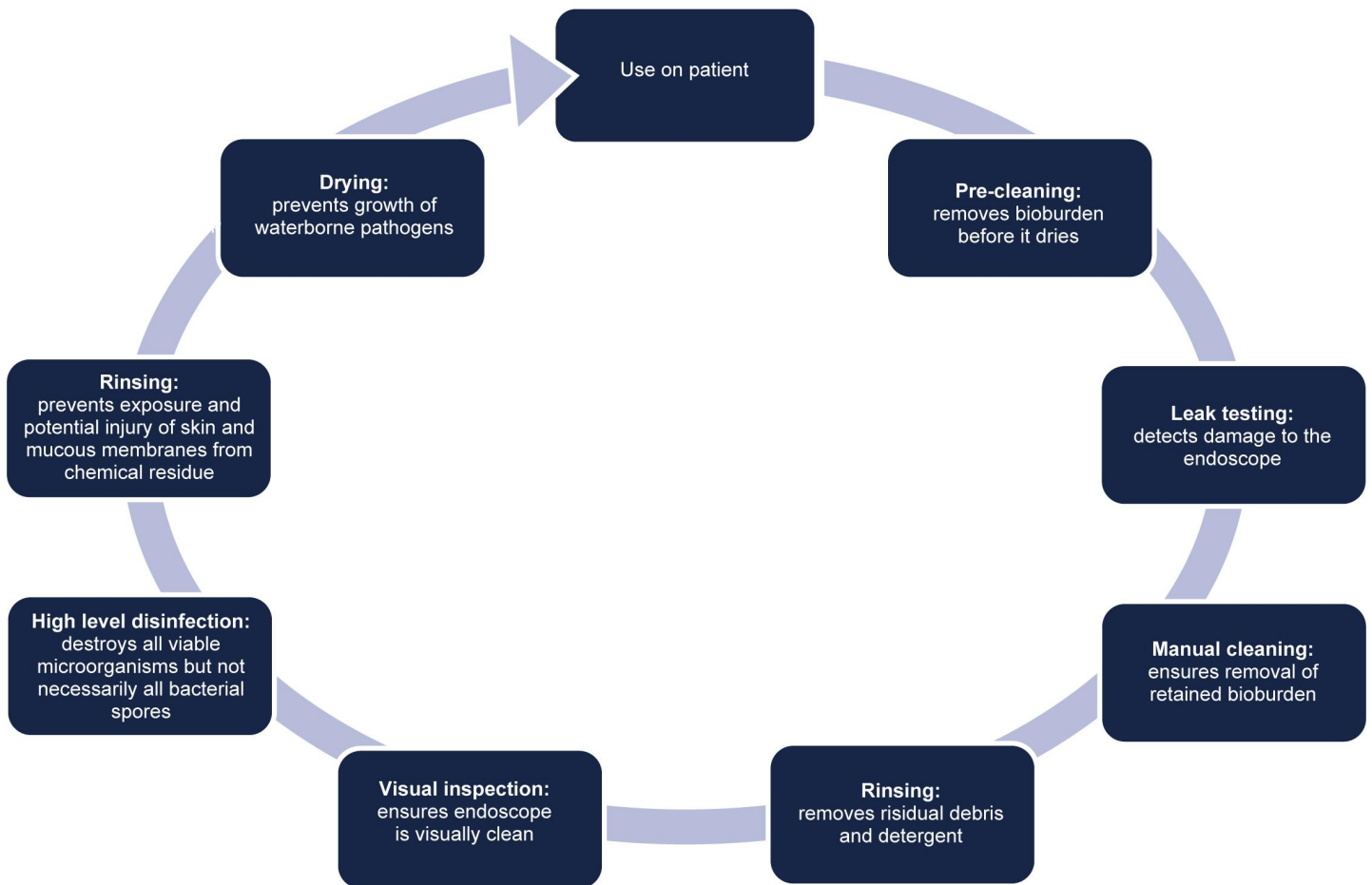
¹⁸Veterans Service Organizations provide a wide range of services for veterans and their dependents, such as assistance obtaining health care and benefits. We contacted the American Legion, Vietnam Veterans of America, and Iraq and Afghanistan Veterans of America.

reprocessed correctly. In addition, VHA policy requires that VHA and VISNs oversee VAMCs' reprocessing of RME and that VAMCs report incidents involving improperly reprocessed RME.

Complexity of RME Reprocessing

According to reports from RME professional associations, the complexity of RME reprocessing has increased as the complexity of medical instruments has increased. While at one time reprocessing surgical and dental instruments such as scalpels and retractors might have been the bulk of a SPS program's tasks, now SPS programs are responsible for reprocessing complex instruments such as endoscopes. Reprocessing these instruments is a detailed and time-consuming process, and their increasing complexity requires a corresponding increase in the skills and time required to safely reprocess them. (See figure 1 for an example of steps that can be required for endoscope reprocessing.)

Figure 1: Example of Endoscope Reprocessing Steps



Source: GAO analysis of American Society for Gastrointestinal Endoscopy information. | GAO-18-474

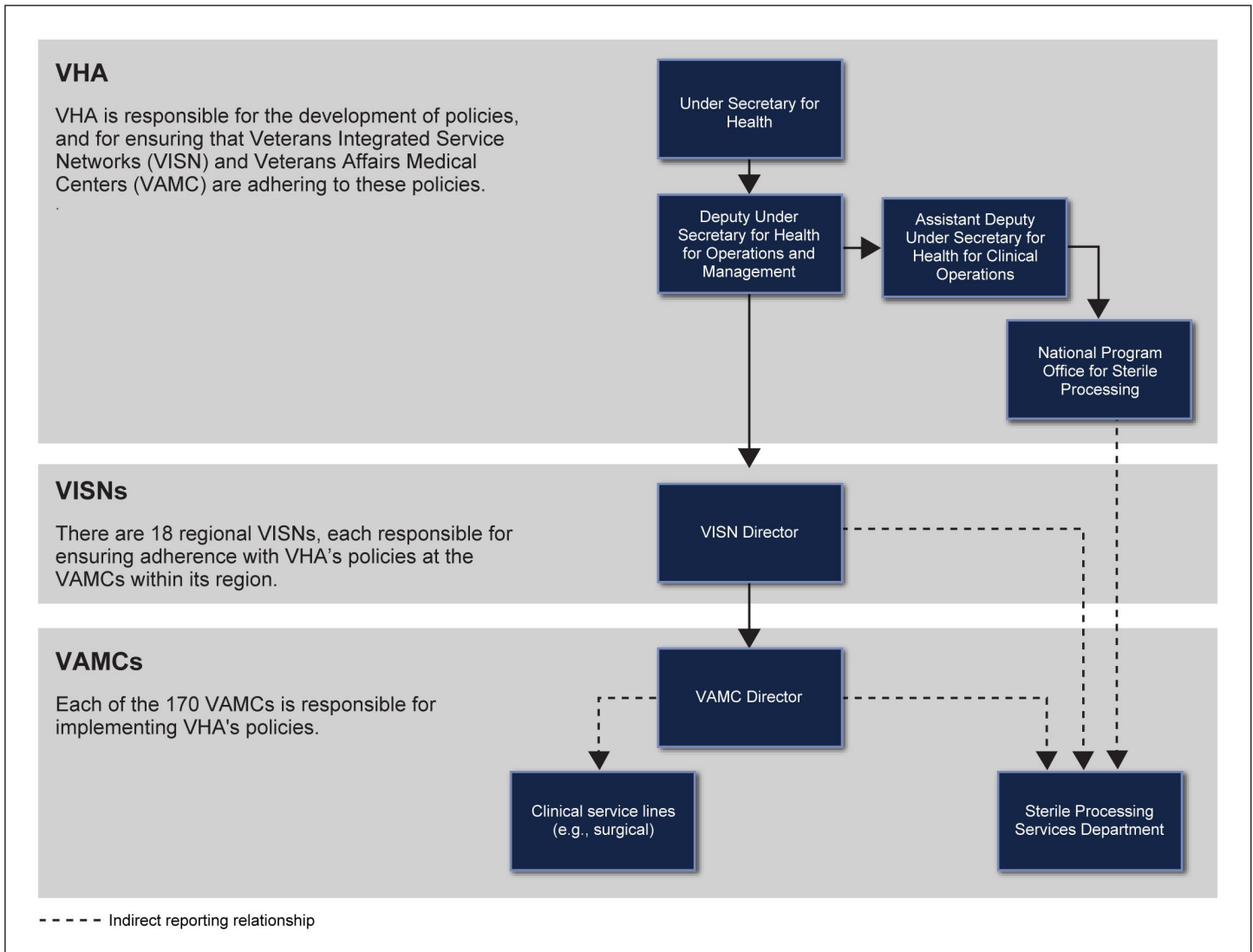
Notes: An endoscope is an instrument used for direct visual inspection of hollow organs or body cavities. Bioburden is a measure of microorganism contamination on an object. High level disinfection is performed via immersion for an appropriate duration of time in a liquid chemical germicide of appropriate concentration. According to the Association of periOperative Registered Nurses, this process is an appropriate standard of treatment for certain reusable medical equipment such as endoscopes.

VHA Roles and Responsibilities for RME Reprocessing

Within VHA, the National Program Office for Sterile Processing under the VHA Deputy Under Secretary of Health for Operations and Management is responsible for developing RME reprocessing policies. It is also responsible for ensuring that VISNs and their respective VAMCs are adhering to its policies. Each of the 18 VISNs are responsible for ensuring

adherence with VHA's RME policies at the VAMCs within its region. In turn, each of the 170 VAMCs are responsible for implementing VHA's policies related to RME. Within each VAMC, the SPS department is primarily responsible for reprocessing RME, which is used by clinicians in the operating room and other clinical service lines such as the dental and gastroenterology service. (See fig. 2.) Additionally, the SPS department collaborates with other VAMC departments such as the Environmental Management and Engineering Services on variables that affect RME reprocessing, such as the climate where RME is reprocessed.

Figure 2: Selected Veterans Health Administration (VHA) Entities' Roles and Responsibilities for Reprocessing Reusable Medical Equipment (RME)



Source: GAO analysis of VHA information. | GAO-18-474

VHA Policies for RME Reprocessing and Related Oversight

In March 2016 VHA issued Directive 1116(2)—a comprehensive policy outlining requirements for SPS programs and for overseeing RME reprocessing efforts.¹⁹

SPS program operation requirements. To help ensure that VAMCs are reprocessing RME correctly, VHA policy establishes various requirements for the SPS programs in VAMCs to follow, such as a requirement that SPS staff monitor sterilizers to ensure that they are functioning properly, use personal protective equipment when performing reprocessing activities, separate dirty and clean RME, and maintain environmental controls. For example, VAMCs are required to maintain certain temperature, humidity, and air flow standards in areas where RME is reprocessed and stored. Additionally, in order to ensure that RME is reprocessed in accordance with manufacturers' guidelines, VAMCs are required to assess staff on their competence in following the related reprocessing steps.

Oversight requirements. To help ensure that VAMCs are adhering to VHA's RME policies, VHA requires inspections, reports on incidents of improperly reprocessed RME, and corrective action plans for both non-adherent inspection results and incidents of improperly reprocessed RME.

- *Inspections.* VISNs are required to conduct annual inspections at each VAMC within their VISN and to report their inspection results to the VHA National Program Office for Sterile Processing. The VISN inspections are a key oversight tool for regularly assessing adherence to RME policies in the SPS, gastroenterology, and dental areas within

¹⁹See VHA Directive 1116(2), *Sterile Processing Services (SPS)* (March 23, 2016). This directive outlines requirements for reprocessing critical and semi-critical RME. RME is generally categorized into critical, semi-critical, or non-critical items based on the degree of risk for infection involved in use of the item. Critical items, such as surgical instruments, are those that enter sterile tissue or the vascular system and require sterilization because they confer a high risk of infection. Semi-critical items, such as certain endoscopes, are those that contact mucous membranes or non-intact skin and require only minimal high-level disinfection. Non-critical items, such as wheelchairs, are those that come into contact with intact skin and may be cleaned with low-level disinfectants. For the purposes of this report, when we refer to RME or RME policies, we are referring to critical or semi-critical RME.

VAMCs and use a standardized inspection checklist known as the SPS Inspection Tool.²⁰ According to VHA officials, VHA developed the SPS Inspection Tool and generally updates it annually.²¹ The most recent fiscal year 2017 SPS Inspection Tool contained 148 requirements.²² Examples of requirements include those regarding proper storage of RME and following manufacturers' instructions when reprocessing RME. Although VAMCs are also required to conduct annual self-inspections using the SPS Inspection Tool and report the results to VHA, the VISN annual inspections are a separate and important level of oversight. Finally, according to VHA officials, while not a formal policy, VHA's National Program Office for Sterile Processing also inspects each VAMC at least once every 3 years.²³ VHA requires VISNs and VAMCs to conduct their own inspections even in years when VHA also conducts inspections.²⁴

- *Incident Reports.* VHA collects incident reports or "issue briefs" generated by VAMCs on incidents involving RME to help determine the extent to which VAMCs are adhering to RME policies, among other things.²⁵ VHA requires VAMCs to report significant clinical

²⁰VISNs are also required to inspect all other clinical areas within their facility or in a community-based outpatient center in which reprocessing occurs using a separate standardized checklist known as the Clinic Inspection Tool.

²¹According to VHA officials, the SPS Inspection Tool is updated based on RME issues identified during the previous year.

²²We considered items on the checklist to be requirements if they asked about compliance. Items that asked for descriptive information such as whether or not the VAMC had an SPS Chief were not included in our review. Of the 148 requirements, 116, 17, and 15 applied to the SPS department, gastroenterology clinic, and dental clinic, respectively. According to VHA officials, there is no formal hierarchy of importance among these requirements, although for subsequent versions of the SPS Inspection Tool, VHA is considering developing a risk-based approach that will identify which requirements are the most critical.

²³In addition to the triennial inspections, VHA may conduct additional inspections for other reasons, such as at the VAMC's request or in response to concerns identified through the incident reporting process.

²⁴Until the end of the first quarter of fiscal year 2017, VISNs and VAMCs were allowed to forgo their own VISN inspection if they participated in the VHA inspection of a given VAMC; in December of 2016, VHA issued a memo that required VISNs and VAMCs to perform their own inspections separately from VHA beginning in the second quarter of fiscal year 2017.

²⁵These issue briefs may be related to the extent to which VAMCs are adhering to RME policies or to other RME-related issues such as plumbing malfunctions that affect RME reprocessing.

incidents or outcomes involving RME that negatively affect groups or a cohort of veterans in an issue brief.²⁶ According to a VHA official, when VAMC staff report incidents involving RME to their facility leadership, these officials should follow VHA guidance to determine which incidents, if any, should be reported in an issue brief to the VAMC's VISN. Similarly, VISN officials, in turn, are responsible for determining whether an incident should be reported in an issue brief to VHA.

- *Corrective Action Plans.* Corrective action plans—which detail an approach for addressing any areas of policy non-adherence identified in inspections or incidents identified in issue briefs—are required at both the VISN and VAMC levels. Specifically, both VISNs and VAMCs are required to develop corrective action plans for any deficiencies identified through their inspections, and VAMCs are required to develop corrective action plans for incidents identified in issue briefs. According to a VHA official, VISNs and VAMCs are not required to send corrective action plans from inspections to VHA; however, VAMCs must send their correction action plans to the VISN and also any related to issue briefs to VHA. Further, according to a VHA official, although neither the VAMC nor VISN corrective action plans from inspections are monitored by VHA, VHA does expect VISN officials to inform it of any critical issues that VISNs believe warrant VHA attention. For example, VHA officials would expect VISNs to report instances when RME issues result in the cancellation of procedures for multiple patients or when the VISN discovers a VAMC is lacking documentation of RME reprocessing competency assessments for a large number of their SPS staff.

Reports on Issues Related to RME Reprocessing

A number of recent reports have identified several RME-related issues at VAMCs, including non-adherence to RME policies. The issues have ranged from improperly reprocessed RME being used on patients to the cancellation of medical procedures due to lack of available RME. For example:

- In March 2018, the VA Office of Inspector General released a report describing problems identified at the Washington, D.C. VAMC, some

²⁶See Deputy Undersecretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs* (June 26, 2017) and VA Directive 0321, *Serious Incident Reports* (June 6, 2012).

of which were RME-related.²⁷ For example, the office determined that ineffective sterile processing contributed to procedure delays due to unavailable RME. The report included specific recommendations, such as ensuring there are clearly defined and effective procedures for replacing missing or broken instruments and implementing a quality assurance program to verify the cleanliness, functionality, and completeness of instrument sets before they are used in clinical areas. The VAMC Director agreed with those recommendations.

- In fiscal year 2017, the VA Office of Inspector General reviewed 29 VAMCs and issued reports for each in response to several RME-related complaints received through its reporting hotline.²⁸ The office identified issues such as staff failure to perform quality control testing on endoscopes or document their competency assessments of SPS staff in employee files. Many of the reports included specific recommendations, such as performing quality control testing on all endoscopes and ensuring SPS staff are assessed for competency at orientation and annually for the types of RME they reprocess. The VAMC Directors agreed with those recommendations.
- In 2016, the VA Office of the Medical Inspector released a report that substantiated allegations that SPS practices led to the delivery of RME with bioburden, debris, or both to the operating room.²⁹ The report included specific recommendations, such as reeducating SPS staff on proper SPS standards and ensuring that all training and assessments of RME reprocessing competency of SPS staff are completed as required. The VAMC Director agreed with those recommendations.
- In 2011, we released a report on VA RME that found issues with RME reprocessing. We found, for example, that VHA did not provide

²⁷Department of Veterans Affairs, Office of Inspector General, Veterans Health Administration. *Critical Deficiencies at the Washington DC VA Medical Center*. Report #17-02644-130. (Washington, D.C.: March 7, 2018.)

²⁸The VA Office of Inspector General published a separate report for each of its 29 reviews. For the most recent report, see Department of Veterans Affairs Office of Inspector General, Office of Healthcare Inspections, *Clinical Assessment Program Review of the VA Eastern Colorado Health Care System, Denver, Colorado*, 16-00546-388. (Washington, D.C.: September 29, 2017). See www.va.gov/OIG/APPS/INFO/OIGOVERSIGHTREPORTS.ASPX, accessed April 9, 2018, for the remaining reports.

²⁹See Department of Veterans Affairs, *Cincinnati Veterans Affairs Medical Center Cincinnati, Ohio, Veterans Integrated Service Network 10*, TRIM 2016-D-1082 (Washington, D.C.: May 8, 2016).

specific guidance on the types of RME that require device-specific training and that the guidance VHA did provide on RME reprocessing training was conflicting. We issued several recommendations for improvement, which VA has implemented.³⁰

VHA's Oversight Does Not Provide Reasonable Assurance that VAMCs Are Following RME Policies

VHA Does Not Have Complete Information on Adherence to RME Policies from Inspections of VAMCs

VHA has not ensured that it has complete information from the annual inspections VISNs conduct—a key oversight tool providing the most current VA-wide information on adherence to RME policies—and therefore does not have reasonable assurance that VAMCs are following RME policies intended to ensure veterans are receiving safe care.³¹

For fiscal year 2017, we determined that VHA should have had records of 144 VISN SPS inspection reports to have assurance that all required VISN SPS inspections had been conducted. However, our review shows that as of February 2018, VHA had 105 VISN SPS inspection reports and was missing 39, or more than one quarter of the required inspection

³⁰See [GAO-11-391](#).

³¹Since VHA generally inspects a given VAMC once every 3 years, it relies on annual inspections led by VISNs and VAMCs for the most current VHA-wide information on the extent of adherence to RME policies. According to a VHA official, the longer a VAMC is not adhering to RME policies, the greater the risk to patient safety.

reports.³² We also determined that there were two VISNs from which VHA did not have any fiscal year 2017 reports. For the missing SPS inspection reports, VISN officials suggested several reasons why the inspections were either not conducted or conducted but the reports were not submitted to VHA. For example, officials from one of the VISNs from which VHA had no SPS inspection reports told us that VISN management staffing vacancies prevented it from conducting all of its inspections.³³ An official from the other VISN from which VHA had no SPS inspection reports provided evidence that it had conducted all but one of the inspections, but the official told us the VISN did not submit reports because it has yet to receive information from VHA regarding VISN inspection outcomes, common findings, or best practices and therefore sees no value in submitting them.

VISNs provided us with evidence showing that they conducted 27 of 39 inspections that were missing from VHA's data. We analyzed these 27 reports to identify the information about non-adherence to RME policy requirements that VHA does not have from these missing VISN inspections. We determined the 10 requirements for which these VAMCs had the most non-adherence were related to quality, training, and environmental issues, among other things, with the extent of non-adherence ranging from 19 to 38 percent.³⁴ For example, there were 19

³²There were 140 "parent" VAMCs in fiscal year 2017 for which a VISN inspection was required, and some of these VAMCs had multiple RME reprocessing locations. According to VHA officials, VHA allows VISNs to submit a single inspection report per parent VAMC, and VISNs can determine whether they want to submit separate reports if there are multiple reprocessing locations—which some did for fiscal year 2017. Until the end of the first quarter of fiscal year 2017, VISNs were allowed to forgo their own VISN inspection if they participated in the VHA inspection of a given VAMC; in December of 2016, VHA issued a memo that required VISNs to perform their own inspections separately from VHA beginning in the second quarter of fiscal year 2017. Therefore, there were a total of 144 SPS inspections reports that VHA should have had for fiscal year 2017. Even when accounting for the SPS inspections VHA was scheduled to conduct itself, there remained 21 SPS inspection reports—15 percent—which VHA did not have from either VISN or VHA inspections in fiscal year 2017. As previously noted, satellite facilities such as community-based outpatient centers or health care centers were not included in our analysis.

³³The VISN provided us with evidence that it conducted one of its eight inspections but was unable to provide evidence that it had submitted them.

³⁴Although we determined that VHA's summary data on the other inspections conducted by VISNs in fiscal year 2017 was not sufficiently reliable to report detailed non-adherence information, we did determine that the categories of requirements with the largest amount of non-adherence in the summary data were generally similar to those we identified among the 27 inspection reports we reviewed.

and 26 percent non-adherence rates to the requirements that instrument and equipment levels be sufficient to meet workloads and having a process in place to ensure staff receive make-up/repeat training, respectively. (See Appendix I.)

We also found that variation in SPS Inspection Tools and related guidance from VHA resulted in incomplete inspection results for the gastroenterology and dental areas. VHA provided VISNs with three different SPS Inspection Tools throughout the course of fiscal year 2017.³⁵ Although VHA guidance stated otherwise, only the third SPS Inspection Tool—which was used during the second half of the fiscal year—contained requirements specific to the gastroenterology and dental areas.³⁶

A VHA Central Office official told us the office hadn't been aware that it did not have all of the VISN inspection reports until it took steps to respond to our data request. The official told us VHA granted VISNs a 3-month extension for fiscal year 2017—meaning that VISNs had until the end of December 2017 to submit their inspection results—and had granted similar extensions for at least the past 4 fiscal years as well. For all of those years, the VHA official told us that the office didn't have all VISN inspection reports, even after granting extensions. As a result, VHA did not have assurance that all of the inspections had been conducted. When asked why VHA hadn't been aware that it didn't have all VISN SPS inspection reports, a VHA official said that the office has largely relied on the VISNs to ensure complete inspection result reporting because it hasn't had the resources to dedicate to monitoring inspections. The official told us that VHA has asked for and just recently received approval to hire a data analyst who could potentially be responsible for monitoring

³⁵VHA instructed the VISNs to continue using the fiscal year 2016 SPS Inspection Tool through December 23, 2016; the fiscal year 2017 SPS Inspection Tool through April 20, 2017; and a revised fiscal year 2017 SPS Inspection Tool beginning April 21, 2017. According to VHA officials, multiple SPS Inspection Tools have been used in prior fiscal years as well.

³⁶Although all three SPS Inspection Tools contained a few questions related to dental and flexible endoscopes, only the third contained an additional 15 and 17 questions specific to the dental and gastroenterology areas, respectively. According to VHA officials, VISNs were expected to use the separate Clinic Inspection Tool to inspect the dental and gastroenterology areas if not covered by one of the first two SPS Inspection Tools in fiscal year 2017; however, not all VISNs did this because VHA's guidance for all three tools stated that the dental area, gastroenterology area, or both were already covered by the SPS Inspection Tool.

the VISN inspection reports. VHA's lack of complete information from inspection results is inconsistent with standards for internal control in the federal government regarding monitoring and information that state management should establish and operate monitoring activities and use quality information to achieve the entity's objectives.³⁷ Without such controls, VHA lacks reasonable assurance that VAMCs are following RME policies designed to ensure that veterans are receiving safe care.

Finally, concerns have been raised that VHA may not be receiving other important information regarding incidents of improperly reprocessed RME that, according to a VHA official, is used to update RME policy. For example, a 2016 VA Office of the Medical Inspector report found that of the 22 issue briefs generated by one VAMC and sent to the VISN between fiscal years 2015 and 2016, only 7 were brought to the attention of VHA.³⁸ When asked about the extent to which they feel comfortable reporting incidents related to RME, almost all of the VAMC staff we spoke to said they felt comfortable doing so, although staff from two VAMCs told us they feel VAMC leadership doesn't always address or resolve reported incidents. For example, one official told us staff at their VAMC are "tired of reporting the same issues repeatedly" to facility leadership because they don't see any changes being made, but the official believes staff will continue to file reports if an incident involved a patient. All VISN officials we spoke to said they believe VAMCs are reporting significant incidents related to RME "most to all of the time." A VHA official told us they believe VHA is receiving issue briefs when necessary and that it encourages the VAMCs and VISNs to err on the side of over- rather than under-reporting; however, according to a VHA official, VHA did not require written corrective action plans for issue briefs until January 2018.³⁹ (See

³⁷See [GAO-14-704G](#).

³⁸According to a VHA Office of Medical Inspector official, the office determined that these issue briefs should have been forwarded from the VISN to VHA. See Department of Veterans Affairs, *Department of Veterans Affairs Cincinnati Veterans Affairs Medical Center Cincinnati, Ohio, Veterans Integrated Service Network 10*, TRIM 2016-D-1082 (Washington, D.C.: May 8, 2016).

³⁹According to a VHA official, prior to January 2018, a written corrective action plan was not required for issue briefs—instead, VAMCs communicated informally with VHA. In addition to issue briefs, according to VISN and VAMC officials, VAMCs internally track incidents involving improperly reprocessed RME that do not rise to the level of requiring an issue brief, such as surgical instruments that were found to be improperly cleaned, but did not affect patient care. According to these officials, the process for reporting such incidents varies across VAMCs. For example, some VAMCs use specialized software to report, investigate, and address such incidents, while other VAMCs use less formal reporting mechanisms, such as paper-based forms.

Appendix II for the percentage of issue briefs in three major categories for fiscal years 2015 through 2017.)

VHA Does Not Consistently Share Information that Could Help VAMCs Follow RME Policies

We also found that VHA does not consistently share information, particularly inspection results, with VISNs and VAMCs, and that VISNs and VAMCs would like more of this information. Specifically, about two-thirds of VISN and VAMC officials told us that sharing information on the common issues identified in the inspections of other VAMCs as well as potential solutions developed to address these issues would allow VAMCs to be proactive in strengthening their adherence to RME policies and ensuring patient safety. For example, a VAMC official told us that there were problems with equipment designed to sterilize heat- and moisture sensitive devices, and seeing how other VAMCs addressed the problem was helpful for their VAMC. Further, officials from some VISNs said VHA cited their VAMCs for issues that had been found at other facilities and, had the VAMCs been aware of the issue beforehand, they could have corrected or improved their processes earlier.

When asked about sharing inspection results and other information, VHA Central Office officials told us the office doesn't analyze or share information from VISN inspections because of a lack of resources. A VHA official told us that the office does create an internal report of common issues identified through the third of VAMCs it inspects each year, but the office doesn't share this report with VISNs and VAMCs because the office lacks the resources needed to prepare reports that are detailed enough to be understood correctly by recipients. According to this official, VHA has occasionally shared information it has identified on common inspection issues through newsletters, national calls, and trainings; however, VHA officials at close to half of the VISNs and VAMCs we spoke to said that they rarely or never get this information. For example, officials from one VISN told us they recall only one or two instances where VHA sent a summary of the top five RME-related issues found during inspections. Insufficient sharing of information is inconsistent with standards for internal control in the federal government regarding communication, which state that management should internally communicate the necessary quality information to achieve the entity's objectives.⁴⁰ Until this

⁴⁰See [GAO-14-704G](#).

sharing becomes a regular practice, VHA is missing an opportunity to help ensure adherence to its RME policies, which are intended to ensure that veterans receive safe care.

VAMCs Report Facing Challenges Related to RME Policies and Workforce Needs, but VHA Has Not Sufficiently Addressed These Challenges

According to interviews with officials from all of the VISNs and selected VAMCs, the top five challenges VAMCs face in operating their SPS programs are related to meeting certain RME policies and challenges addressing SPS workforce needs. In particular, officials told us that VAMCs have challenges (1) meeting two RME policy requirements related to climate control monitoring and a reprocessing transportation deadline, and (2) addressing SPS workforce needs related to lengthy hiring timeframes, the need for consistent overtime, and limited pay and professional growth. (See Table 1.)

Table 1: Top Five Challenges Reported in Operating Sterile Processing Services (SPS) Programs

Challenges		Examples provided by Veterans Integrated Service Network (VISN) and Veterans Affairs Medical Center (VAMC) Officials
Meeting Reusable Medical Equipment (RME) Policy Requirements	Climate control monitoring ^a	<i>Facilities, particularly older facilities, have challenges meeting airflow and humidity requirements, especially when outside temperatures and humidity are above average.</i>
	Reprocessing transportation deadline ^b	<i>Picking up and transporting contaminated reusable medical equipment (RME) within the deadline is a challenge, particularly for offsite clinics that must send their RME to the nearest VAMC with a SPS program.</i>
Addressing SPS Workforce Needs	Lengthy hiring process timeframes	<i>It typically takes at least 3-4 months for the hiring process to be completed; as a result, VAMCs may go without SPS staff for long periods of time and lose the opportunity to hire qualified candidates.</i>
	Need for consistent overtime	<i>Staff have to work overtime to keep up with RME workload.</i>
	Limited pay and professional growth	<i>The limited pay and professional growth potential for SPS staff creates challenges in maintaining sufficient staff in SPS programs.</i>

Source: GAO analysis of interviews with VISN and VAMC officials | GAO-18-474

Note: The challenges listed in this table are results from GAO interviews with officials from the 18 VISNs and three selected VAMCs. VISN and VAMC officials outlined challenges they faced in operating their RME programs and GAO assessed which of those challenges were experienced most frequently to identify the five top challenges.

^aUnder VHA Directive 1116(2)'s climate control monitoring requirements, airflow needs to be carefully controlled in areas where RME is reprocessed and stored to minimize movement of air from dirty areas to clean areas (e.g., areas where used instruments are brought to be reprocessed and areas where unused instruments are stored before usage). Also, humidity must be monitored in the areas RME is reprocessed and stored so that humidity levels do not exceed certain thresholds.

^bUnder VHA Directive 1116(2)'s reprocessing deadline requirement, all used RME must be transported to the location where it will be reprocessed within 4 hours (or 12 hours for offsite facilities if a specific pre-cleaning spray is used, per a VHA memorandum issued on June 1, 2016).

Regarding the challenges VAMCs face in meeting RME policy requirements, the majority of VISN and selected VAMC officials interviewed reported experiencing challenges adhering to two requirements from 2016 VHA issued Directive 1116(2).

- **Climate control monitoring requirement.** Officials reported that meeting the climate control monitoring requirement related to airflow and humidity is challenging for their VAMCs.⁴¹ Under the requirement VAMCs must monitor the humidity and airflow in facility areas where RME is reprocessed and stored in order to ensure that humidity levels do not exceed a certain threshold and thereby allow the growth of microorganisms. According to almost all VISN officials, meeting the requirement is a challenge for some, if not all, of their VAMCs and in

⁴¹Officials from 16 VISNs and 2 VAMCs reported experiencing challenges adhering to the airflow and humidity climate control monitoring requirement.

particular for older VAMCs that lack proper ventilation systems. We also found some instances of non-adherence on this issue in the group of VISN inspection reports we reviewed. In a September 2017 memorandum, VHA relaxed the requirement (e.g., adjusted the thresholds). Additionally, according to a VHA official, VHA wants to renovate all outdated VAMC heating, ventilation, and air conditioning systems to help VAMCs meet the requirement.⁴² Further, according to VHA officials, VHA also allows VAMCs to apply for a waiver exempting them from having to meet this requirement if they have an action plan in place that shows they are working toward meeting the requirement.

- *Reprocessing transportation deadline requirement.* Officials reported that meeting the reprocessing transportation deadline was also challenging for their VAMCs.⁴³ Under the requirement, used RME must be transported to the location where it will be reprocessed within 4 hours of use to prevent bioburden or debris from drying on the instrument and causing challenges with reprocessing. Officials reported this requirement as particularly challenging for VAMCs that must transport their RME to another facility for cleaning, such as community based outpatient clinics in rural areas that must transport their RME to their VAMC's SPS department. We also found some instances of non-adherence on this issue in the group of VISN inspection reports we reviewed. In June 2016, VHA issued a memorandum allowing the use of a pre-cleaning spray solution that, if used, allows offsite facilities such as community based outpatient clinics to transport that RME within 12 hours instead of the required 4 hours.

VHA has made some adjustments to these requirements, although some officials told us the requirements remain difficult to meet. Specifically, over half of the VISN officials reported that the climate control monitoring requirement continues to be a challenge for their VAMCs. Further, some of the officials told us that meeting the 12-hour reprocessing transportation requirement using the pre-cleaning spray was still challenging, due to the distance between clinics and their VAMC's SPS

⁴²VHA issued a memorandum, effective in September 2017, which updated the environmental conditions provided in VHA Directive 1116(2). The update provides interim guidance on the compliance and implementation requirements. Further, a VHA official told us that the office wants to update all HVAC systems 25 years or older still in use across the VA.

⁴³Officials from 16 VISNs and two VAMCs reported experiencing challenges adhering to the reprocessing deadline requirement.

department; as a result, some facilities have decided to use disposable medical equipment that does not require reprocessing to avoid this requirement completely.⁴⁴ When we shared this information with a VHA official, the official stated that providing general information on how all facilities can meet the climate control monitoring requirement is impossible due to the uniqueness of each facility and that VHA has no further plans to adjust the reprocessing transportation deadline requirement. However, these challenges remain and some officials have expressed frustration with the limited support they've received from VHA. In September 2017 we recommended that VHA establish a mechanism by which program offices systematically obtain feedback from VISNs and VAMCs on national policy after implementation and take the appropriate actions.⁴⁵ Our findings provide further evidence of the need for VA to address this recommendation.

Regarding the challenges VAMCs face in meeting SPS workforce needs, almost all of the 18 VISN officials and officials from the three selected VAMCs reported experiencing challenges related to lengthy hiring timeframes, need for consistent overtime, and limited pay and professional growth. According to officials, these challenges result in SPS programs having difficulty maintaining sufficient staffing levels.

- *Lengthy hiring timeframes.* Officials reported that the lengthy hiring process for SPS staff creates challenges in maintaining sufficient SPS workforce.⁴⁶ For example, officials from one VISN estimated that on

⁴⁴According to the officials, using disposable medical equipment is expensive; officials from one VISN said that one VAMC spends nearly \$250,000 a year on disposable medical equipment. VHA officials told us that the cost for disposable medical equipment may still be less than using RME, depending on the situation.

⁴⁵VHA agreed with our recommendation, however, as of March 2018 had not implemented it. GAO, VA Health Care: Additional Actions Could Further Improve Policy Management, [GAO-17-748](#) (Washington, D.C.: September 22, 2017).

⁴⁶In our review, officials from 14 VISNs and three VAMCs reported experiencing challenges with lengthy hiring process time frames.

average it can take 3 to 4 months for a person to be hired.⁴⁷ Officials from a few other VISNs noted that not only does the lengthy hiring process create challenges in recruiting qualified candidates (because they accept other positions where they can be more quickly employed), but that it also results in long periods of time when SPS programs are short-staffed.

- *Need for overtime.* Officials reported that needing their SPS staff to work overtime is a challenge.⁴⁸ Specifically, 16 of the 18 VISN officials stated that there is a need for staff at their VAMCs to work overtime either “all, most, or some of the time.” Further, officials from one VISN told us their VAMCs have used overtime to meet the increased workload required to implement VHA’s RME policies; one official noted that the overtime has led to dissatisfaction and retention issues among SPS staff.
- *Limited pay and professional growth.* Officials identified limited pay and professional growth associated with the current pay grade as the biggest SPS workforce challenge.⁴⁹ Almost all officials stated that the current pay grade limits the pay and potential for professional growth for the two main SPS positions—medical supply technicians, who are responsible for reprocessing RME, and SPS Chiefs, who have supervisory responsibility. Specifically, the relatively low maximum allowable pay discourages staff from accepting or staying in positions and the current pay grade does not create a career path for SPS medical supply technicians to grow within the SPS department. Officials from one VISN told us that all VAMCs in their VISN have lost SPS staff due to the low pay grade for both positions. VHA officials said a proposed increase in the pay grade for SPS staff has been drafted; however, they do not know when or if it will be made effective.

⁴⁷Lengthy hiring timeframes are not unique to SPS programs at VHA. For example, in our previous report, Veterans Health Administration, *Better Data and Evaluation Could Help Improve Physician Staffing, Recruitment, and Retention Strategies*, [GAO-18-124](#) (Washington, D.C.: October 19, 2017), we identified challenges with recruitment and hiring processes for physicians that caused vacancies for up to 12 months. In addition, in our previous testimony, Veterans Health Administration, *Actions Needed to Better Recruit and Retain Clinical and Administrative Staff*, [GAO-17-475T](#) (Washington, D.C.: March 22, 2017) we reported VA human resources staff experience challenges with keeping pace with work demands and that led to delays in the hiring process.

⁴⁸In our review, officials from 16 VISNs and two VAMCs reported experiencing challenges with the need for staff to work overtime.

⁴⁹In our review, officials from all 18 VISNs and three VAMCs reported experiencing challenges with relatively low pay. Officials from 14 VISNs and 1 VAMC reported experiencing challenges with professional growth for SPS staff.

Further, according to officials with knowledge of the proposed changes, the changes could still be insufficient to recruit and retain SPS staff with the necessary skills and experience.

Some VISN and VAMC officials told us that difficulties maintaining sufficient SPS staff levels have in some instances adversely affected patients' access to care and increased the potential for reprocessing errors that could affect patient safety. According to these officials, staffing challenges can affect access to care when facilities have to limit or delay care—such as surgeries—because there aren't enough staff available to process all the necessary RME. An official at one VAMC told us that their SPS staff must review available RME daily to determine whether scheduled surgeries or other procedures can proceed. Further, among the 18 operating room nurse managers who responded to our inquiries, 15 indicated they have experienced operating room delays because of RME issues. In addition, some VISN and VAMC officials told us staffing challenges can potentially have an impact on patient safety, because when SPS staffing is not sufficient, mistakes are more likely to occur. For example, officials told us that if SPS staffing levels are low, particularly if they are low for an extended period of time, there is an increased chance RME will be improperly reprocessed and, if used on a patient, put that patient's safety at risk. A 2018 VA Office of Inspector General report on the Washington D.C. VAMC found that consistent SPS understaffing was a factor in SPS staff not being available to meet providers' need for reprocessed RME; according to the report, "veterans were put at risk because important supplies and instruments were not consistently available in patient care areas."⁵⁰

While VHA is aware of these workforce challenges cited by VISN and VAMC officials, it has not studied SPS staffing at VAMCs. As a result, it does not know whether or to what extent the workforce challenges VISNs and VAMCs report adversely affect VAMCs' ability to effectively operate their SPS programs and ensure safe care for veterans. A National Program Office of Sterile Processing official indicated that while the office might have access to some of the necessary data from VAMC SPS departments, it does not have all the necessary data or staff needed to

⁵⁰Department of Veterans Affairs, Office of Inspector General, Veterans Health Administration. *Critical Deficiencies at the Washington DC VA Medical Center*. Report #17-02644-130. (Washington, D.C.: March 7, 2018.)

assess SPS staffing levels.⁵¹ Furthermore, the official added, conducting such a study would not be the responsibility of her office. Officials from the Workforce Management and Consulting Office said VHA is considering a study of SPS staffing, given the results of the VA Office of Inspector General 2018 review that identified high vacancy rates as a contributing factor to the challenges with the SPS program at the Washington D.C. VAMC. However, VHA does not have definitive plans to complete this type of study or a timeframe for when the decision will be made. Until the study is conducted and actions are taken based on the study, as appropriate, VHA will not have addressed a potential risk to its SPS programs. This is inconsistent with standards for internal control in the federal government for risk assessment, which state that management should identify, analyze, and respond to risks related to achieving defined objectives.⁵² Without examining SPS workforce needs, and taking action based on this assessment, as appropriate, VHA lacks reasonable assurance that its approach to SPS staffing helps ensure veterans' access to care and safety.

Conclusions

The proper reprocessing of surgical instruments and other RME used in medical procedures is critical for ensuring veterans' access to safe care. We have previously found that VA had not provided enough guidance to ensure SPS staff were reprocessing RME correctly; in 2016, VA issued Directive 1116(2)—with requirements for the SPS program. While this is a good step, our current review shows that VHA needs to strengthen its oversight of VAMCs' adherence to these requirements. VHA has not ensured that it has complete information from inspections of VAMCs, nor does VHA consistently share inspection results and other information that could help VAMCs meet the requirements. Without analysis of complete information from inspections and consistent sharing of this information,

⁵¹In our review we found that VHA has some, but not all, of the necessary data to conduct an assessment to help determine the extent to which VAMCs have sufficient SPS staff. For example, VAMCs can collect and report to VHA data on vacancy rates and other information in an SPS staffing tool. VHA distributed a staff analysis tool for VAMCs in September 2015 and encouraged facilities to use the tool to determine the staff hours needed to operate their RME programs. Similarly, VA's National Surgery Office collects data on the number of surgical procedures cancelled due to RME issues. The surgical procedure cancellation data show that for the 12 months beginning on April 1, 2016, there were a total of 307 (or 0.8%) surgical procedures cancelled due to unavailable RME.

⁵²See [GAO-14-704G](#).

VHA does not have reasonable assurance that VAMCs are following all RME policies, and VHA is missing an opportunity to strengthen VAMCs' adherence to RME requirements.

Furthermore, officials from some VISNs and selected VAMCs report challenges meeting two RME policy requirements—the climate control and the reprocessing transportation deadline requirements. If VHA implements a recommendation we made in 2017 for the agency to obtain feedback from VISNs and VAMCs on their efforts to implement VHA policies and take the appropriate actions, it could help with these challenges. Additionally, while nearly all of the officials from the 18 VISNs and selected VAMCs interviewed reported challenges maintaining a sufficient SPS workforce, VHA does not know whether the current SPS workforce addresses VAMCs' SPS workforce needs. VHA officials say that VHA is considering studying its SPS workforce; however, it has not done so or announced a timeframe for doing so. Until it conducts such a study, VHA will not know whether or to what extent reported SPS workforce challenges adversely affect the ability of VAMCs to effectively operate their SPS programs and ensure access to safe care for veterans.

Recommendations for Executive Action

We are making the following three recommendations to VHA:

- The Under Secretary of Health should ensure all RME inspections are being conducted and reported as required and that the inspection results VHA has are complete. (Recommendation 1)
- The Under Secretary of Health should consistently analyze and share top common RME inspection findings and possible solutions with VISNs and VAMCs. (Recommendation 2)
- The Under Secretary of Health should examine the SPS workforce needs and take action based on this assessment, as appropriate. (Recommendation 3)

Agency Comments

We provided a draft of this report to VA for comment. In its written comments, which are provided in appendix III, VA concurred with our recommendations.

In its comments, VA acknowledged the need for complete RME inspection information, stating that VHA will establish an oversight process for reviewing and monitoring findings from site inspections and for reporting this information to VHA leadership. Further, VA noted that VHA will analyze data from RME inspections and share findings and possible solutions with VISNs and VAMCs via a written briefing that will be published on VHA's website and discussed during educational sessions and national calls. VA also noted that VHA has an interdisciplinary work group that has identified actions it can take to address SPS workforce needs, including implementing an enhanced market-based approach for determining pay levels and developing a staffing model so VAMCs can determine what staffing levels they need to more effectively operate their SPS programs. VA expects VHA to complete all of these actions by July 2019 or earlier.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees and the Secretary of Veterans Affairs. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Sharon M. Silas at (202) 512-7114 or silass@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sharon Silas", written in a cursive style.

Sharon Silas
Acting Director, Health Care

Appendix I: Top VHA Reusable Medical Equipment Issues among Select Veterans Affairs Medical Centers, Fiscal Year 2017

Our review of the 27 fiscal year 2017 inspections of VAMCs conducted by Veterans Integrated Service Networks (VISN) for which VHA did not have inspection reports identified a number of common reusable medical equipment (RME) issues among the select VAMCs. The top 10 are listed in table 2 below.

Table 2: Top 10 VHA Reusable Medical Equipment (RME) Policy Requirements to which Select Veterans Affairs Medical Centers (VAMC) were Non-adherent, Fiscal Year 2017

Category	Requirement	Percentage non-adherence
Quality	Demineralized water is monitored and the results are accessible to staff that reprocess RME	38
Enviro	Air pressure differential is being monitored for airflow direction in areas where RME is reprocessed	33
Quality	Random quality assurance checks are performed on instrument trays and sterile packaged items located in clean sterile storage areas	33
Training	There is a process in place to ensure staff receive make-up/repeat training	26
Enviro	A cleaning schedule or log is maintained and followed for certain cleaning	23
Training	Sterile Processing Services Level 2 certification is maintained by completing 12 continuing education units per year	22
Quality	There is use of only lint-free materials for reprocessing, storage, or protection of RME	22
Quality	The correct water is available for the final rinse cycle according to manufacturer's instructions for use	22
Admin	Instrument and equipment levels are sufficient to meet the current workload as required by stakeholders.	19
Safety	Personal Protective Equipment and work attire are provided and worn in accordance with VHA policy	19

Source: GAO analysis of Veterans Integrated Service Network data. | GAO-18-474

**Appendix I: Top VHA Reusable Medical
Equipment Issues among Select Veterans
Affairs Medical Centers, Fiscal Year 2017**

Notes: This analysis was conducted using the 27 fiscal year 2017 Veterans Integrated Service Network (VISN) Sterile Processing Services (SPS) inspection reports that VHA did not have and were provided to us by the VISNs. Due primarily to the fact that some requirements weren't applicable for all 27 inspections; we chose the top 10 requirements for which there was information in at least 26 of the 27 inspection reports. Denominators for the percentages in this table are therefore either 26 or 27. VHA provided VISNs with three different SPS Inspection Tools throughout the course of fiscal year 2017. The requirements included in this analysis represent those that were present in all three versions of the tools.

Appendix II: Percentage of Issue Briefs Related to Reusable Medical Equipment by Category, Fiscal Years 2015-2017

Our review of the Veterans Health Administration (VHA) summary of issue briefs for fiscal years 2015 through 2017 identified three major categories of issues related to reusable medical equipment (RME). See table 3 below for the percentage of all issue briefs that fell into each of these three categories.

Table 3: Percentage of Issue Briefs Related to Reusable Medical Equipment (RME) by Category, Fiscal Years 2015 through 2017

Category	Examples of issues in this category	Percentage of all issue briefs in this category
Process failures	Failure to follow standard operating procedures, expired items, provider misuse (e.g. improperly cleaned endoscope)	32
Physical system failures	Plumbing; heating, ventilation, and air conditioning; or sterilizer malfunction (e.g. operating room ceiling leak)	27
Physical evidence of problems	Debris or staining on reusable medical equipment (e.g. foreign objects on sterile surgical instrument tray)	19

Source: GAO analysis of VHA data. | GAO-18-474

Notes: These percentages are out 308 total RME-related issue briefs received by the National Program Office of Sterile Processing within the Veterans Health Administration (VHA) from fiscal year 2015 through 2017. Figures do not add to 100 percent because some of the issue briefs we reviewed were administrative in nature or did not provide enough detail to categorize and are not included in this table. Administrative issue briefs are sent to VHA as a notification that the Veterans Affairs Medical Center (VAMC) has been audited by another entity such as the VA Office of Inspector General or the Joint Commission. One or more VAMC departments may be involved in problems cited in issue briefs, such as Sterile Processing Services, Environmental Management Services, and Engineering Services.

Appendix III: Comments from the Department of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

JUL - 9 2018

Ms. Sharon Silas
Acting Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Silas:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "**VA HEALTH CARE: Improved Oversight Needed for Reusable Medical Equipment**" (GAO-18-474).

The enclosure provides our general comment and sets forth the actions to be taken to address the GAO draft report recommendations.

VA appreciates the opportunity to comment on your draft report.

Sincerely,


Jacquelyn Hayes-Byrd
Acting Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Improved Oversight Needed for
Reusable Medical Equipment”***
(GAO-18-474)

General Comment:

The Veterans Health Administration (VHA) is strongly committed to developing long-term solutions that mitigate risks to the timeliness, cost-effectiveness, quality and safety of the Department of Veterans Affairs (VA) health care system. We will use your findings to continue to make improvements and fulfill our mission of honoring America's Veterans by providing exceptional health care that improves their health and well-being.

The National Program Office for Sterile Processing (NPOSP) is dedicated to sustainable corrective actions. This is achieved through communication, education and training as well as commitment to collaborative policy changes with key stakeholders which include Workforce Management and Consulting, Logistics, Contracting, Facilities Management, Risk Management and Patient Safety.

As evidence of our commitment to sustainable improvements, NPOSP has implemented several actions to enhance the reporting of findings and improve communication with the field, Veterans Integrated Service Networks (VISN), and national stakeholders to provide support for success of the Sterile Processing Services (SPS) services. These actions include updating triennial action plans every 60 days, follow-up on all Issue Briefs relating to SPS, and regular calls with SPS challenged facilities. In addition, NPOSP has organized a variety of communication methods and forums to share trends. NPOSP is in the process of leading a national initiative consisting of a point in time audit, follow up training, and a VISN audit, all occurring in the next 90 days. These events will assist in establishing reliability of the SPS audit tool and ensure the NPOSP has a complete and accurate data set indicating the current performance of all SPS facilities. To assist in identifying facilities at risk, NPOSP is developing a risk assessment tool which will be available for testing in approximately 90 days.

NPOSP recognizes deficiencies and is aggressively creating cultural changes in quality improvement processes, as well as strengthening executive communication with all levels of executive leadership in order to expedite effective change and accountability.

VA is leveraging long-standing staffing models for primary care, mental health, and nursing; and is developing, evaluating, and refining additional staffing models for other functional areas. VA will continue to evolve its clinical staff modeling and workforce planning for other practice areas such as Sterile Processing.

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Improved Oversight Needed for Reusable Medical
Equipment”***
(GAO-18-474)

In addition, VA is establishing a manpower capacity for the entire Department, and is committed to deploying a position management solution for both clinical and non-clinical requirements. An updated, efficiently aligned position categorization structure will enable VA facilities to more precisely define their clinical and non-clinical staffing requirements. Such a structure will also enable staffing predictive power on the part of VA medical centers and VISNs.

Enclosure

Department of Veterans Affairs (VA) Comments to
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***“VA HEALTH CARE: Improved Oversight Needed for Reusable Medical
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Recommendation 1: The Under Secretary for Health should ensure all RME inspections are being conducted and reported as required and that the inspection results VHA has are complete.

VA Comment: Concur. The Veterans Health Administration (VHA) National Program Office for Sterile Processing (NPOSP) will establish an oversight process for reviewing and monitoring findings from site inspections and reporting to headquarters leadership. NPOSP's oversight process will include follow-up and feedback loops with Veterans Integrated Service Networks (VISN) on their oversight of facility corrective action plans. The Office of the Deputy Under Secretary for Health for Operations and Management will ensure Sterile Processing Service (SPS) and Reusable Medical Equipment issues are reported to a current or future governance body for risk assessment and response. The target completion date reflects implementation of the new oversight and governance processes and time for data collection. The target completion date is July 2019.

Recommendation 2: The Under Secretary for Health should consistently analyze and share top common RME inspection findings and possible solutions with VISNs and VAMCs.

VA Comment: Concur. NPOSP will analyze data from site inspections; identify trends or risks; in collaboration with VISN, develop possible solutions; and provide a written briefing to governance, VISNs, and facilities. NPOSP will publish the briefing and possible solutions on the NPOSP website. Additionally, NPOSP will communicate the report with the VISN and VA medical center leadership through current educational sessions and national calls. The target completion date is July 2019.

Recommendation 3: The Under Secretary for Health should examine the SPS workforce needs, and take action based on this assessment, as appropriate.

VA Comment: Concur. VHA's Workforce Management and Consulting (WMC) is championing an interdisciplinary work group with the Office of Nursing Service (ONS), NPOSP, and the Quality, Safety and Value (QSV) High Reliability Systems and Consultation Service. The work group has identified actions to address the SPS workforce needs, including a revised qualification standard that will encompass a specified assignment for a VISN level SPS Program Manager, implementation of an enhanced market based approach to pay, and establishment of an occupational specific recruitment and development infrastructure. Additionally, WMC will provide workforce related data, as available, to assist partners in ONS, NPOSP, and QSV in their development of a staffing model for the occupation. This will allow VA medical centers

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and health care systems to appropriately determine resources needs to more effectively
execute mission requirements. The target completion date is December 2018.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Sharon Silas, (202) 512-7114 or silass@gao.gov

Staff Acknowledgments

In addition to the contact named above, Karin Wallestad (Assistant Director), Teresa Tam (Analyst-in-Charge), Kenisha Cantrell, Michael Zose, and Krister Friday made major contributions to this report. Also contributing were Kaitlin Farquharson, Diona Martyn, and Muriel Brown.

Appendix V: Accessible Data

Agency Comment Letter

Text of Appendix III: Comments from the Department of Veterans Affairs

Page 1

Dear Ms. Silas:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "VA HEALTH CARE: Improved Oversight Needed for Reusable Medical Equipment" (GAO-18-474).

The enclosure provides our general comment and sets forth the actions to be taken to address the GAO draft report recommendations.

VA appreciates the opportunity to comment on your draft report.

Sincerely,

Jacquelyn Hayes-Byrd
Acting Chief of Staff

Enclosure

Page 2

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Page 4

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