

May 2011

# VA HEALTH CARE

## Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety



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## Why GAO Did This Study

Department of Veterans Affairs (VA) clinicians use expendable medical supplies—disposable items that are generally used one time—and reusable medical equipment (RME), which is designed to be reused for multiple patients. VA has policies that VA medical centers (VAMC) must follow when purchasing such supplies and equipment, tracking these items at VAMCs, and reprocessing—that is, cleaning, disinfecting, and sterilizing—RME. GAO was asked to evaluate (1) purchasing, tracking, and reprocessing requirements in VA policies and (2) VA’s oversight of VAMCs’ compliance with these requirements. GAO reviewed VA policies and selected two purchasing requirements, two tracking requirements, and two reprocessing requirements. At the six VAMCs GAO visited, GAO interviewed officials and reviewed documents to examine the adequacy of the selected requirements to help ensure veterans’ safety. GAO also interviewed officials from VA headquarters and from six Veterans Integrated Service Networks (VISN), which oversee VAMCs, and obtained and reviewed documents regarding VA’s oversight.

## What GAO Recommends

GAO is making several recommendations for VA to address the inadequacies identified in selected tracking and reprocessing requirements and the weaknesses in its oversight over selected purchasing and reprocessing requirements. VA concurred with these recommendations.

View [GAO-11-391](#) or key components. For more information, contact Randall B. Williamson at (202) 512-7114 or [williamsonr@gao.gov](mailto:williamsonr@gao.gov).

## VA HEALTH CARE

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## What GAO Found

GAO found that the VA tracking and reprocessing requirements selected for review are inadequate to help ensure the safety of veterans who receive care at VAMCs. GAO did not identify inadequacies in selected VA purchasing requirements that may create potential risks to veterans’ safety. GAO found the following:

- *Tracking requirements.* Because VA does not require VAMCs to enter information about certain expendable medical supplies and RME in their facilities into VA’s inventory management systems, VAMCs may have incomplete inventories of these items. This, in turn, creates potential risks to veterans’ safety. For example, in the event of a manufacturer recall involving these items, VAMCs may be unable to readily determine whether the items are in their facilities and should be removed and not used when providing care to veterans.
- *Reprocessing requirements.* Although VA requires VAMCs to develop device-specific training for staff on how to correctly reprocess RME, VA has not specified the types of RME for which this training is required. VA has also provided conflicting guidance to VAMCs on how to develop this training. This lack of clarity may have contributed to delays in developing the required training. Without appropriate training on reprocessing, VAMC staff may not be reprocessing RME correctly, which poses potential risks to the safety of veterans. VA headquarters officials told GAO that VA has plans to develop training for certain RME, but VA lacks a timeline for developing this training.

GAO also found weaknesses in VA’s oversight of VAMCs’ compliance with the selected purchasing and reprocessing requirements. These weaknesses render VA unable to systematically identify and address noncompliance with the requirements, which poses potential risks to the safety of veterans. GAO did not identify weaknesses in VA’s oversight of VAMCs’ compliance with the selected tracking requirements. GAO found the following:

- *Oversight over purchasing requirements.* In general, VA does not oversee VAMCs’ compliance with the selected purchasing requirements. While VA intends to improve oversight over these requirements, it has not yet developed a plan for doing so.
- *Oversight over reprocessing requirements.* Although VA headquarters receives information from the VISNs on any noncompliance they identify as well as VAMCs’ corrective action plans to address this noncompliance, VA headquarters does not analyze this information to inform its oversight. According to VA headquarters officials, VA intends to develop a plan for analyzing this information to systematically identify areas of noncompliance that occur frequently, pose high risks to veterans’ safety, or have not been addressed across all VAMCs.

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## Abbreviations

AEMS/MERS	Automated Engineering Management System/ Medical Equipment Reporting System
GIP	Generic Inventory Package
HIV	Human Immunodeficiency Virus
MQAS	Management Quality Assurance Service
OIG	Office of Inspector General
RME	reusable medical equipment
SOP	standard operating procedure
SPD	Supply, Processing, and Distribution
VA	Department of Veterans Affairs
VAMC	Veterans Affairs medical center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

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**United States Government Accountability Office**  
**Washington, DC 20548**

May 3, 2011

The Honorable Jeff Miller  
Chairman  
The Honorable Bob Filner  
Ranking Member  
Committee on Veterans' Affairs  
House of Representatives

The Honorable Charles E. Grassley  
United States Senate

The Honorable Russ Carnahan  
House of Representatives

The Department of Veterans Affairs (VA) operates one of the largest integrated health care delivery systems in the United States, providing care to over 5.5 million veterans annually. Organized into 21 Veterans Integrated Service Networks (VISN), VA's health care system includes 153 VA medical centers (VAMC) nationwide that offer a variety of outpatient, residential, and inpatient services.<sup>1</sup> In providing health care services to veterans, clinicians at VAMCs use supplies and equipment purchased by VA. These include expendable medical supplies, such as needles and scalpel blades, which are generally used once and discarded, and reusable medical equipment (RME), which is designed to be reused for multiple patients and includes such equipment as endoscopes and some surgical instruments. Because RME is used when providing care to multiple veterans, this equipment must be reprocessed—that is, cleaned and disinfected or sterilized—between uses. VA has established requirements for VAMCs to follow for purchasing items such as expendable medical supplies and RME; for tracking—that is, accounting for—these items at

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<sup>1</sup>The management of VAMCs is decentralized to 21 VISNs.

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their facilities;<sup>2</sup> and for reprocessing RME.<sup>3</sup> These policies are designed, in part, to help ensure the safety of the veterans who receive care at VAMCs.

Recent press articles have reported lapses in compliance with VA's reprocessing requirements at some VA medical centers, which may have put the safety of thousands of veterans receiving care at these facilities at risk.<sup>4</sup> For example, one article reported that between 2009 and 2010, about 1,800 veterans were potentially exposed to infectious diseases at the St. Louis VAMC, because they received care using improperly reprocessed dental instruments.<sup>5</sup> Moreover, in a September 2010 congressional hearing, we presented our preliminary observations on veterans' safety issues related to expendable medical supplies and RME. We reported examples of noncompliance with VA's requirements for purchasing and tracking certain medical supplies and equipment, which may pose risks to veterans' safety. In response, a congressional committee and certain members of Congress have raised questions about the adequacy of VA's requirements for purchasing, tracking, and reprocessing to help ensure veterans' safety. In addition, questions have been raised regarding the adequacy of VA's oversight of VAMCs' compliance with these requirements. In this report, we examine (1) VA purchasing, tracking, and reprocessing requirements in VA policies, which were selected based on their relevance to patient safety incidents, and (2) VA's oversight of VAMCs' compliance with these selected requirements.

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<sup>2</sup>See, for example, VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements* (Aug. 16, 2002) and Veterans Health Administration (VHA) Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009).

<sup>3</sup>VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*; VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* (Feb. 9, 2009); and VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements* (June 26, 2009).

<sup>4</sup>According to press articles, patient safety incidents involving improperly reprocessed RME have also occurred at non-VA hospitals. For example, a Pittsburgh Tribune-Review article from September 16, 2009, noted that patients at a non-VA hospital in Pennsylvania were potentially exposed to infectious diseases due to the improper reprocessing of surgical instruments. See W.F. Roche, "UPMC's Venango County facility improperly sterilized equipment," *TribLIVE News* (Sept. 16, 2009). Accessed on February 16, 2011, at [http://www.pittsburghlive.com/x/leadertimes/s\\_643419.html](http://www.pittsburghlive.com/x/leadertimes/s_643419.html).

<sup>5</sup>See M. Owens, "St. Louis VA Medical Center dental infections: Nearly 2,000 at risk," *KSDK.com* (June 29, 2010). Accessed on February 16, 2011, at <http://www.ksdk.com/news/local/story.aspx?catid=3&storyid=205262>.

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To examine VA purchasing, tracking, and reprocessing requirements, we reviewed relevant VA policies, and from these policies we judgmentally selected two purchasing requirements, two tracking requirements, and two reprocessing requirements that we determined were relevant to patient safety incidents that were identified at certain VAMCs.<sup>6</sup> After selecting these requirements for our review, we judgmentally selected six VAMCs from the following locations to visit: Albany, New York; Cheyenne, Wyoming; Detroit, Michigan; Miami, Florida; Palo Alto, California; and St. Louis, Missouri. These VAMCs represent different surgical complexity groups<sup>7</sup> and geographic regions<sup>8</sup> and serve veteran populations of different sizes. At these six VAMCs, we examined the adequacy of the selected purchasing, tracking, and reprocessing requirements to help the facilities ensure the safety of veterans who received care at these facilities. To do this, we examined how the selected requirements in these policies were implemented and whether or to what extent the selected requirements directly or indirectly created a potential risk to the safety of the veterans receiving care at the VAMCs. We reviewed applicable VAMC committee meeting minutes<sup>9</sup> and other documentation on the implementation of these requirements. We also interviewed VAMC officials who were responsible for implementing the selected requirements in VA policies to determine whether the selected requirements are adequate to help ensure veterans' safety.

To examine VA's oversight of VAMCs' compliance with the purchasing, tracking, and reprocessing requirements we selected, we reviewed VA's

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<sup>6</sup>We reviewed applicable VA policies, including VHA Handbook 1761.02, *VHA Inventory Management*; VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements*; VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*; VA Handbook 7002, *Logistics Management Procedures* (July 10, 2009); VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*; and VA Standard Operating Procedure #AM 5, *Inventory of Equipment in Use Standard Operating Procedure* (Feb. 17, 2011).

<sup>7</sup>VA assigns each VAMC a complexity score between 1 and 3, with level 1 being the most complex, using a facility complexity model. Level 1 is broken down further into 1a, 1b, and 1c. That model uses multiple variables to measure facility complexity arrayed along four categories, namely patient population served, clinical services offered, education and research complexity, and administrative complexity.

<sup>8</sup>Each of the six VAMCs we visited is located within a different VISN.

<sup>9</sup>We reviewed minutes from the following committees: commodity standards, equipment, medical executive, infection control, and RME.

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oversight of these requirements and evaluated whether this oversight provides VA with adequate information to identify and address noncompliance. As part of this review, we assessed VA's oversight in the context of federal standards for internal control for monitoring.<sup>10</sup> The internal control for monitoring refers to an agency's ability to assure that ongoing review and supervision activities are conducted, with the scope and frequency depending on the assessment of risks; deficiencies are communicated to at least one higher level of management; and actions are taken in response to findings or recommendations within established timelines. We interviewed officials responsible for overseeing VAMCs' compliance with the requirements we selected for review from VA headquarters, VA's Office of Inspector General (OIG), and six VISNs that are responsible for overseeing compliance at the VAMCs we visited. In addition, we obtained and reviewed relevant documents regarding VA oversight, including internal reports, VAMCs' plans to correct problems identified through oversight activities, and policy memorandums.

We conducted this performance audit from March 2010 to May 2011 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. See appendix I for more information on our scope and methodology.

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## Background

VA is required by law to provide hospital care and medical services to certain veterans and may provide care to other veterans.<sup>11</sup> In general, veterans must enroll in VA health care to receive VA's medical benefits package that includes a range of services such as preventative health care services and inpatient hospital services. Veterans may receive certain other health care services, such as dental care, without enrolling.<sup>12</sup> VA

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<sup>10</sup>See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999) and GAO, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

<sup>11</sup>38 U.S.C. §§ 1710(a)(1)-(3), 1701(5), (6). Requirements for VA health care services are effective in any fiscal year only to the extent and in the amount provided in advance in appropriations acts for such purposes. 38 U.S.C. § 1710(a)(4).

<sup>12</sup>See 38 C.F.R. § 17.37 (2010).



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provides these services at various types of facilities, including VAMCs. In providing these services to veterans, clinicians at VAMCs use expendable medical supplies and RME. VA has established roles and responsibilities within its system for purchasing, tracking, and reprocessing of these items and policies that VAMCs are required to follow when purchasing and tracking these items at their facilities. VA also has policies that VAMCs are required to follow regarding the reprocessing of RME.

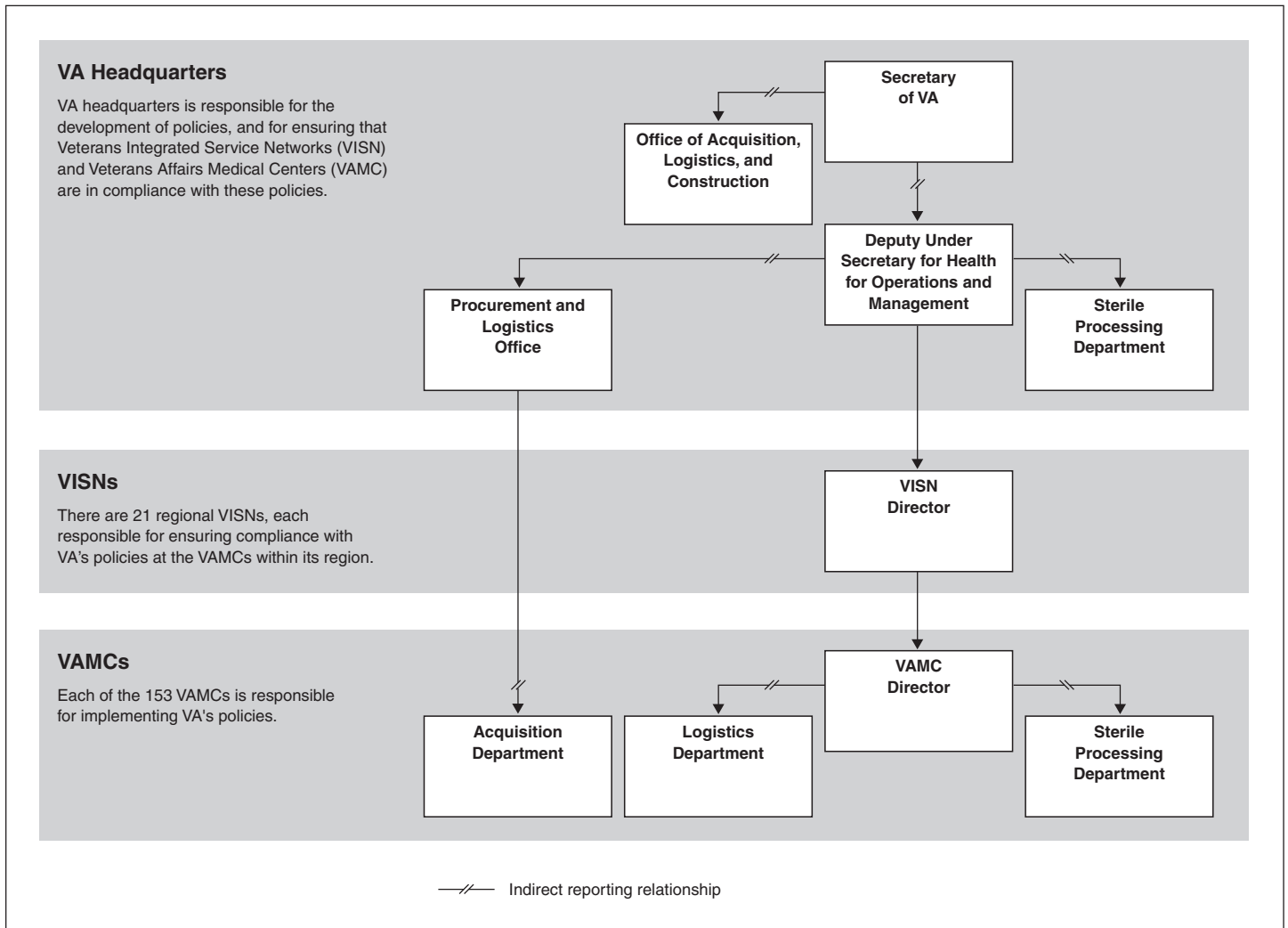
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### VA Roles and Responsibilities for Purchasing, Tracking, and Reprocessing

VA headquarters is responsible for the development of policies related to purchasing, tracking, and reprocessing and is ultimately responsible for ensuring that VISNs and VAMCs are in compliance with these policies. Within VA headquarters, the Office of Acquisition, Logistics, and Construction and the Procurement and Logistics Office, are responsible for policies related to the purchasing and tracking of expendable medical supplies and RME, while the Sterile Processing Department is responsible for policies related to the reprocessing of RME.

Each of the 21 regional VISNs is responsible for ensuring compliance with VA's policies at the VAMCs within its region. VISNs report to the Deputy Under Secretary for Health for Operations and Management within VA headquarters. In turn, each of the 153 VAMCs is responsible for implementing VA's policies. Within each VAMC, the Acquisition Department is responsible for purchasing expendable medical supplies and RME, the Logistics Department is responsible for tracking these items, and the Sterile Processing Department is responsible for reprocessing RME. (See fig. 1 for an overview of VA's organizational structure.)

**Figure 1: Selected Veterans Affairs (VA) Entities' Roles and Responsibilities for Purchasing, Tracking, and Reprocessing**



Source: GAO.

## VA Policies for Purchasing, Tracking, and Reprocessing

VA policies specify how VAMCs can purchase expendable medical supplies and RME. VAMCs can purchase expendable medical supplies and RME through their acquisition departments or through their clinical departments, such as the radiology department. VA's policies include the following requirements related to veterans' safety that VAMCs must follow when purchasing expendable medical supplies and RME:

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*Committee review and approval.* A designated VAMC committee must review and approve proposed purchases of any expendable medical supplies or RME that have not been previously purchased by the VAMC.<sup>13</sup> The committee, which typically includes administrative staff and clinicians from various departments, reviews the proposed purchases to evaluate the cost of the purchase as well as its likely effect on veterans' care.<sup>14</sup> For example, the committee that reviews and approves proposed RME purchases often includes a representative from the department responsible for reprocessing RME in order to determine whether the VAMC has the capability to reprocess the item correctly and to ensure that staff are appropriately trained to do so. Proper reprocessing of RME is important to ensure that RME is safe to use and that veterans are not exposed to infectious diseases, such as Human Immunodeficiency Virus (HIV), during treatment.

*Signatures from two officials.* All approvals for purchases of expendable medical supplies and RME must be signed by two officials, the official placing the order and the official responsible for approving the purchase.<sup>15</sup> This process helps ensure that purchases of expendable medical supplies and RME are appropriate to use when providing care to veterans.

VA has two inventory management systems that it requires VAMCs to use to track the type and quantity of expendable medical supplies and RME used in its facilities. VAMCs use information about the items in their facilities for a variety of purposes, for example to readily determine whether they have expendable medical supplies or RME that are the subject of a manufacturer recall or a patient safety alert. VA policy requires that each VAMC enter information about certain expendable medical supplies and RME in their facilities into the appropriate system. Specifically, VA policies include two key requirements related to veterans' safety that VAMCs must follow for tracking expendable medical supplies and RME:

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<sup>13</sup>Generally, a VAMC's commodity standards committee reviews and approves purchases of expendable medical supplies and a VAMC's equipment committee reviews and approves purchases of RME.

<sup>14</sup>See VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*.

<sup>15</sup>VA Handbook 7002, *Logistics Management Procedures*.

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*Tracking of expendable medical supplies.* VAMCs must enter information on all expendable medical supplies that are ordered on a recurring basis into the Generic Inventory Package (GIP).<sup>16</sup>

*Tracking of RME.* VAMCs must enter information on all RME that is classified as nonexpendable equipment by VA's Office of Acquisition, Logistics, and Construction into the Automated Engineering Management System / Medical Equipment Reporting System (AEMS/MERS).<sup>17</sup>

VA policies include requirements designed to help ensure that VAMCs reprocess RME correctly,<sup>18</sup> in order to help ensure that RME is safe for use when providing care to veterans. VA's reprocessing policies include two key types of requirements:

*Training requirements.* To ensure that RME is reprocessed in accordance with manufacturers' guidelines, VA requires that each VAMC develop device-specific training for reprocessing RME. To develop this training, VA requires VAMCs to create device-specific standard operating procedures (SOP), which provide step-by-step instructions for reprocessing. VA also requires VAMCs to assess staff annually on their competence to reprocess RME in accordance with these SOPs.

*Operational requirements.* To ensure that reprocessing activities are performed safely and that RME is reprocessed correctly, VA policies establish operational requirements for VAMCs, which include that VAMC staff must monitor sterilizers to ensure that they are functioning properly, use personal protective equipment when performing reprocessing activities, and segregate dirty and clean RME.

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<sup>16</sup>According to VHA Handbook 1730.01, *Use and Management of the Government Purchase Card Program* (Aug. 27, 2008), purchases are defined as recurring if they are made four or more times per year. In contrast, VHA Handbook 1761.02, *VHA Inventory Management*, states that expendable medical supplies that are ordered on a recurring basis must be entered into GIP but does not specify the number of times per year a purchase must be made in order to qualify as recurring.

<sup>17</sup>Nonexpendable equipment has a life expectancy of 2 years or more. See VA Standard Operating Procedure #AM 5, *Inventory of Equipment in Use Standard Operating Procedure* and VA Handbook 7002, *Logistics Management Procedures*.

<sup>18</sup>See VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*, VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, and VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements*.

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## Selected VA Requirements for Tracking and Reprocessing Are Inadequate to Help Ensure Veterans' Safety

We found that both the tracking and reprocessing requirements we reviewed are inadequate to help ensure the safety of veterans who receive care at VAMCs. These inadequacies create potential risks to the safety of veterans who receive care at VAMCs. However, we did not identify any inadequacies in the purchasing requirements we selected for review that may create potential risks to veterans' safety.

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## VAMCs Are Not Required to Track Certain Expendable Medical Supplies and RME

VA does not require VAMCs to enter information about certain expendable medical supplies and RME into their inventory management systems, and therefore, VAMC inventories have incomplete information on these items. Specifically, VAMCs are not required to enter into GIP information on expendable medical supplies purchased on a nonrecurring basis. Furthermore, VAMCs are not required to enter into AEMS/MERS information on RME that VA's Office of Acquisition, Logistics, and Construction does not classify as nonexpendable equipment. RME that is not classified as nonexpendable equipment includes certain surgical and dental instruments. As a result, none of the six VAMCs we visited had complete inventories of all of the expendable medical supplies or RME in their facilities. Incomplete inventories of these items at VAMCs can pose potential risks to veterans' safety.

At all six of the VAMCs we visited, we identified examples of potential risks to veterans' safety that may result from these inadequacies in VA's tracking requirements. For example:

Limited ability to identify items on which there are alerts or recalls. In the event of a manufacturer recall or patient safety alert related to an expendable medical supply item or RME, VAMCs may be unable to use their inventory management systems to systematically determine whether the affected item is in their facilities and should therefore be removed so that it is not used when providing care to veterans. Rather, VAMC officials would have to rely on a physical search for the item throughout their facilities—and a physical search could miss items. As we reported in our 2010 testimony,<sup>19</sup> VAMC officials and officials from the VA OIG told us that

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<sup>19</sup>See GAO, *VA Health Care: Preliminary Observations on the Purchasing and Tracking of Supplies and Medical Equipment and the Potential Impact on Veterans' Safety*, [GAO-10-1038T](#) (Washington, D.C.: Sept. 23, 2010).

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in response to a patient safety alert in December 2008 regarding an auxiliary water tube—a type of RME that is used with a colonoscope—VAMC officials checked their inventory management systems and concluded—incorrectly—that the tube was not used in the facility.<sup>20</sup> However, in March 2009, the VAMC discovered that the tube was in use in the facility and was not being reprocessed correctly, potentially exposing 2,526 veterans to infectious diseases such as HIV, hepatitis B, and hepatitis C.<sup>21</sup>

Difficulty maintaining appropriate inventories. Because GIP helps VAMCs to ensure that they maintain appropriate quantities of supply items in their facilities, VAMCs with incomplete information in GIP about the supplies in their facilities may have difficulty ensuring that they maintain appropriate quantities of these items. This may result in expendable medical supplies being unavailable for veterans' care if needed or, alternatively, excess supplies accumulating and expiring before they can be used. For example, in 2009 and 2010, VA headquarters officials identified expired expendable medical supplies, which were not being properly tracked in GIP, at three of the six VAMCs we visited. Had these VAMCs been properly tracking these supply items in GIP, they may have been able to maintain appropriate quantities of items and therefore avoid unavailable or expired supplies.

Challenges developing required training. VAMCs with incomplete information about the RME in their inventories face challenges identifying the equipment for which they must develop device-specific reprocessing training. None of the six VAMCs we visited relied on their inventory management systems to systematically determine which types of RME they had in their facilities. In fact, officials at all six VAMCs told us that they had to use alternate methods, such as contacting individual staff members or conducting searches in each clinical department, to determine if the facility had a specific type of RME. These methods of searching for

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<sup>20</sup>Officials from this VAMC also checked with staff responsible for reprocessing in the gastrointestinal department, which is where colonoscopies are performed, to determine whether the VAMC possessed this type of RME. See VA Office of Inspector General, *Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, 09-01784-146 (Washington, D.C.: June 2009).

<sup>21</sup>As of August 17, 2010, the VAMC reported that it has successfully notified 2,523 of the 2,526 veterans of possible exposure to infectious diseases and that there were 17 new positive test results. VA reports that these results are not necessarily linked to RME issues and it is continuing its evaluation.

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RME make it difficult for VAMCs to ensure that they identify all of the RME in their facilities for which they must develop device-specific reprocessing training—without inadvertently missing items—and may have contributed to delays in developing this training. Approximately 1 year after VA instituted the requirement for developing device-specific training for reprocessing, three of the six VAMCs we visited had not yet fully developed this training. Without appropriate training for reprocessing RME, VAMCs cannot ensure that staff in their facilities are reprocessing RME correctly so that these items are safe for use when caring for veterans.

At the time of our review, VA did not have plans to immediately address the inadequacies we identified in the tracking requirements by requiring VAMCs to enter information about all expendable medical supplies and RME into VA's inventory management systems. VA headquarters officials told us that they plan to address the inadequacies we identified in the tracking requirements following implementation of a new inventory management system—Strategic Asset Management. However, VA had suspended the implementation of this system as of March 2011. Although VA did not plan on revising its tracking requirements immediately, officials from two of the six VAMCs we visited told us that they have taken steps to improve the information they maintain on the expendable medical supplies at their facilities. Officials told us that they are requiring staff to enter information about all expendable medical supplies at these VAMCs into GIP, including those that are purchased on a nonrecurring basis.

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### Selected VA Reprocessing Requirements Are Inadequate

The VA reprocessing requirements we selected for review are inadequate to help ensure veterans' safety in two respects: (1) they do not specify the types of RME for which VAMCs must develop device-specific training, and (2) VA has provided VAMCs with conflicting guidance on how to develop this training.<sup>22</sup>

Lack of specificity about types of RME that require device-specific training. The VA reprocessing requirements we reviewed do not specify the types of RME for which VAMCs must develop device-specific training. This inadequacy has caused confusion among VAMCs and contributed to

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<sup>22</sup>According to VA headquarters officials, certain RME are difficult to reprocess because they need to be fully disassembled in order to be reprocessed correctly, so developing device-specific training for reprocessing these items is important to help ensure veterans' safety.

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inconsistent implementation of training for RME reprocessing. While VA headquarters officials told us that the training requirement is intended to apply to RME classified as critical—such as surgical instruments—and semi-critical—such as certain endoscopes,<sup>23</sup> officials from five of the six VAMCs we visited told us that they were unclear about the RME for which they were required to develop device-specific training.

Officials at one VAMC we visited told us that they did not develop all of the required reprocessing training for critical RME—such as surgical instruments—because they did not understand that they were required to do so. Officials at another VAMC we visited also told us that they had begun to develop device-specific training for reprocessing non-critical RME, such as wheelchairs, even though they had not yet fully completed device-specific training for more critical RME. Because these two VAMCs had not developed the appropriate device-specific training for reprocessing critical and semi-critical RME, staff at these VAMCs may not have been reprocessing all RME properly, which potentially put the safety of veterans receiving care at these facilities at risk.

Conflicting guidance on the development of RME reprocessing training.

While VA requires VAMCs to develop device-specific training on reprocessing RME, VA headquarters officials provided VAMCs with conflicting guidance on how they should develop this training. For example, officials at three VAMCs we visited told us that certain VA headquarters or VISN officials stated that this device-specific training should very closely match manufacturer guidelines—in one case verbatim—while other VA headquarters or VISN officials stated that this training should be written in a way that could be easily understood by the personnel responsible for reprocessing the RME. This distinction is important, since VAMC officials told us that some of the staff responsible for reprocessing the RME may have difficulty following the more technical

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<sup>23</sup>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 minimally require 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.



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manufacturers' guidelines.<sup>24</sup> In part because of VA's conflicting guidance, VAMC officials told us that they had difficulty developing the required device-specific training and had to rewrite the training materials multiple times for RME at their facilities. Officials at five of the six VAMCs also told us that developing the device-specific training for reprocessing RME was both time consuming and resource intensive.

VA's lack of specificity and conflicting guidance regarding its requirement to develop device-specific training for reprocessing RME may have contributed to delays in developing this training at several of the VAMCs we visited. Officials from three of the six VAMCs told us that they had not completed the development of device-specific training for RME since VA established the training requirement in July 2009. As of October 2010, 15 months after VA issued the policy containing this requirement, officials at one of the VAMCs we visited told us that device-specific training on reprocessing had not been developed for about 80 percent of the critical and semi-critical RME in use at the facility.

VA headquarters officials told us that they are aware of the lack of specificity and conflicting guidance provided to VAMCs regarding the development of training for reprocessing RME, and were also aware of inefficiencies resulting from each VAMC developing its own training for reprocessing types of RME that are used in multiple VAMCs. In response, VA headquarters officials told us that they have made available to all VAMCs a database of standardized device-specific training developed by RME manufacturers for approximately 1,000 types of RME and plan to require VAMCs to implement this training by June 2011. The officials also told us that VA headquarters is planning to develop device-specific training available to all VAMCs for certain critical and semi-critical RME for which RME manufacturers have not developed this training, such as dental instruments. However, as of February 2011, VA headquarters has not completed device-specific training for these RME and has not established plans or corresponding timelines for completing this training.

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<sup>24</sup>VA officials stated that manufacturer guidelines for reprocessing RME may be technically complex and may include steps that VAMCs are unable to follow. For example, these officials stated that guidelines from RME manufacturers may require the use of a specific disinfectant that is not available in the United States. The Food and Drug Administration has responsibility for overseeing RME, including the guidelines written by manufacturers for reprocessing these items.

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## VA's Oversight of VAMCs' Compliance with Selected Purchasing and Reprocessing Requirements Has Weaknesses

VA's oversight of VAMCs' compliance with selected purchasing and reprocessing requirements has weaknesses, which result in VA not being able to systematically identify and address noncompliance. We did not identify any weaknesses in VA's oversight of the tracking requirements we selected for review.<sup>25</sup> Oversight of VAMCs' compliance with the selected purchasing, tracking, and reprocessing requirements is important because, at each of the six VAMCs we visited, we identified examples of noncompliance, which may result in risks to veterans' safety. VA headquarters officials told us that VA intends to improve oversight over the selected purchasing requirements, but has not yet developed a plan for doing so. In addition, VA recently made changes to its oversight of VAMCs' compliance with selected reprocessing requirements; however, this oversight continues to have weaknesses.

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## VA Has Limited Oversight of VAMCs' Compliance with Selected Purchasing Requirements

We found that, in general, VA does not oversee VAMCs' compliance with the purchasing requirements we selected for review. Specifically, neither VA headquarters nor the six VISNs that oversee the VAMCs we visited provided oversight for the committee review and approval requirement and only one of the six VISNs provided oversight of the double signature requirement.<sup>26</sup> Consistent with the federal internal control for monitoring, which is applicable to all federal agencies, we would expect VA to oversee VAMCs' compliance with the requirements we selected, assess the risk of

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<sup>25</sup>VA headquarters' Management Quality Assurance Service (MQAS) oversees each VAMC's compliance with the selected VA tracking requirements approximately once every 7 to 8 years as part of broader compliance reviews. MQAS uses a standardized checklist to conduct these reviews. Following each review, VAMCs are required to develop corrective action plans to address areas of noncompliance. MQAS subsequently analyzes information on VAMC noncompliance and corrective action plans to identify the extent of noncompliance across all VAMCs, including those that occur frequently or have not been resolved. Although we did not identify any weaknesses in VA's oversight of the selected tracking requirements, as described earlier in this report, we did identify inadequacies in those requirements that pose risks to the safety of veterans.

<sup>26</sup>VA policy requires VISNs to conduct annual audits of some purchases—those made using purchase cards—which may include examining whether the two required signatures were obtained. However, according to a VA headquarters official, these audits are conducted inconsistently across VISNs. See VHA Handbook 1730.01, *Use and Management of the Government Purchase Card Program*.

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VAMCs' noncompliance with these requirements, and ensure that noncompliance is addressed.<sup>27</sup>

Without oversight of the selected purchasing requirements, VA is unable to identify and address VAMCs' noncompliance with the selected purchasing requirements. During our site visits to six VAMCs, we identified examples of noncompliance with these requirements that created potential risks to veterans' safety.<sup>28</sup>

VAMC committee review and approval. Officials from four of the six VAMCs we visited told us that certain expendable medical supplies—for example, those used in a limited number of clinical departments—were sometimes purchased without the required VAMC committee review and approval. Furthermore, officials from one of those four VAMCs told us that none of the expendable medical supplies it purchased were reviewed and approved by a VAMC committee. Without obtaining the required review and approval, these VAMCs may have purchased expendable medical supplies without evaluating their cost-effectiveness or likely effect on veterans' care.

Signatures of purchasing and approving officials. At one of the six VAMCs we visited, VAMC officials discovered that one staff member working in a dialysis department purchased expendable medical supplies without obtaining the required signature of an appropriate approving official. That staff member ordered the wrong supplies, which incorrectly allowed blood to pass into dialysis machines. Those supplies were used for 83 veterans, resulting in potential cross-contamination of these veterans' blood, which may have exposed them to infectious diseases, such as HIV, hepatitis B, and hepatitis C.<sup>29</sup>

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<sup>27</sup>The federal internal control for monitoring states that an agency should be able to ensure that ongoing review and supervision activities are conducted, with the scope and frequency depending on the assessment of risks, and that actions in response to findings or recommendations are taken within established timelines. See [GAO/AIMD-00-21.3.1](#) and [GAO-01-1008G](#).

<sup>28</sup>We previously reported examples of noncompliance with selected VA purchasing and tracking requirements from five VAMCs we visited. See [GAO-10-1038T](#). We have since conducted a site visit to a sixth VAMC.

<sup>29</sup>As of June 2, 2010, the VAMC reported that all testing has been completed and that no veterans have acquired infectious diseases as a result of this incident. The VAMC found that 1 of the 83 veterans identified was dialyzed on an uncontaminated machine and therefore this veteran was not notified or tested for these infectious diseases.

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In January 2011, VA headquarters officials told us that they intend to develop an approach to oversee VAMCs' compliance with the selected purchasing requirements, although VA has not yet established a timeline for developing and implementing this oversight. In addition, an official from one VISN told us in January 2011 that the VISN planned to begin overseeing VAMCs' compliance with VA's requirement that two signatures be obtained for purchases of expendable medical supplies and RME. However, the official told us that the VISN had not yet established a timeline for developing and implementing this oversight.

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### Despite Changes Intended to Improve Its Oversight of VAMCs' Compliance with Selected Reprocessing Requirements, VA's Oversight Has Weaknesses

Beginning in fiscal year 2011, VA headquarters directed VISNs to make three changes intended to improve its oversight of VAMCs' compliance with the selected reprocessing requirements at VAMCs.<sup>30</sup>

- VA headquarters recently required VISNs to increase the frequency of site visits to VAMCs—from one to three unannounced site visits per year—as a way to more quickly identify and address areas of noncompliance with selected VA reprocessing requirements.
- VA headquarters also recently required VISNs to begin using a standardized assessment tool to guide their oversight activities.<sup>31</sup> According to VA headquarters officials, requiring VISNs to use this assessment tool will enable the VISNs to collect consistent information on VAMCs' compliance with VA's reprocessing requirements. Before VA established this requirement, the six VISNs that oversee the VAMCs we visited often used different assessment tools to guide their oversight activities. As a result, they reviewed and collected different types of information on VAMCs' compliance with these requirements.

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<sup>30</sup>VA headquarters generally delegates responsibility for this oversight to the VISNs. In addition to oversight conducted by the VISNs, some entities within VA headquarters conduct oversight of VAMCs' compliance with VA reprocessing requirements, including those we selected for review. Specifically, VA's OIG and Sterile Processing Department conduct site visits to investigate allegations of VAMC noncompliance with VA reprocessing requirements. In addition, since around 2005, the System-wide Ongoing Assessment and Review Strategy has included reviews of the selected VA reprocessing requirements as part of broader reviews of VAMC compliance with VA policies in preparation for external accreditation reviews approximately every 3 years. In 2010, VA's OIG also conducted reviews of the selected VA reprocessing requirements as part of broader ongoing reviews of VAMC compliance with VA policies.

<sup>31</sup>VA headquarters officials told us that they may refine this assessment tool over time.

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- VISNs are now required to report to VA headquarters information from their site visits. Specifically, following each unannounced site visit to each VAMC, VISNs are required to provide VA headquarters with information on VAMCs' noncompliance with VA's reprocessing requirements and VAMCs' corrective action plans to address areas of noncompliance. Prior to fiscal year 2011, VISNs were generally not required to report this information to VA headquarters.<sup>32</sup>

Despite the recent changes, VA's oversight of VAMCs' compliance with its reprocessing requirements, including those we selected for review, has weaknesses in the context of the federal internal control for monitoring. Consistent with the internal control for monitoring, we would expect VA to analyze this information to assess the risk of noncompliance and ensure that noncompliance is addressed. However, VA headquarters does not analyze information to identify the extent of noncompliance across all VAMCs, including noncompliance that occurs frequently or poses high risks to veterans' safety. As a result, VA headquarters has not identified the extent of noncompliance across all VAMCs with, for example, VA's operational reprocessing requirement that staff use personal protective equipment when performing reprocessing activities, which is key to ensuring that clean RME are not contaminated by coming into contact with soiled hands or clothing. Three of the six VAMCs we visited had instances of noncompliance with this requirement. Similarly, because VA headquarters does not analyze information from VAMCs' corrective action plans to address noncompliance with VA reprocessing requirements, it is unable to confirm, for example, whether VAMCs have addressed noncompliance with its operational reprocessing requirement to separate clean and dirty RME. Two of the six VAMCs we visited had not resolved noncompliance with this requirement. Compliance with this requirement is important to ensure that clean RME does not become contaminated by coming into contact with dirty RME.

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<sup>32</sup>While VISNs were not generally required to report to VA headquarters information on VAMCs' noncompliance with VA's reprocessing requirements, VISNs were required to report to VA headquarters information about noncompliance that may have resulted in harm to veterans. VA headquarters officials told us that, following a review of that information and collection of additional information, as needed, a panel of experts would determine whether the noncompliance identified in the reviews resulted in risks to veterans' safety and, if so, whether veterans should be notified. See VHA Directive 2008-002, *Disclosure of Adverse Events to Patients* (Washington, D.C.: Jan. 18, 2008).

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VA headquarters officials told us that VA plans to address the weaknesses we identified in its oversight of VAMCs' compliance with reprocessing requirements. Specifically, VA headquarters officials told us that they intend to develop a systematic approach to analyze the information on VAMCs' noncompliance and corrective action plans to identify areas of noncompliance across all VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed in a timely manner.<sup>33</sup> While VA has established a timeline for completing these changes, certain VA headquarters officials told us that they are unsure whether this timeline is realistic due to possible delays resulting from VA's ongoing organizational realignment, which had not been completed as of April 6, 2011.<sup>34</sup>

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## Conclusions

Weaknesses exist in VA's processes for tracking expendable medical supplies and RME and reprocessing RME that create potential safety risks to veterans. Because VA does not require VAMCs to track information about certain expendable medical supplies and RME in their inventory management systems, VAMCs may be unaware of the complete inventory of such items at their facilities. This knowledge is critical to maintain available supplies on hand to serve veterans, to properly identify items for which manufacturers have issued recalls, and to develop training on reprocessing the RME in their inventory. Moreover, VA's lack of specificity and conflicting guidance for developing device-specific training for reprocessing RME has led to confusion among VAMCs about which types of RME require device-specific training and how VAMCs should develop that training. This confusion has contributed to some VAMCs not developing training for their staff for some critical and semi-critical RME. Until these weaknesses are addressed, the safety of veterans receiving care at VAMCs could potentially be at risk.

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<sup>33</sup>VA headquarters officials also told us that a temporary staff member was assigned in March 2011 to begin reviewing some information from VISNs' oversight activities. Specifically, that staff member will be responsible for reviewing whether VAMCs have developed the required device-specific training for reprocessing RME and the extent to which VAMCs are utilizing flash sterilization, a sterilization technique that should be used only in limited circumstances.

<sup>34</sup>As part of this realignment, VA headquarters is establishing a new position within the Office of the Deputy Under Secretary for Health for Operations and Management, which will be responsible for overseeing certain departments, including VA headquarters' Sterile Processing Department.

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A general lack of oversight of VAMCs' compliance with selected purchasing requirements makes it difficult for VA to identify and resolve situations wherein items are purchased without proper review and approval. A failure to review and approve these purchases poses safety risks to veterans being treated in VAMCs. In fact, during our visits to VAMCs, we noted examples of expendable medical supplies that were purchased without appropriate review and approval. As a result, some supplies may have been purchased without evaluating the likely effect on veterans' care, or worse yet, the wrong supplies were ordered—a mistake that potentially led to some veterans being exposed to infectious diseases. Furthermore, weaknesses in oversight of VAMCs' compliance with the selected reprocessing requirements do not allow VA to identify and subsequently address areas of noncompliance across all VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed by VAMCs. Providing effective oversight over purchasing and reprocessing requirements consistent with the federal standards for internal control would help VA prevent potentially harmful incidents from occurring.

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## Recommendations for Executive Action

To help ensure veterans' safety through VA's purchasing, tracking, and reprocessing requirements, we are making four recommendations. We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take the following four actions:

- Require VAMCs to enter information about all expendable medical supplies and RME into an appropriate inventory management system.
- Develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VAMCs. Additionally, hold VAMCs accountable for implementing device-specific training for all of these RME.
- Develop and implement an approach to oversee compliance at all VAMCs with the selected purchasing requirements.
- Use the information on noncompliance identified by the VISNs and information on VAMCs' corrective action plans to identify areas of noncompliance across all 153 VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed, and take action to improve compliance in those areas.

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## Agency Comments and Our Evaluation

VA provided written comments on a draft of this report, which we have reprinted in appendix II. In its comments, VA concurred with our recommendations and described the department's planned actions to implement them. VA also provided technical comments, which we incorporated, as appropriate.

To address our recommendation that VA require VAMCs to enter information about all expendable medical supplies and RME into an appropriate inventory management system, VA stated that it plans to take several actions that include the following. By September 30, 2011, the department plans to implement a process for tracking information on certain expendable medical supplies, which are currently not being tracked in GIP, to ensure that these items can be identified in the event of a recall. Furthermore, by September 30, 2011, VA plans to implement a pilot program for tracking certain RME, such as surgical and dental instruments, which are currently not being tracked in AEMS/MERS.

To address our recommendation that VA develop an approach for providing standardized training to VAMCs on reprocessing all critical and semi-critical RME, VA stated that it is taking several actions, which include revising VA's requirement for developing device-specific reprocessing training and providing staff training through a professional organization that specializes in RME reprocessing. In our report, we stated that VA headquarters is planning to develop device-specific training available to all VAMCs for certain critical and semi-critical RME for which RME manufacturers have not developed this training, such as dental instruments, but had not developed a time frame for developing this training. VA's comments did not provide an update on when this training would be developed. To hold VAMCs accountable for implementing training for critical and semi-critical RME, VA reiterated that it is strengthening its oversight of VAMCs and is requiring VAMCs to develop corrective action plans to ensure that noncompliance with the training requirement is addressed.

To address our recommendation that VA develop and implement an approach to oversee compliance with selected purchasing requirements at all VAMCs, VA stated that it plans to oversee VAMCs' purchasing activities, including VAMCs' compliance with our selected purchasing requirements. To do this, VA stated that by September 30, 2011, VA headquarters' Purchasing and Logistics Office will begin requiring VISN officials to conduct routine site visits to VAMCs to help the latter develop action plans for addressing noncompliance with the purchasing requirements. The Purchasing and Logistics Office also plans to review and approve these



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action plans and follow up with VAMCs to ensure that any noncompliance is addressed.

To address our recommendation that VA use information on noncompliance to identify areas of noncompliance across all VAMCs and take action to improve compliance in those areas, VA plans to analyze the results of its oversight activities to identify national concerns and target future Sterile Processing Department initiatives. In our report we stated that while VA has established a timeline for conducting this analysis, certain VA headquarters officials told us that they were unsure whether this timeline is realistic. In its comments, VA did not provide information on whether it anticipates meeting its expected timeline. VA also reiterated changes that it has made that are intended to improve its oversight of VAMCs' compliance with its requirements.

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We are sending copies of this report to the Secretary of Veterans Affairs, appropriate congressional committees, and other interested parties. In addition, the report is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or [williamsonr@gao.gov](mailto:williamsonr@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.



Randall B. Williamson  
Director, Health Care

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# Appendix I: Scope and Methodology

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To examine Department of Veterans Affairs (VA) purchasing, tracking, and reprocessing requirements, we reviewed relevant VA policies<sup>1</sup> and from these policies we judgmentally selected two purchasing requirements, two tracking requirements, and two reprocessing requirements that we determined were relevant to veterans' safety issues that were identified at certain VA medical centers (VAMC) in 2008 and 2009. Specifically, the purchasing requirements we selected were relevant to a patient safety incident at the VAMC in Palo Alto, California, resulting from the improper purchase and use of dialysis supplies; the tracking requirements we selected were relevant to a patient safety incident resulting from the improper reprocessing of endoscopy equipment at the VAMC in Miami, Florida; and the reprocessing requirements we selected were relevant to patient safety incidents resulting from the improper reprocessing of endoscopy equipment at the VAMCs in Augusta, Georgia; Miami, Florida; and Murfreesboro, Tennessee.

After selecting these requirements for our review, we judgmentally selected six VAMCs at the following locations to visit: Albany, New York; Cheyenne, Wyoming; Detroit, Michigan; Miami, Florida; Palo Alto, California; and St. Louis, Missouri. These VAMCs represent different surgical complexity groups,<sup>2</sup> serve veteran populations of different sizes, and are located in different Veterans Integrated Service Networks (VISN). (See table 1.)

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<sup>1</sup>We reviewed applicable VA policies, including VHA Handbook 1761.02, *VHA Inventory Management* (Oct. 20, 2009); VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure And Reprocessing Requirements* (June 26, 2009); VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* (Feb. 9, 2009); VA Handbook 7002, *Logistics Management Procedures* (July 10, 2009); VA Handbook 7176, *Supply, Processing and Distribution (SPD) Operational Requirements* (Aug. 16, 2002); and VA Standard Operating Procedure #AM 5, *Inventory of Equipment in Use Standard Operating Procedure* (Feb. 17, 2011).

<sup>2</sup>VA assigns each VAMC a complexity score between 1 and 3, with level 1 being the most complex, using a facility complexity model. Level 1 is broken down further into 1a, 1b, and 1c. That model uses multiple variables to measure facility complexity arrayed along four categories, namely patient population served, clinical services offered, education and research complexity, and administrative complexity.

**Table 1: Characteristics of VAMCs Selected for Site Visits**

VAMC location	Surgical complexity group <sup>a</sup>	Size of patient population served, 2009	VISN
Albany, New York	2	Greater than 24,999 and less than 50,000	2
Cheyenne, Wyoming	3	Less than 25,000	19
Detroit, Michigan	1c	Greater than 24,999 and less than 50,000	11
Miami, Florida	1b	Greater than 49,999	8
Palo Alto, California	1a	Greater than 49,999	21
St. Louis, Missouri	1a	Greater than 49,999	15

Source: GAO analysis of VA data.

<sup>a</sup>VA assigns each VAMC a complexity score between 1 and 3, with level 1 being the most complex, using a facility complexity model. Level 1 is broken down further into 1a, 1b, and 1c. That model uses multiple variables to measure facility complexity arrayed along four categories, namely patient population served, clinical services offered, education and research complexity, and administrative complexity.

At these six VAMCs, we examined the adequacy of the selected purchasing, tracking, and reprocessing requirements to help ensure the safety of veterans who received care. To do this, we examined how the requirements in these policies were implemented and whether the requirements indirectly created a potential risk to the safety of veterans who receive care at VAMCs. Specifically, at each VAMC we visited, we reviewed applicable VAMC committee meeting minutes<sup>3</sup> and other documentation on the implementation of these requirements. We also interviewed VAMC officials who were responsible for implementing the selected requirements to determine whether the requirements were adequate to help ensure veterans’ safety. At each VAMC, these officials included members of the executive leadership team, the nurse executive, the chief of the Sterile Processing Department, the patient safety manager, infection preventionists, and members of the quality management staff.<sup>4</sup>

<sup>3</sup>We reviewed minutes from the following committees: commodity standards, equipment, medical executive, infection control, and reusable medical equipment (RME).

<sup>4</sup>The patient safety manager is responsible for overseeing the response to patient safety advisories and alerts from VA headquarters and for addressing patient safety incidents at the VAMC; infection preventionists are responsible for helping to ensure that infection control standards are followed by VAMC staff; and the quality management staff is responsible for monitoring the quality of care at VAMCs.

To examine VA's oversight of VAMCs' compliance with the purchasing, tracking, and reprocessing requirements we selected, we reviewed VA's oversight of these requirements and evaluated whether this oversight provides VA with adequate information to identify and address noncompliance. As part of this review, we reviewed VA's oversight in the context of federal standards for internal control for monitoring.<sup>5</sup> The internal control for monitoring refers to an agency's ability to assure that ongoing review and supervision activities are conducted, with the scope and frequency depending on the assessment of risks, deficiencies are communicated to at least one higher level of management, and actions are taken in response to findings or recommendations within established timelines.

We then interviewed officials from VA headquarters, including the Sterile Processing Department, the Infectious Disease Program Office, and the System-wide Ongoing Assessment and Review Strategy; VA's Office of Inspector General; and the six VISNs that oversee the VAMCs we visited who are responsible for overseeing compliance with VA's requirements, including those we selected for our review. Through our interviews, we obtained information on the oversight activities conducted by each of these entities and the extent to which these entities followed up with VAMCs to ensure that they corrected problems identified through these oversight activities. In addition, we obtained and reviewed relevant documents regarding VA oversight, including internal reports, VAMCs' plans to correct problems identified through oversight activities, and policy memorandums.

We conducted this performance audit from March 2010 to May 2011 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.

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<sup>5</sup>See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999) and GAO, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

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# Appendix II: Comments from the Department of Veterans Affairs

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DEPARTMENT OF VETERANS AFFAIRS  
Washington DC 20420

April 11, 2011

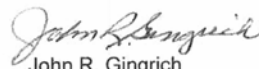
Mr. Randall B. Williamson  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Williamson:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, *VA HEALTH CARE: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety* (GAO-11-391). VA generally agrees with GAO's conclusions and concurs with GAO's recommendations.

The enclosure specifically addresses each of GAO's recommendations and provides comments on the draft report. VA appreciates the opportunity to comment on your draft report.

Sincerely,

  
John R. Gingrich  
Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Response to  
Government Accountability Office (GAO) Draft Report  
***VA HEALTH CARE: Weaknesses in Policies and Oversight Governing  
Medical Supplies and Equipment Pose Risks to Veterans' Safety***  
(GAO-11-391)

**GAO recommendation:** To help ensure veterans' safety through VA's purchasing, tracking, and reprocessing requirements, we are making four recommendations. We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take the following actions:

**Recommendation 1:** Require VAMCs to enter information about all expendable medical supplies and RME into an appropriate inventory management system.

VA response: Concur. In accordance with Veterans Health Administration (VHA) Directive 1761.1, Standardization of Supplies and Equipment, dated January 26, 2001, and VHA Handbook 1761.02, VHA Inventory Management, dated October 20, 2009, the Generic Inventory Package (GIP) Inventory System is used to maintain inventory of reoccurring expendable medical supplies used at VA medical centers (VAMC). All reoccurring expendable medical supplies, except one time use or specialty items used on a specific patient or procedure, are required to be maintained in the GIP Inventory System. All VAMCs are required to utilize GIP and bar code technology to monitor inventory of expendable medical supplies.

For specialty items that do not meet the criteria established in the GIP Inventory System, VHA's Procurement and Logistics Office (PLO) will develop a process to capture information on such items to ensure that they can be identified in the event of a medical device recall. The anticipated completion date for development of policy guidance and implementation is September 30, 2011.

PLO will also develop a plan that will restrict the use of purchase cards for purchasing clinical items and require all clinical expendable supplies to be acquired through the Facility Logistics Program. This will help to ensure that information on purchases of expendable medical supplies is reported and accounted for accurately. The anticipated completion date for development of policy guidance and implementation is September 30, 2011.

Reusable medical equipment (RME) such as surgical and dental instruments do not have individual identifiers for tracking and are not maintained in the Automated Engineering Management System/Medical Equipment Reporting inventory system. In an effort to track individual instruments in a production management system, a pilot of the Real Time Location System (RTLS) will be initiated under the auspices of the Secretary's Major Initiatives. Based on the information gained from the pilots, the PLO will work closely with the RTLS Program Office for a broader implementation plan. The anticipated completion date is September 30, 2011.

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Enclosure

Department of Veterans Affairs (VA) Response to  
Government Accountability Office (GAO) Draft Report  
**VA HEALTH CARE: Weaknesses in Policies and Oversight Governing  
Medical Supplies and Equipment Pose Risks to Veterans' Safety**  
(GAO-11-391)

In accordance with a February 11, 2011, memorandum from the Deputy Under Secretary for Health for Operations and Management, Veterans Integrated Service Network (VISN) Chief Logistics Officers must validate VAMC compliance with applicable directives and policies relating to management of expendable and non-expendable inventory by conducting site visits to each VAMC by April 30, 2011, and providing a summary report to the PLO that includes action plans to correct any deficiencies identified during such site visits. These site visits will be conducted using the revised Management Quality Assurance Service Checklist, dated October 1, 2010, and include the appropriate use of the GIP Inventory System and validation of the proper review and approval of items procured for use at VAMCs. The VISN Chief Logistics Officers will be required to follow-up and validate that action plans have been completed and report the results to PLO for review by June 30, 2011.

**Recommendation 2:** Develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VAMCs. Additionally, hold VAMCs accountable for implementing device-specific training for all of these RME.

VA response: Concur. VHA has implemented a new inspection process that requires a total of nine reviews per year per facility (six performed by facility officials and three by VISN officials annually). A standardized inspection tool is being used to verify standardized operating procedures (SOP) and employee competencies. This standardized inspection tool has already been released to the field, is available on the SharePoint site, and is being used by both the facility and VISN inspection teams. The inspection tool asks questions targeted to address those issues that are of a higher risk to patient safety. The results of the inspections will be reviewed, tracked, and trended nationally.

Facilities that are not in compliance, as identified by the results of the inspections, are required to develop action plans, which are reviewed and monitored by the VISN Sterile Processing Department (SPD) Board and by VA Central Office SPD Operations. According to VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements, the SPD Board has the "authority and accountability for ensuring" that reprocessing occurs in accordance with current manufacturers' instructions and VHA policy.

Training of staff that reprocess RME is accomplished using standardized SOPs and Tech Ready Documents. VA Directive 7176, Supply Processing and Distribution, requires facility managers to annually validate competencies of staff and document this

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Enclosure

Department of Veterans Affairs (VA) Response to  
Government Accountability Office (GAO) Draft Report  
***VA HEALTH CARE: Weaknesses in Policies and Oversight Governing  
Medical Supplies and Equipment Pose Risks to Veterans' Safety***  
(GAO-11-391)

in their training records. All 153 facilities report through their VISN offices that initial training is completed and competencies are maintained on critical and semi-critical equipment used in their facilities. As staff, equipment, or manufacturer's instructions change, the training is updated and made available at all facilities through OneSource.

SPD Operations has also partnered with the VHA Office of Clinical Consultation and Compliance (OCCC) to conduct a standardized, extensive educational program and maintain records of attendance through the International Association of Healthcare Central Services Material Management (IAHCSMM). IAHCSMM is an internationally recognized professional organization dedicated to the education and certification of SPD personnel. The IAHCSMM recognizes VHA Level 2 certification as an alternate means of certification. During fiscal year (FY) 2010, VHA's own Level 2 training was revised to include a standardized curriculum and certification examination. During FY 2010, four Level 2 classes were offered and attended by more than 200 SPD professionals and managers. VA employees are being encouraged to apply for this alternate IAHCSMM certification.

Training requirements in the current VA Directive 7176 are being re-written to include extensive requirements for training and verification of competencies for staff reprocessing RME. This directive is currently in draft form and being reviewed for content by a group of field-based and national SPD experts and managers. It will enter VA's formal concurrence process on or before April 30, 2011, with an expected publication date of September 30, 2011.

**Recommendation 3:** Develop and implement an approach to oversee compliance at all VAMCS with the selected purchasing requirements.

VA response: Concur. GAO selected two specific purchasing requirements for review. The first requirement establishes processes for committee review and approval, and the second requires specific signatures for approval. To address these specific purchasing requirements, as well as to establish a uniform approach to ensure appropriate review and approval of all new items utilized at VAMCs, the Deputy Under Secretary for Health for Operations and Management in January 2011 directed all VISNs to establish Network Commodity Standardization Committees. The new Committees will ensure that items to be purchased are first reviewed and approved before they are used at a facility.

PLO also is establishing a Program Executive Office (PEO) that includes an Operations/Policy Division to provide oversight and support of VHA facility purchasing activities, including compliance with appropriate VHA directives and policies, including those selected by GAO in its review. PLO will develop a compliance review process to

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Enclosure

Department of Veterans Affairs (VA) Response to  
Government Accountability Office (GAO) Draft Report  
***VA HEALTH CARE: Weaknesses in Policies and Oversight Governing  
Medical Supplies and Equipment Pose Risks to Veterans' Safety***  
(GAO-11-391)

ensure routine site visits are performed at each VAMC by VISN Logistics Office staff. A site visit report and corresponding action plan will be developed for each site visit and forwarded to PLO for review and approval. PLO will perform follow-up reports to ensure all action items are implemented and closed out. The anticipated completion date is September 30, 2011.

Further, to ensure VAMC compliance with the use of mandatory national standardized contracts, the PEO will establish management controls to ensure that VHA program offices are included in the development of contract requirements and solutions to improve compliance with selected purchasing requirements. The anticipated completion date is September 30, 2011.

**Recommendation 4:** Use the information on noncompliance identified by the VISNs and information on VAMC's corrective action plans to identify areas of noncompliance across all 153 VAMCs, including those that occur frequently, pose high risk to veterans' safety, or have not been addressed, and take action to improve compliance in those areas.

VA response: Concur. As noted in the response to Recommendation 2, facility and VISN officials will conduct an increased number of inspections to ensure proper reprocessing of RME. The results of these inspections will be reviewed, tracked, and trended nationally to identify national concerns and target future SPD initiatives.

The Office of Deputy Under Secretary for Operations and Management, SPD Operations, is developing a standardized tool to aggregate the information from the standardized VISN and/or facility inspection results. This tool will assist in identifying any common deficiencies or areas nationwide where additional training of staff that performs reprocessing may be required. This tool will be deployed nationwide on or before September 30, 2011. VISNs will also be required to identify specific deficiencies at facilities and develop action plans that will be tracked by the VISN SPD board in order to improve compliance at the facility level. The anticipated completion date is September 30, 2011.

Staff from the Office of Deputy Under Secretary for Operations and Management, SPD Operations, will continue to perform site visits to provide additional oversight to ensure that annual training and competency assessments are completed. During FY 2010, a total of 22 site visits were performed, and to date in FY 2011, a total of eight site visits have been performed with a total of 18 pending visits prior to the end of FY 2011. The staff from SPD Operations will use the same standardized inspection tool as the VISN and facility to ensure equal comparisons of information and deficiencies are identified.

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO Contact

Randall B. Williamson, (202) 512-7114 or [williamsonr@gao.gov](mailto:williamsonr@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Mary Ann Curran, Assistant Director; David Barish; Kye Briesath; Alana Burke; Melanie Krause; and Michael Zose made key contributions to this report. Lisa Motley provided legal support and Krister Friday assisted in the message and report development.

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