

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Alleged Unapproved
Acquisition of a Robotic
Surgical System for the W.G.
(Bill) Hefner Veterans Affairs
Medical Center

Salisbury, North Carolina



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Executive Summary

In November 2017, the VA Office of Inspector General (OIG) received an anonymous complaint that the W.G. (Bill) Hefner VA Medical Center located in Salisbury, North Carolina, (Salisbury VAMC) purchased a robotic surgical system for about \$2.3 million without adequate planning and approval. The complaint allegations included that

- The purchase was made using leftover funds without approval, and
- The purchase was unnecessary because the Salisbury VAMC building was unsuitable to house robotic surgical systems and the VAMC had an unused system purchased in 2012.

What the Review Found

The OIG substantiated that Veterans Integrated Service Network (VISN) 6 staff permitted the order of the new robotic surgical equipment for the Salisbury VAMC during year-end spending without review and approval from authorized VISN or VA Central Office officials. This occurred due to an ineffective VISN 6 capital investment review process and weak internal controls over the ordering process at the VISN level. Purchasing robotic surgical systems without the required planning, review, and approval increases the risk that programs will acquire expensive equipment without alignment of VA's resources, such as site preparation and recurring maintenance on systems purchased. The OIG did not substantiate that the VAMC building was inappropriate to house surgical systems. The OIG also did not substantiate that the robotic surgical system purchased in 2012 was not used, as there was evidence reflecting use.

What the OIG Recommended

The OIG recommended that the Deputy Under Secretary for Health for Operations and Management and the VISN 6 network director clarify approval requirements and ensure the Capital Investment Board meets annually to review requests in a timely manner.

Management Comments

The Executive in Charge, Office of the Under Secretary for Health, reviewed the draft report and responded on behalf of the Deputy Under Secretary for Health for Operations and Management.¹ The Executive in Charge and the VISN 6 network director concurred with the recommendations and submitted acceptable corrective action plans. The OIG will monitor implementation of planned actions and will close the recommendations when VA provides sufficient evidence demonstrating progress in addressing the issues identified.

LARRY M. REINKEMEYER

Larry M. Reinkengen

Assistant Inspector General

for Audits and Evaluations

¹ The Executive in Charge has the authority to perform the functions and duties of the Under Secretary for Health.

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Abbreviations

ADUSH Assistant Deputy Under Secretary for Health

CIB Capital Investment Board

DUSHOM Deputy Under Secretary for Health for Operations and Management

FY fiscal year

HTM Healthcare Technology Management

OIG Office of Inspector General

OPAL Office of Procurement, Acquisition, and Logistics

VA Department of Veterans Affairs

VAMC Veterans Affairs Medical Center

VHA Veterans Health Administration

VISN Veterans Integrated Service Network



Introduction

In November 2017, the VA Office of Inspector General (OIG) received an anonymous complaint that the W.G. Hefner VA Medical Center located in Salisbury, North Carolina, (Salisbury VAMC) purchased a robotic surgical system for about \$2.3 million without adequate planning and approval. The complaint allegations have been summarized as

- The purchase was made using leftover funds without approval, and
- The purchase was unnecessary because the Salisbury VAMC building was unsuitable to house robotic surgical systems and the VAMC had an unused system purchased in 2012.

The OIG conducted this review to evaluate the merits of these allegations.

To review the allegations, the OIG team interviewed key staff at the Salisbury VAMC, Veterans Integrated Service Network (VISN) 6, and VA Central Office. The team reviewed documents from VA electronic systems to determine whether VA officials followed required procedures. The team also analyzed data generated by the robotic surgical systems from the vendor and medical facility records to verify whether the facility used the systems.

Robotic Surgical System Acquisition

The Veterans Health Administration's (VHA) use of robotic surgery, a computer-assisted minimally invasive surgery technique, has increased as more VA medical centers obtain robotic surgical systems and apply the technique to different procedure types. Potential advantages of this technique include fewer complications, reduced blood loss, and quicker recovery time. VA established controls for acquisition of robotic surgical systems, in part because the systems have significant acquisition costs and require training and specialized sterilization equipment to operate. As of August 2018, VA officials reported they approved 55 robotic surgery programs at VAMCs. Approved robotic surgery programs may have more than one robotic surgical system. VHA purchased 84 robotic surgical systems from 2004 through July 2018 at costs ranging from \$1 million to \$2.3 million per system, depending on the model purchased.² The Salisbury VAMC purchased one robotic surgical system in 2012 and an additional system in 2017.

Required Approvals

The Deputy Under Secretary for Health for Operations and Management (DUSHOM) categorizes electronic medical equipment costing over \$1 million as High Cost, High Tech equipment. All purchases of High Cost, High Tech equipment, including robotic surgical

² The OIG team included new system purchases as well as system trade-ins in the total number of systems acquired. The costs of a system vary depending on the model configuration.

systems, must be approved by the Assistant Deputy Under Secretary for Health (ADUSH) for Administrative Operations prior to acquisition.³ Within the office of the ADUSH for Administrative Operations, the Healthcare Technology Management (HTM) Program Office

VHA-Required High Cost, High Tech Equipment Approval Process and Actors for VISN 6

VAMC Leadership

Determination of VAMC Need for Robotic Surgical Equipment

1 VAMCs with existing robotic surgical programs determine their need for robotic surgical systems. Because this equipment costs more than \$1 million to purchase, VAMCs require authorization to acquire this equipment.

VISN 6 Capital Investment Review Board

VISN Purchase Review and Approval

VISN 6 Capital Investment Board (CIB) annually reviews and approves proposed capital asset purchases.

VISN 6 Director

Approval for Use of VISN Funds

- 3 VISN 6 director approves the use of VISN funds based on the CIB recommendation.
- 4 VISN biomedical engineer submits a High Cost, High Tech Medical Equipment application to the HTM Program Office.

HTM Program Office

Equipment Purchase Application Review

HTM Program Office verifies VAMC has an approved robotic surgical program, evaluates the application, and makes an application approval recommendation.

Assistant Deputy Under Secretary for Health (ADUSH) for Administrative Operations

Equipment Purchase Application Approval

Figure 1: VHA-required High Cost, High Tech equipment approval process for VISN 6 (Source: VA OIG analysis)

manages the approval processes for High Cost, High Tech equipment. In addition, VA requires VISN equipment committees and VISN biomedical engineers to develop, review, and apply medical equipment planning criteria for all High Cost, High Tech needs within their VISN. VISN 6 implemented this requirement in part by developing local policies requiring VISN approval for equipment purchases over \$250,000.

Acquisition Planning and Approval Process in VISN 6

VHA requires facilities to seek two separate approvals for the acquisition of robotic surgical systems. First, facilities must develop a business case and application for approval to expand their current surgical programs to include robotic surgery. Second, VAMCs with approved robotic surgical programs must obtain a separate approval to purchase each

³ Deputy Under Secretary for Health for Operations and Management (DUSHOM) memo, *Process Changes to High Cost High Tech Medical Equipment Acquisitions*, June 3, 2013.

robotic surgical system they seek to acquire.⁴ According to VHA policy, purchase approval cannot occur without program approval.

VHA policy states that VAMCs generally make local decisions on the timing and execution of major medical equipment purchases, such as robotic surgical systems. It also establishes that local surgical services at VAMCs identify this need and must get approval to pursue VISN and VHA approvals from the VAMC leaders at their facility.

VISN 6 policy requires a Capital Investment Board (CIB) review of VISN-managed expenditures for all proposed VAMC hospital equipment expenditures costing over \$250,000, including robotic surgical systems. The deputy network director is responsible for determining schedules, methodologies, and procedures to ensure effective management of VISN capital assets, including the frequency with which the VISN 6 CIB meets. The VISN network director must also approve the disbursement of discretionary funds for the purchase of local equipment costing over \$250,000, based on the recommendation of the CIB. VAMC and VISN fiscal offices are responsible for ensuring available funds for ordering robotic surgical systems.

VHA policy requires that VA medical centers submit a request to purchase a robotic surgical system to the ADUSH for Administrative Operations. VISN biomedical engineers must coordinate with the requesting VAMC to develop and submit an application for purchase approval through an electronic portal managed by the HTM Program Office. The HTM Program Office assesses the information in facility applications for "completeness, justification, return on investment, and alignment of the capital investment with other resource elements such as staffing, site preparation construction, and recurring maintenance," before recommending items for approval to the ADUSH for Administrative Operations. The HTM Program Office communicates the ADUSH for Administrative Operations' approval decisions to network directors and VISN biomedical engineers, ensuring facilities place orders for equipment with the required approvals from both the VISN and VA Central Office.

Robotic surgical systems are purchased through a national contract established by the VA Office of Procurement, Acquisition, and Logistics (OPAL) Strategic Acquisition Center. In 2012 and again in 2014, VA awarded sole-source national contracts for robotic surgical systems to

⁴ VHA has an approval process for robotic surgical programs but the OIG team considered this process to be outside the scope of this hotline review. The allegations the OIG team examined concerned approvals for the acquisition of a robotic surgical system for use in an approved program.

⁵ VISN 6 Memorandum 10N6-2015-014, Veterans Integrated Service Network (VISN) 6 Capital Investment Board (CIB), April 16, 2015.

⁶ VISN 6 Memorandum 10N6-2015-014; Veterans Health Administration Directive 2009-017, *Acquisition of High-Cost*, *High-Technical Medical Equipment*, March 20, 2009.

⁷ Department of Veterans Affairs, Financial Policy, Volume II Chapter 5, Obligations Policy, January 2018.

⁸ Deputy Under Secretary for Health for Operations and Management Memo, *Process Changes to High Cost High Tech Medical Equipment Acquisitions*, June 3, 2013; HTM Service Bulletin, *High Cost/High Tech Medical Equipment*, May 21, 2013, SB2013-003.

Intuitive Surgical, Inc., the manufacturer of daVinci© Surgical Systems. The current contract covers two versions of systems: the Si and the Xi. The VHA Procurement and Logistics Office, which is organizationally independent of OPAL, places orders for systems against the 2014 national contract developed by the OPAL Strategic Acquisition Center.

Results and Recommendations

Finding 1: Required Purchase Approvals for the Robotic Surgical System Were Not Obtained

The OIG substantiated that VISN 6 staff permitted the unauthorized order and receipt of new robotic surgical systems for the Salisbury VAMC in September 2017 during year-end spending. To be authorized, the VAMC equipment purchase must have review and approval from the VISN 6 network director, VISN 6 CIB, HTM Program Office, and ADUSH for Administrative Operations. VISN 6 staff did not seek or obtain these authorizations. This occurred due to inadequate acquisition planning, an ineffective VISN 6 capital investment review process, and weak internal controls over ordering procedures at the VISN level. Purchasing surgical robot systems without the required planning, review, and approval increases the risk that programs will acquire expensive equipment without alignment of VA's resources, such as site preparation and recurring maintenance on systems purchased. In this instance, the Salisbury VAMC requested almost immediate delivery of equipment without adequately assessing and completing site preparation requirements, which delayed activation of the new system by almost five months.

Timeline of VISN 6 Acquisition of Xi Robotic Surgical System

In early September 2017, the Salisbury surgical service formalized a proposal to purchase a second surgical robot, an Xi system, for its VHA-approved robotic surgical program. Also in early September, VISN and Salisbury VAMC chief financial officers said they became aware of the availability of year-end funds to cover additional fiscal year (FY) 2017 equipment purchases. The order was placed without the advanced acquisition planning necessary to obtain VISN and ADUSH for Administrative Operations approval for the equipment purchase. The VISN executed the use of funds within a seven-day window to support the VAMC's purchase of a second surgical robot:

- September 7, 2017: The VISN chief financial officer said he was made aware of the facility request to purchase the robotic surgical system and that he identified and transferred additional funds to Salisbury for equipment purchases based on developments in the VISN's budget execution process.
- September 12, 2017: The Salisbury VAMC's facility Equipment and Medical Supply Committee and interim director formally approved the purchase based on their review of the VAMC's proposal and the confirmed availability of funds. The manufacturer's ordering guidance, which contained information on new sterile processing requirements, did not circulate with the proposal.
- September 14, 2017: The VISN Centralized Accounting Unit approved the obligation of funds for this purchase, 11 business days before the end of the fiscal year.

 September 14, 2017: The VHA Procurement and Logistics contracting office supporting VISN 6 ordered the new equipment using an OPAL national contract with Intuitive Surgical, Inc., based on the specifications provided by the Salisbury VAMC surgical service.

VISN 6 Officials Permitted the Purchase of Unauthorized Equipment

VISN 6 staff did not follow VHA or VISN policies for authorizing the purchase of the Salisbury VAMC Xi system. Because of the compressed ordering timeline, VISN 6 staff said they did not ensure the ADUSH for Administrative Operations, HTM Program Office, VISN 6 CIB, or VISN 6 network director reviewed or approved the proposed purchase before they allowed the Salisbury VAMC staff to order equipment through the VHA Procurement and Logistics Office.

VHA policy requires facilities to obtain approval from the ADUSH for Administrative Operations for equipment that costs over \$1 million. The policy also states that VISN biomedical engineers are responsible for reviewing and coordinating facilities' applications for approval through the HTM Program Office. The VISN 6 biomedical engineer said she was on business travel and leave during the time frame that the Salisbury VAMC order was placed and was not contacted by other VISN 6 staff regarding the Xi system purchase request. As a result, the purchase was not reviewed by the VISN biomedical engineer, the HTM Program Office application for approval was not submitted, and the ADUSH for Administrative Operations authorization was not obtained. Officials in the HTM Program Office and the ADUSH for Administrative Operations said they were unaware of the purchase.

The VISN chief financial officer and the VISN equipment specialist did not present the Salisbury VAMC Xi system to the VISN 6 CIB for review in either FY 2017 or 2018. According to the VISN deputy director and CIB chair, the VISN 6 CIB collected FY 2018 equipment expenditure proposals for its annual review process during FY 2017, however the Xi system proposal was not submitted. These FY 2018 purchases were not approved until November 2017. The VISN chief financial officer and the VISN equipment specialist, who were both CIB members, knew about the purchase of the Xi system in advance of its delivery, but did not present this purchase for CIB review. The network director said she was not consulted to approve the disbursement of funds for the system.

Finally, officials cited procedural differences among contracting offices as a contributing factor for these deficiencies. The national contracting process set up by the OPAL Strategic Acquisition Center in 2014 allowed the VHA Procurement and Logistics Office to place surgical robot orders without documentation of HTM approval. VISN 6 staff contrasted this process with the procedure for ordering non-robotic High Cost, High Tech equipment, which is centralized at OPAL's National Acquisition Center. According to VISN 6 staff, National Acquisition Center officials do not place orders for High Cost, High Tech equipment without HTM approval, thus reinforcing VISN compliance with the DUSHOM memo requirement.

The VISN 6 CIB policy did not reference the VHA HTM Program Office approval process or communicate the steps to ensure equipment order approval prior to processing. VHA is currently updating policies related to High Cost, High Tech medical equipment acquisitions, according to the HTM Program Office, including consolidating policies into one VHA Directive.

The Facility Was Not Prepared to Use the Xi System

On September 22, 2017, the Salisbury VAMC accepted delivery of the Xi system and, per the contract terms, the manufacturer warranty period began. However, the Salisbury VAMC did not place the Xi system in service until February 27, 2018. Although the building had been approved for a robotic surgery program and the Si system was being used, the compressed ordering timeline and the request for almost immediate delivery meant that the Salisbury VAMC was not prepared to place the new system into service immediately. Specifically, the ultrasonic bath needed to clean the Xi system was different than the existing ultrasonic bath the Salisbury VAMC used to clean the Si system. Intuitive Surgical, Inc., included this information in a footnoted section of the ordering guide, but facility staff said they did not see the requirement. Identifying and sourcing the required equipment contributed to delayed activation of the Xi system. A total of almost five months passed from acceptance of the system until it was placed in service. During the period the equipment could not be used, it was not available to veterans who may have needed procedures performed using the system. The delay also wasted almost five months of the one-year warranty included in the purchase price.

Conclusion

The OIG substantiated that VISN 6 staff permitted the purchase of a robotic surgical system for the Salisbury VAMC without all required approvals and without full site preparation. This occurred due to the compressed ordering timeline, ineffective management of the VISN 6 CIB review process, and weak internal controls over ordering procedures at the VISN level. Action to increase compliance with the development, review, and approval process for High Cost, High Tech purchases in robotic surgical systems is needed to increase assurance that these investments align with VHA's strategic investment goals and meet operational objectives.

Recommendations 1–3

- 1. The Deputy Under Secretary for Health for Operations and Management directs the Healthcare Technology Management Program Office to clarify High Cost, High Tech approval requirements to Veterans Integrated Service Network 6 officials, including biomedical engineers, logistics staff, equipment specialists, and financial officers, and to the Veterans Health Administration Procurement and Logistics Office.
- 2. The Veterans Integrated Service Network 6 network director updates and disseminates VHA requirements to request Assistant Deputy Under Secretary for Health for

- Administrative Operations approvals for High Cost, High Tech purchases that cost over \$1 million, including surgical robots, to the members of the Veterans Integrated Service Network 6 Capital Investment Board and Veterans Integrated Service Network 6 staff.
- 3. The Veterans Integrated Service Network 6 Capital Investment Board meets each fiscal year to ensure that all facility equipment requests more than \$1 million are reviewed in a timely manner, including fiscal year-end purchases.

Management Comments

The Executive in Charge, Office of the Under Secretary for Health, concurred with Recommendation 1, and the VISN 6 network director concurred with Recommendations 2–3.9 In response to Recommendation 1, the Executive in Charge agreed VHA would issue a memorandum to clarify and reinforce the High Cost, High Tech approval process to VISN network directors. He also agreed that VISN staff would receive training on the approval process. The Executive in Charge reported that VHA central office reviews approximately 100 High Cost, High Tech medical equipment applications in various categories per year, including 25 applications from VISN 6 in FYs 2016-2018. Appendix B provides the full text of the Executive in Charge's comments.

In response to Recommendation 2, the VISN 6 network director stated that the VISN has streamlined and automated the Standard Operating Procedure for the Capital and Station-Level Equipment Acquisition process, which specifically mentions DUSHOM approval for all items over \$1 million. The VISN 6 network director stated that the revised VISN 6 procedures were communicated to responsible CIB members and stakeholders in January 2019.

In response to Recommendation 3, the VISN 6 network director stated that the VISN 6 CIB will meet in July 2019 to review FY 2020 requests and that future out of cycle and emergency requests will be reviewed and approved in accordance with recently revised VISN procedures. Appendix C provides the full text of the VISN 6 network director's comments.

OIG Response

The Executive in Charge's comments and corrective action plans are responsive to the intent of Recommendation 1. The VISN 6 network director's comments and corrective action plans are responsive to the intent of Recommendations 2 and 3. The OIG will monitor implementation of planned actions and will close recommendations when VA provides sufficient evidence demonstrating progress in addressing the issues identified.

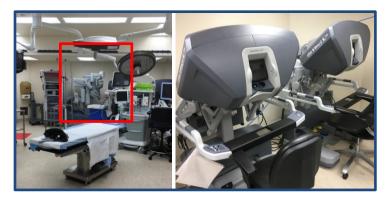
⁹ The Executive in Charge has the authority to perform the functions and duties of the Under Secretary for Health.

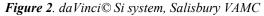
Finding 2: The VAMC Had an Approved Building to Support a Robotic Surgical Program and It Used the System Purchased in 2012

The OIG did not substantiate the allegation that the Salisbury VAMC building was inappropriate to support robotic surgical systems, nor that the Si system purchased in 2012 was unused. According to the complaint, the purchase of the robotic surgical system was inappropriate in part due to the age of the building in which it would be located. However, during a 2012 site visit conducted as a part of the VHA-required surgical program expansion approval process, the National Surgery Office concluded that the facility infrastructure, including the building, was appropriate for the addition of the robotic surgical program. A review of data provided by Intuitive Surgical, Inc., showed surgeons at the Salisbury VAMC had used the Si system to perform 411 procedures.

Facility Infrastructure Assessment and Program Approval

On November 27, 2012, the Under Secretary for Health approved the expansion of the Salisbury VAMC's surgical service to include robotic surgery. As a part of the VHA-required surgical program expansion approval process, VHA officials conducted a site visit on October 11, 2012, to assess the facility infrastructure, including the building, and determined that it could support a robotic surgical program. ¹⁰ VHA officials stated that the purchase of the Xi system in 2017 did not require an additional infrastructure assessment.





(Source: VA OIG site visit)



Figure 3. daVinci© Xi system, Salisbury VAMC

(Source: VA OIG site visit)

Use of Previously Purchased System

The Salisbury VAMC placed its approved Si system into service in March 2013. Intuitive Surgical, Inc., receives data from its systems, allowing the OIG to determine the number of times

¹⁰ Veterans Health Administration Directive 2009-001, Restructuring of VHA Clinical Programs, January 2009.

the Salisbury VAMC Si system had been used to conduct procedures. OIG analysis of the data showed 411 procedures were performed from March 2013 through March 2018. It also showed six different Salisbury VAMC surgeons used the Si system from March 2013 through March 2018 for 14 types of surgeries at the Salisbury facility. VAMC staff provided a sample of medical records for these procedures, which the review team cross-referenced with the manufacturer's data to confirm the use of the equipment.

Conclusion

The OIG did not substantiate that the Salisbury VAMC building was inappropriate to house a robotic surgical system, nor that the Si system purchased in 2012 was not used. The OIG found that VHA had determined the facility building could support a robotic surgical program in 2012 and that both systems housed on-site were in use.

Appendix A: Scope and Methodology

Scope

The OIG team conducted review work from April 2018 through March 2019. The team reviewed relevant actions taken by VA, VISN 6, and Salisbury VAMC officials regarding the approvals obtained during the 2017 acquisition of a robotic surgical system, the suitability of the facility infrastructure for the use of robotic surgical systems, and the use of the system purchased in 2012.

Methodology

To assess the allegations, the review team retrieved documents from the electronic Contract Management System, interviewed Salisbury VAMC and VISN 6 staff during a site visit in April 2018, and reviewed provided documentation. The team interviewed the director of the National Surgery Office, the director of the Health Care Technology Management Program Office, and the deputy director of the VHA Non-Expendable Program Office. The review team also interviewed staff in the VA Office of Procurement, Acquisition, and Logistics (OPAL) and the VHA Procurement and Logistics Office supporting VISN 6. The OIG team reviewed approval memos from the HTM Program Office's SharePoint portal to determine whether VISN 6 officials sought HTM approval. The team obtained and analyzed information from the Salisbury VAMC regarding ordered and accepted equipment. The team also obtained documentation of the National Surgery Office recommendation to approve the Salisbury VAMC robotic surgical program. This included the results of the National Surgery Office site visit to determine the suitability of the facility to conduct robotic surgeries.

To verify use of the Si robotic surgical system, the review team obtained a count of procedures and descriptive information regarding 411 procedures generated for both surgical systems from the surgical robot vendor, Intuitive Surgical, Inc. To validate these data, the team reviewed 30 corresponding redacted surgical note fields for procedures performed with the Si from the local facility's Veterans Information Systems and Technology Architecture system and corroborated this information with interviews with Salisbury VAMC staff. The team received and reviewed nine corresponding surgical notes fields for the Xi system to verify that the system was in service in February 2018.

Data Reliability

The OIG team's review included the use of computer-processed data, such as data collected by robotic surgical systems, data pulled from the Veterans Information Systems and Technology Architecture system and the electronic Contract Management System, and data pulled from the HTM Program Office SharePoint portal. The review team assessed the appropriateness and

reliability of such data by corroborating it when possible. The team cross-referenced the data in the Salisbury VAMC's medical records notes with data collected by the manufacturer's robotic surgical systems and testimonial evidence collected during its field work. The review team determined the data used were sufficiently reliable for the review's purposes.

Government Standards

The OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation*.

Appendix B: Management Comments Executive in Charge

Department of Veterans Affairs Memorandum

Date: April 18, 2019

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Alleged Unapproved Acquisition of a Robotic Surgical System for the Salisbury

Veterans Affairs Medical Center 2018-03260-D2-0127 (VIEWS 00220477)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review the OIG draft report, Alleged Unapproved Acquisition of a Robotic Surgical System for the Salisbury Veterans Affairs Medical Center.

- 2. I have reviewed the draft report and understand the findings, investigative results and recommendations. The plan of action has been established for recommendation 1.
- 3. Attached are the Veterans Integrated Service Network 6 responses and supporting documentation for recommendations 2 and 3.
- 4. Thank you for the opportunity to review the draft report. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO OIG Accountability Liaison (GOAL) Office at VHA 1 OEGGOALAction@va.gov.

(Original signed by)

Richard A Stone, M.D.

Executive in Charge, Office of the Under Secretary for Health

Attachment

VETERANS HEALTH ADMINISTRATION (VHA) Action Plan

OIG Draft Report: Alleged Acquisition of a Robotic Surgical System for the Salisbury VAMC

Date of Draft Report: March 5, 2019

Recommendations/ Status Completion Date
Actions

Recommendation 1: The Deputy Under Secretary for Health for Operations and Management directs the Healthcare Technology Management Program Office to clarify High Cost, High Tech approval requirements to Veterans Integrated Service Network 6 officials, including biomedical engineers, logistics staff, equipment specialists, and financial officers, and to the Veterans Health Administration Procurement and Logistics Office.

VHA Comments: Concur

The VHA Healthcare Technology Management Program Office will clarify and reinforce the High Cost High Tech Medical Equipment approval process to Veterans Integrated Service Network (VISN) officials and other process participants. A memorandum will be issued to the VISN Network Directors to reinforce the High Cost High Tech Medical Equipment approval process. Additionally, the Healthcare Technology Management Program Office will conduct a training session for VISN personnel about the process.

Approximately 100 High Cost, High Tech Medical Equipment applications are submitted through the Veterans Health Administration Central Office review and approval process each year for MRI Scanners, Positron Emission Tomography/Computed Tomography Scanners, Linear Accelerators, Cardiac Cath Labs, Robotic Surgical Systems, and other equipment. Applications have been submitted from all VISNs; VISN 6 submitted 25 applications over the past 3 years (fiscal year 2016-2018).

VHA will consider this recommendation complete when:

- 1. A memorandum has been issued to VISN Network Directors reinforcing the approval process.
- 2. Refresher training has been provided to VISN personnel.

Status: In process Target Completion Date: October 2019

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

Appendix C: Management Comments VA Mid-Atlantic Health Care Network Director, VISN 6

Department of Veterans Affairs Memorandum

Date: April 4, 2019

From: Network Director, VA Mid-Atlantic Health Care Network, VISN 6 (10N6)

Subj: Request for Action Plan - Draft Report, Alleged Unapproved Acquisition of a Robotic Surgical

System for the Salisbury

To: VHA 10NS OIG/GAO Action

1. The attached is forwarded for your review and further action. I have reviewed the Action Plan and concur with the recommendations.

2. If you have further questions, please contact Lisa Shear, VISN 6 QMO, at (919) 956-5541.

(Original signed by)

DEANNE M. SEEKINS, MBA, VHA-CM

VA Mid-Atlantic Health Care Network Director, VISN 6

Attachment

VETERANS HEALTH ADMINISTRATION (VHA) Action Plan

OIG Draft Report: Alleged Acquisition of a Robotic Surgical System for the Salisbury VAMC

Date of Draft Report: March 5,	2019		
Recommendations/	Status	Completion Date	
Actions			

Recommendation 2: The Veterans Integrated Service Network 6 Network Director updates and disseminates VHA requirements to request Assistant Deputy Under Secretary for Health for Administrative Operations approvals for High Cost, High Tech purchases that cost over \$1 million, including surgical robots, to the members of the Veterans Integrated Service Network 6 Capital Investment Board and Veterans Integrated Service Network 6 staff.

VHA Comments: Concur

A rapid process improvement event was completed in August 2018 with key stakeholders to revise the Veterans Integrated Service Network (VISN) review and approval process for high cost high tech equipment. The Standard Operating Procedure (SOP) for Capital and Station-Level Equipment Acquisition was revised from a 35-step; person-dependent process to a 15-step, automated approval process that prevents procurement of items without proper approval. The SOP was updated to include the requirement of Deputy Under Secretary for Health for Operations and Management approval for any medical device/ device system greater than one million dollars (>\$1M) as well as the requirement for approval of the Clinical Restructuring Requests for new items. The procedure was communicated to all Capital Investment Board (CIB) members/stakeholders in January 2019. The equipment review and approval process is audited for compliance during the Annual Workplace Evaluation /Biomedical Engineering surveys conducted by the VISN 6 Biomedical Engineer.

Status: Complete **Target Completion Date:**

<u>Recommendation 3</u>: The Veterans Integrated Service Network 6 Capital Investment Board meets each fiscal year to ensure that all facility equipment requests more than \$1 million are reviewed timely manner, including fiscal year-end purchases.

VHA Comments: Concur

The Capital Investment Board (CIB) is scheduled to meet July 31, 2019, to review fiscal year 2020 procurement requests greater than \$250,000. The CIB will submit recommendations for approval to the Network Director, who will then provide approval of items to be funded. Additionally, the Standard Operating Procedure for Capital and Station-Level Equipment Acquisition mandates that out of cycle and emergency requests above the dollar threshold are reviewed by the Resource Workgroup and approved by the Network Director prior to procurement.

Status: Target Completion Date:

In process July 2019

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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	Susanna Fischer Brendon Gregoire

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House Committee on Veterans' Affairs

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies

House Committee on Oversight and Reform

Senate Committee on Veterans' Affairs

Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies

Senate Committee on Homeland Security and Governmental Affairs

National Veterans Service Organizations

Government Accountability Office

Office of Management and Budget

U.S. Senate: Richard Burr, Thom Tillis

U.S. House of Representatives: Alma Adams, Ted Budd, G. K. Butterfield, Virginia Foxx, George Holding, Richard Hudson, Patrick T. McHenry, Mark Meadows, David Price, David Rouzer, Mark Walker

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