Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Follow-Up Evaluation of Dental Instrument Reprocessing Deficiencies St. Louis VA Medical Center St. Louis, Missouri

Report No. 10-03346-152

April 5, 2012

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted a review to follow-up on our report, *Reprocessing of Dental Instruments, John Cochran Division of the St. Louis VA Medical Center, St. Louis, Missouri,* OIG Report No. 10-03346-112, dated March 7, 2011. The purpose was to determine whether adverse conditions identified have been resolved and whether OIG's recommendations were implemented.

In the past 18 months, St. Louis VA Medical Center (STLVAMC) managers have taken corrective actions and some of the conditions identified in the 2011 OIG report have been resolved. However, the STLVAMC's Reusable Medical Equipment (RME) Committee was not effective in monitoring compliance with some mandatory requirements and the Veterans Integrated Service Network (VISN) 15 Supply, Processing, and Distribution (SPD) Management Board did not provide the necessary level of oversight and did not routinely verify the adequacy of some practices or the accuracy of data and status reports.

During the course of this review, we determined that routine environment of care (EOC) inspections did not adequately identify and resolve outstanding deficiencies. We also found that the lack of consistent Processing & Distribution (P&D) section leadership has contributed to the ongoing P&D problems. The STLVAMC Director recognizes the importance of having skilled and qualified staff in P&D leadership and management positions, but has had difficulty recruiting qualified candidates.

Recommendations 1 and 2 from our 2011 report will remain open until all action plans outlined by the facility are effectively implemented. Recommendation 3 related to administrative actions was addressed and resolved. In this report, we made an additional recommendation related to the EOC. We will follow up on the planned actions until they are complete and STLVAMC managers can demonstrate that the conditions have been fully resolved.

The Veterans Integrated Network and VAMC Directors concurred with our recommendations and provided an acceptable action plan. We will follow up on the planned actions until they are completed.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Heartland Network (10N15)

SUBJECT: Healthcare Inspection—Follow-up Evaluation of Dental Instrument Reprocessing Deficiencies, St. Louis VA Medical Center, St. Louis, Missouri

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to follow-up on our report, *Reprocessing of Dental Instruments, John Cochran Division of the St. Louis VA Medical Center, St. Louis, Missouri* (OIG Report No. 10-03346-112 dated March 7, 2011).[1] The purpose was to determine whether OIG's recommendations were implemented and whether adverse conditions identified have been resolved.

Background

The St. Louis VA Medical Center (STLVAMC) is a two-division, tertiary care facility in Veterans Integrated Service Network (VISN) 15. The John Cochran division is located in downtown St. Louis. It has 136 acute care beds and provides acute medical and surgical services as well as a wide range of specialty care. The Jefferson Barracks division is located in south St. Louis County. This division provides primary care and has 102 acute care beds, 50 domiciliary beds, and 71 Community Living Center beds.

Supply, Processing, and Distribution (SPD)[2] is a section of the STLVAMC that receives, stores, and distributes medical supplies and is also responsible for reusable medical equipment (RME) reprocessing. At the STLVAMC, the SPD organizational structure is split, with Logistics (Supply & Distribution) and Processing and Decontamination (P&D) separated into two departments.

RME refers to items which are manufactured for reuse or for which the manufacturer has provided specific written reprocessing instructions. Common RME includes dental drills,

[1] http://www.va.gov/oig/54/reports/VAOIG-10-03346-112.pdf.
[2] SPD has recently been retitled Supply Processing Service. In this report, we use the previous title of SPD for the purposes of clarity and continuity.

probes, and retractors; endoscopes and their auxiliary parts; and surgical instruments like scissors, forceps, and scalpels. Reprocessing is the term used to encompass cleaning, disinfection, sterilization, and preparation of equipment to full readiness for its subsequent use.

In 2010, nine members of Congress asked us to investigate allegations of deficient dental instrument reprocessing practices and related concerns at the John Cochran division of the STLVAMC. In our 2011 report, we noted that dental RME reprocessing issues were a long-standing problem that went unrecognized by STLVAMC and VISN managers. While Veterans Health Administration's (VHA) Infectious Disease Program Office (IDPO) identified the deficiencies in March 2010 during a routine, facility-wide review, the corrective actions taken did not always resolve the issues. Responsible managers did not verify the adequacy of RME reprocessing practices, nor did they assure that corrective actions were consistently implemented. As a result, standard operating procedures (SOPs) were not developed in a timely manner and were not always consistent with manufacturers' instructions, and Dental Clinic staff had not received training on dental RME pre-treatment or reprocessing. We did conclude, however, that STLVAMC appropriately managed the patient disclosure process regarding possible exposure to blood borne pathogens.

We recommended that the STLVAMC comply with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance; that the VISN SPD Management Board monitor and ensure that SOPs based on manufacturers' instructions were implemented and staff training and competencies were current; and that responsible managers take appropriate administrative actions based on the findings of an administrative board of investigation (ABI) and the IDPO report.

Scope and Methodology

We visited the STLVAMC January 11-12, 2012. Our primary focus was to determine whether actions taken in response to the 2011 OIG report were implemented and effective, and to evaluate whether conditions had improved. We interviewed employees; reviewed SOPs and manufacturers' instructions, training records, employee competencies, and oversight committee minutes; and toured the Dental Clinic and SPD. We referenced VHA Directives 2009-004[3] and 2009-031,[4] as well as SPD Handbook 7176 during the course of our review. We did not observe items being reprocessed at STLVAMC.

[3] *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009.
[4] *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements*, June 26, 2009.

We conducted the inspection in accordance with the *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Follow-Up to Previous OIG Recommendations

Recommendations 1 and 2 will remain open. Below we list the OIG's original recommendations, the VISN and STLVAMC's initial and intended response to the recommendations, and our follow-up to determine whether the corrective actions were implemented.

2011 OIG Report Recommendation 1	VISN and Medical Center Response
The VISN Director requires the STLVAMC Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance.	The STLVAMC RME Committee will enhance oversight by reviewing, monitoring, and implementing all necessary action plans to maintain compliance with relevant VHA RME guidance through standing agenda items in the RME Committee. These agenda items include: 1) Staff Competencies, 2) SOPs, 3) Staff Education and Training, 4) Workload Level Evaluation, and 5) Quality Indicators such as Early Releases, Environmental Monitoring, and Biological testing. STLVAMC will complete a minimum of six self inspections using standardized review tools and a multi-disciplinary team [team members/disciplines listed]. Action plans will be developed, reported, and tracked in STLVAMC RME and VISN SPD Management Board [minutes]. The RME minutes will be reviewed on a monthly basis in the Executive Management Meeting chaired by the Medical Center Director.

In 2012, OIG Determined:

The STLVAMC's RME Committee[5] was not effective in monitoring compliance with some mandatory requirements. The STLVAMC RME Committee was to review, monitor, and implement action plans. We reviewed committee minutes from the 4th quarter fiscal year (FY) 2011, and 1st quarter FY 2012, which showed that staff competencies, SOPs, staff education and training, workload,[6] and quality indicators were standing agenda items. However, the minutes did not reflect an analysis of the problems or a reasonable discussion of the causes and solutions. Further, the minutes typically did not reflect a continuity of follow-up from one month to the next. The minutes for the

[5] Local policy defines this committee's membership. We noted inconsistent or non-attendance by several key members.
[6] We did not evaluate workload issues during this review.

RME Committee should provide greater detail to document compliance with STLVAMC's action plan in response to Issue 1. We found the following conditions that should have been identified and addressed, but were not:

Competencies

VHA Directive 2009-004 defines competence as "the assurance that an individual has received the appropriate training and has demonstrated an achieved skill level required to independently and appropriately perform an assigned reprocessing task or responsibility" and calls for documented initial and continued staff competence at least annually. To certify competence, an employee with a current competency must observe the employee complete each step of reprocessing according to the manufacturer's instructions for each piece of RME. Competency worksheets should reflect the specific name and type of RME and list each step in the reprocessing procedure.

Although STLVAMC staff reported substantial compliance with competency completion, we found problems with the majority of the 16 competency folders we reviewed. We found competency worksheets that were lined through, crossed out, or marked "NA;" did not reflect the title of the device-specific item; did not reflect the dates of competency demonstration and observation for some items; or did not reflect consistent/compatible signature dates between the employee and preceptor. We found one employee who was allegedly certified as competent on 18 pieces of RME in one day. Given that the RME, collectively, included 338 steps, and that some steps required up to 15 minutes of soaking, rinsing, or sterilizing, it is improbable that these competency certifications were completed correctly.

SOPs

VHA requires that SOPs reflect current manufacturers' instructions for each type of RME used. We evaluated two dental instrument SOPs and compared them with the competency worksheets and the manufacturer's instructions. For example, the manufacturer's instructions matched the competency worksheet, but the corresponding SOP did not include two steps in the sterilization process. In addition, we found some inconsistencies between the list of dental RME and their corresponding SOPs.

Staff Education and Training

VHA requires that personnel assigned to reprocess RME be trained according to device-specific SOPs in order to ensure proper cleaning and high-level disinfections and sterilization. Employees must receive initial device-specific training and retraining if there are changes to the reprocessing steps. We reviewed 25 P&D employees' training records for the past 2 years and found minimal evidence that staff were receiving the required training. The training titles, as listed in VA's Talent Management System

(TMS), were often too vague to determine the topic and content of the training. We found minimal references to RME reprocessing training.

Quality Indicators

VHA Handbook 7176 outlines specific quality indicators that are designed to ensure P&D practices align with reprocessing requirements for the delivery of RME that is safe for patient care. While full compliance is expected, exceptions can and do occur. In these cases, exceptions must be documented to include corrective actions. We found multiple conditions that were reported in the RME Committee minutes, some recurring over several months, but little evidence of follow-up or action planning.

- Early release of implantable devices. Implantable items, such as surgical screws and pins, must be sterilized and quarantined in SPD for a period of 48 hours. They can only be released during this quarantine period for emergent situations and with the approval of the Chief of Staff or designee. We reviewed the RME meeting minutes and attachments which showed 25 early releases during calendar year 2011. We randomly selected five cases for review and determined that none were emergencies.

- Environmental monitoring. Humidity in the clean/sterile supply areas (rooms 127 and 128) must be maintained between 20–60 percent.[7] The humidity monitors for December 2011 and January 2012 showed 31 low (<20) readings. In addition, there were 41 days when the humidity was not recorded and 35 days when the temperature was not recorded. Proper humidity and temperature is required to maintain the integrity of sterile items and packaging.

- Biological testing. RME sterilizers must be monitored, via spore testing, at least once every day that they are used. This testing ensures that the sterilizers are free of contaminants. We reviewed biological testing results for each month in FY 2011 and found multiple dates where spore test results were missing on multiple sterilizers. However, the Infection Prevention Committee (IPC) minutes did not reflect discussion of the spore test reports and closed these items without action.

Environment of Care

During our site visit, we toured the SPD area including the clean/sterile supply area in the main hospital (Building 2) and the decontamination and preparation area in the trailer. Although not part of our original follow-up review, we identified several environments of care conditions requiring management attention.

[7] Handbook 7176 requires humidity be maintained between 35–75 percent, but a DUSHOM memorandum (dated January 4, 2012) titled *Interim Guidance for Ventilation Requirements for Sterile Processing Service*, January 4, 2012, has modified that range to 20–60 percent.

Clean/sterile supply area. Sterile items must be stored in carefully controlled conditions. Environmental Management Service (EMS) must have a schedule of cleaning activities in SPD to include, among other things, wet mopping or wet vacuuming of floors at least once a day and more often if necessary. Sterile storage areas must remain locked and must have carefully controlled traffic patterns with limited access. Further, sterile storage areas must be under positive air pressure, which makes it difficult for airborne dust and dirt microorganisms to enter the space. The lower shelves in storage areas must be solid to prevent contamination from dirty floors and floor cleaning solutions. Fire barriers must be continuous from outside wall to outside wall.[8] We found:

- The EMS cleaning log reflected missed cleanings of the area, and our inspectors' surgical booties were dirty when they left the area.
- There was no positive air pressure as the door had been propped open.
- There was one storage supply shelf with open grates on the bottom.
- There was one penetration in the ceiling.

General SPD areas. This includes the decontamination and preparation areas and the common corridors and spaces adjacent to SPD operations. We found:

- Fire extinguishers were not consistently checked each month in 2011 as required.
- An exit door 15-20 feet from the open sterile supply door had a rusted-out hole on the bottom. There was a rodent/insect trap placed just inside the hole. We did not see evidence of insects, rodents, or other vermin.
- There were four shelving units in the preparation area with open grates on the bottom.
- There was excess clutter in the corridors in violation of regulations regarding egress.[9] [10]
- Eye wash stations in the decontamination and preparation areas were not inspected weekly as required.[11]

We reviewed EOC inspection reports dating back to June 2011 and found ongoing issues with general cleanliness, but there were no clear follow-up actions documented. An August 2 inspection report documented cluttered hallways (which were reportedly abated on August 9); however, this condition was again present during our site visit in January.

We found multiple examples of possible non-compliant conditions and data being reported to oversight committees, but frequently, there was no evidence of trending and

[8] The National Fire Protection Association (NFPA) 101, Life Safety Code, 2012.

[9] JC.LS.03.01.20, EP 6

[10] The August 2, 2011, EOC inspection report identified cluttered hallways (which was reportedly corrected by August 9), but this condition was present during our site visit.

[11] VHA Directive 2009-026, *Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment*, May 13, 2009.

critical analysis of the data. Further, minutes did not always contain evidence of thorough discussion of the problem(s), corrective action planning, or evaluation of actions.

The recommendation will remain open. We are making a separate recommendation related to EOC inspections and follow-up.

2011 OIG Report Recommendation 2	VISN and Medical Center Response
The VISN Director ensure that the VISN SPD Management Board monitors to ensure that SOPs are in place and staff training and competencies are current.	The VISN SPD Board is using the tool developed by Central Office in [fiscal year 2011] for the VISN oversight reviews. This tool provides detailed information on SOPs, competency completion and training documentation. The VISN SPD Board is also adding two sections to its SPD tool. Those sections are: 1. The Medical Center process for maintaining SOPs. 2. The Medical Center process for maintaining competencies. In addition, SOPs, competencies and training are being added as a standing agenda item to each Board meeting.

In 2012, OIG Determined:

The VISN 15 SPD Management Board did not provide the necessary level of oversight as required by VHA Directive 2009-031. We reviewed meeting minutes for April 18, 2011, through December 12, 2011, but did not find evidence that the Board routinely evaluated compliance with SOP, staff competency, and staff training requirements. While the minutes did include these elements as standing agenda items, the "discussions" were typically generic. For example, the July minutes state "In terms of reviews, when looking at SOPs and competencies, everyone has a handle on these." None of the minutes contained any aggregate data or reference to individual facilities' compliance with SOPs, competencies, or training.

In addition to the responsibilities listed above, the Board also oversees RME quality indicators including flash sterilization, environmental controls, surgical set completion, and bioburden monitors for all VISN 15 facilities. Again, the discussions were typically generic, often focusing on reporting requirements rather than problem identification and corrective action. For example, the STLVAMC reported an incomplete surgical set rate of 21 percent, 13 percent, and 8 percent, respectively, for the 2nd–4th quarters of FY 2011. When an incomplete surgical set is released, an explanation must be documented. Despite the substantial rate of non-compliance in the 2nd quarter, and the continuing (if lesser) non-compliance in the 3rd–4th quarters without explanation, the VISN SPD Board minutes did not reflect any discussion of the problem or corrective actions needed.

This recommendation will remain open.

2011 OIG Report Recommendation 3	VISN and Medical Center Response
The VISN Director take appropriate administrative actions based on the findings of the ABI and IDPO report.	The Directors have taken the recommended administrative actions based on the findings of the ABI and IDPO report.

In 2012, OIG Confirmed:

Administrative actions were taken. We consider this recommendation closed.

Issue 2: Leadership and Oversight

SPD-related deficiencies have been a continuing problem. In February 2010, we visited STLVAMC and cited RME reprocessing and environmental conditions in the SPD area in our report, *Alleged Endoscope Reprocessing Issues, St. Louis VA Medical Center, St. Louis, Missouri*, (Report No. 10-01141-133, April 21, 2010). In March 2010, the IDPO conducted a facility-wide assessment and found multiple deficiencies in RME reprocessing, infection control practices, and environmental cleanliness and safety. In August and September 2010, we conducted site visits and found that some conditions identified by the IDPO still existed 6 months later. Our recent visit, in January 2012, revealed that while some previously cited conditions had been addressed and resolved, others continued.

After each site visit and report, STLVAMC managers developed and initiated corrective action plans, but some conditions were not fully resolved and in some cases, new deficiencies were identified. While it is difficult to determine why the corrective actions have not been fully effective, the lack of stable, ongoing P&D leaders and managers over the past 3 years has been problematic.

Leadership and Management Changes

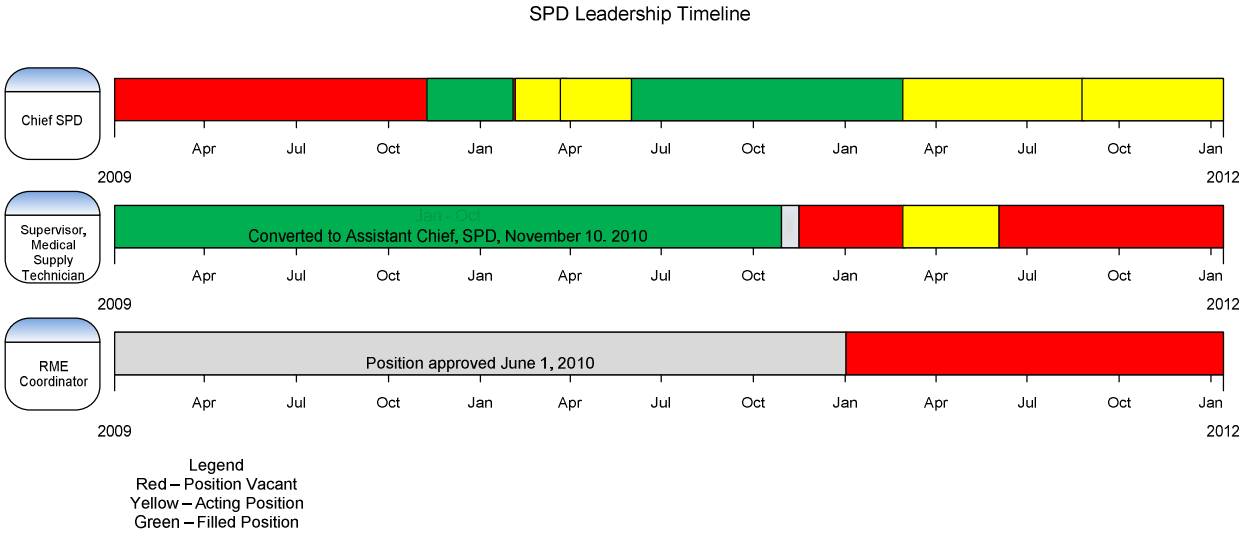
It is widely recognized that there is a positive correlation between strong, stable leadership and high performance. At STLVAMC, key P&D leadership and management positions have been in flux for several years.

Prior to 2009, the STLVAMC did not have a P&D chief. The longest serving employee with managerial responsibility for RME processes was the P&D supervisor, who had been functioning in her position since April 2006. She has since retired.

The P&D chief's position was approved in January 2009 but not filled until November; the incumbent remained in the position until February 2010. An acting P&D chief served for about 6 weeks and a second acting P&D chief served for another 2 months. In June

2010, a permanent P&D chief was installed but was removed after 8 months. There have been two additional acting chiefs since March 2011. The current acting P&D chief also serves as the associate chief nurse for surgical operations and is responsible for RME operations until the RME coordinator's position is filled.

The P&D supervisor position was converted to an assistant P&D chief's position in November 2010. The position was vacant for several months, filled by an acting assistant chief for 3 months, and has been vacant since June 2011. The RME coordinator position was approved in June 2010 but has never been filled despite repeated announcements and incentive bonuses.



Supervision

It was not clear that the P&D chiefs, acting chiefs, and those in supervisory roles always possessed the necessary technical expertise and skills to determine the fundamental problems, implement the needed changes, and assure ongoing compliance.

According to VHA Handbook 7176, "The Chief, SPD, has supervisory responsibility over the organization known as SPD. The nature of the work environment places the Chief, SPD, in a key position requiring tact, diplomacy, and reliable decision-making abilities to carry out assigned responsibilities. The Chief, SPD, will be certified by completing the VA SPD Certification Program and maintaining certification requirements while in the position." Two of the three P&D (or acting) chiefs did not complete the required certification program. While one did have the Level 2 certification, she was removed from the position after 8 months. The current acting Chief of P&D is a nurse who spent the last 6 years in an administrative position and whose past clinical experience was in medical/surgical and community health nursing, not in the operating room.

Through interviews and our review of meeting minutes and other documents, it appeared to us that STLVAMC staff responsible for P&D operations believed they were complying with guidelines and routinely reported to leadership and oversight committees on the status of their efforts in key areas. However, the ongoing lack of compliance suggests otherwise.

Oversight

Managers, leaders, and other oversight bodies did not routinely verify the adequacy of some practices or the accuracy of data and status reports. This condition was also cited in our 2011 report. It appeared that responsible managers relied on supervisory and tenured employees to understand the expectations, monitor practices, and implement changes in accordance with VHA guidance. Responsible STLVAMC and VISN leaders received generally favorable reports and updates and presumably believed that corrective actions were effective and that conditions were improving. The STLVAMC Director confirmed that this was precisely what she thought. Central to the problem, however, was that the accuracy of the data and information presented was not routinely validated.

The STLVAMC Director recognizes the importance of having skilled and qualified staff in P&D leadership and management positions. The paradox, however, has been that the STLVAMC, with its ongoing and well-publicized P&D and RME problems, has had difficulty attracting superior candidates for the P&D Chief position. As a result, many of the deficient conditions are only partially resolved or remain unresolved.

Conclusion

In the past 18 months, STLVAMC leadership has taken corrective actions and some of the conditions identified in the 2011 OIG report have been resolved. The STLVAMC's RME Committee was not effective in monitoring compliance with some mandatory requirements and the VISN 15 SPD Management Board did not provide the necessary level of oversight and did not routinely verify the adequacy of some practices or the accuracy of data and status reports. As a result, recommendations 1 and 2 remain open issues. Recommendation 3 related to administrative actions were addressed and resolved and we consider the issue closed.

During the course of this review, we determined that routine EOC inspections did not adequately identify and resolve outstanding deficiencies. We also found that the lack of consistent P&D leadership has contributed to the ongoing P&D problems. The STLVAMC Director recognizes the importance of having skilled and qualified staff in P&D leadership and management positions but has had difficulty recruiting qualified candidates.

Recommendations

Original recommendations 1 and 2 remain open. Recommendation 3 reflects the newly identified EOC conditions. We will follow up on the planned actions until they are complete and STLVAMC managers can demonstrate that the conditions have been fully resolved.

Recommendation 1. The VISN Director requires the STLVAMC Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance.

Recommendation 2. The VISN Director ensures that the VISN SPD Management Board monitors to ensure that SOPs are in place and staff training and competencies are current.

Recommendation 3. The VISN Director requires a comprehensive baseline inspection of all SPD areas, and that identified deficiencies are promptly corrected and monitored for ongoing compliance.

Comments

The VISN and Facility Directors concurred with our recommendations and provided an acceptable action plan (see Appendixes A and B, pages 12-17, for the Directors' comments). We will follow up on the planned actions until they are completed.

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

Appendix A

VISN 15 Director Comments

Department of Veterans Affairs **Memorandum**

Date: March 23, 2012

From: Acting Director, VA Heartland Network (10N15)

Subject: Follow-Up Evaluation of Dental Instrument Reprocessing Deficiencies, St. Louis VA Medical Center, St. Louis, MO

To: Director, Atlanta Office of Healthcare Inspections (54AT)

Thru: Director, VHA Management Review Service (10A4A4)

I have reviewed and concur with the Follow-Up Evaluation of Dental Instrument Reprocessing and the St. Louis VA Medical Center status response(s). Thank you for this opportunity of review as a process to ensure that we continue to provide exceptional care to our Veterans.

If you have any questions regarding the information provided, please contact Jimmie Bates, VISN 15 Quality Management Officer at 816-701-3043.

(original signed by)

William P. Patterson, MD, MSS
Acting Network Director
VA Heartland Network (VISN 15)

Appendix B

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Department of Veterans Affairs **Memorandum**

Date: March 14, 2012

From: Director, St. Louis VA Medical Center (657/00)

Subject: Follow-Up Evaluation of Dental Instrument Reprocessing Deficiencies, St. Louis VA Medical Center, St. Louis, MO

To: Director, VA Heartland Network (10N15)

On behalf of the VA St Louis Health Care System, I would like to express my appreciation to the Office of the Inspector General (OIG) Survey Team for their cooperative and collaborative comprehensive follow up review conducted January 11-12, 2012.

I have reviewed the findings from the report. Our facility responses addressing each recommendation are attached. The responses include actions that are in progress and those that have already been completed.

Please feel free to contact us if you have any concerns or questions regarding the responses.

/S/
RimaAnn O. Nelson, RN, MPH/HSA
Medical Center Director

Appendix B

St. Louis VA Medical Center Director Comments

Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendation(s) in the Office of Inspector General's Report:

OIG Recommendation(s)

Recommendation 1. The VISN Director requires the VASTLHCS Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance.

Concur

Facility's Response:

The following actions have been taken to strengthen the monitoring and oversight of the facility's compliance with all the appropriate elements of RME reprocessing, SOPs, staff training and staff competencies.

1. An audit of all (1,855) Sterile Processing Service competencies was conducted to identify administrative errors in documentation. A revised process for utilizing the competency assessment tools was implemented in order to prevent further errors. Examples include requiring the verification method to be handwritten and requiring the assessor to circle the method used. **Completed February 9, 2012**

2. The RME Committee charter was revised and approved by the Executive Board, chaired by the Medical Center Director, on March 14, 2012. Changes were made to enhance not only the clinical oversight but to provide expertise in in-depth analysis, trending of data and monitoring of systems to ensure implementation of sustainable actions. The following actions were completed.
   - Enhanced the RME committee leadership by changing the co-chair responsibilities from the Chief of Staff's Office to the Office of Quality Management to provide expertise in principles of Quality Management Systems and System Redesign.
   - Enhanced the representation from services on the committee to ensure all services are present at each meeting.
   - Enhanced oversight function by reassigning the RME Committee reporting assignment from the Clinical Executive Board to the

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Quality Executive Board. The Quality Executive Board membership contains the expertise in Quality Management Systems, emphasizing the focus on trends based on data analysis versus a general clinical overview of RME systems and processes.

- Redefined data elements and reporting formats to include data definitions, performance thresholds, and corrective and preventive actions plans. **Completed March 16, 2012**

3. The Quality Management System plan for RME was implemented to clearly define quality control indicators and to strengthen monitoring processes. The plan has been developed and reviewed by local Sterile Processing Service leadership, Quality Management and VISN representatives. **Completed March 16, 2012**

4. A System Redesign review related to the flow of the data and information to and from the RME Committee was completed. The process is documented in the policy which outlines the Quality Management System for RME. **Completed March 16, 2012**

5. RME Committee meeting minutes will be submitted to the VISN leadership on a monthly basis. This has been initiated. **Completed March 2012**

6. Monthly briefings from the RME Committee to the Executive Board, chaired by the Medical Center Director, will be continued. **Completed March 2012**

7. Recruitment efforts to establish stable leadership in the Sterile Processing Service in order to achieve the sustainable resolution of issues will continue. The Chief of Sterile Processing Service was hired and entered on duty on February 26, 2012. Recruitment continues for the Assistant Chief of Sterile Processing, the RME Coordinator and the vacant Sterile Processing Technician positions. **Completion Date: Ongoing**

Status: Implementation is in process

Recommendation 2. The VISN Director ensures that the VISN SPD Management Board monitors to ensure that SOPs are in place and staff training and competencies are current.

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Concur **Target Completion Date: May, 2012**

Facility's Response:

Based on review findings, and to promote program integration, the VISN RME Board membership was expanded to include all staff involved in SPS/RME including all SPS managers, Nurse Executives, Quality Managers, Infection Preventionists, Patient Safety Managers, Chiefs of Staff, and other hospital leaders. The presence of a large diverse membership improved overall communication and coordination, but it did limit discussion of hospital specific oversight topics.
VISN 15 will review and modify the Charter for the SPS Board. In addition to having the extended membership meeting, the Board will set aside additional time at each meeting for the core SPS Board members to ensure oversight related issues are discussed and tracked.
Oversight requirements from appropriate VA Directives and Handbooks will be covered in the Core Board meeting. The VISN SPS Board Chair and QMO will ensure that Board recommendations are implemented.

Status: Ongoing

Recommendation 3. The VISN Director requires a comprehensive baseline inspection of all SPS areas, and that identified deficiencies are promptly corrected and monitored for ongoing compliance.

Concur

Facility's Response:

The Sterile Processing Service area, containing the instrument decontamination and preparation sections, are currently located in temporary space while the Medical Center completes a state of the art renovation of the Sterile Processing Service. This project is a $7 million project, which will be completed in June 2012. An ongoing investment in the infrastructure of the whole organization is evident from the $54 million dollars in projects that are currently underway at the VA St Louis Health Care System in FY 2012.

1. The following actions were taken to address the findings identified by the inspectors during the site review in the clean storage/ supply area.
    - The area was thoroughly inspected by the Chief of Environment Management Services on January 13, 2012. The responsibility

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and importance of completing the documentation, once the area was cleaned, was reiterated and reinforced to the Environment Management Service personnel. Although the cleaning was completed during the scheduled timeframe, the high volume of traffic in the area required a more frequent cleaning schedule. This would have been identified if the cleaning schedule documentation was completed on time. The policy and procedures outlining the expectations was reviewed with the staff. **Completed January 16, 2012**

- Additional measures to minimize dust in high traffic areas were implemented. Tacky mats have been placed outside doorways to remove items on cart wheel before entering the clean supply/storage area. **Completed January 13, 2012.**
- Additional measures were taken to ensure doors were closed in the clean supply/storage area to maintain air pressure gradients. An automatic door opening and closing device has been ordered and will be installed on March 30, 2012. Large laminated signs were place on both sides of the door reading "Keep Door Closed". **Completed January 16, 2012**
- Plastic shelf covers were place on the bottom of open storage supply shelves as required. **Completed January 12, 2012.**
- The ceiling tile with the penetration was replaced. **Completed January 12, 2012.**

2. The facility completed interdisciplinary Environment of Care rounds for the SPS areas. All identified gaps and deficiencies in the report have been abated. Completed February 28, 2012

3. In February 2012, the Environment of Care rounds and inspection in the clean storage/supply area was changed from quarterly to weekly.. Weekly inspections were conducted until all outstanding environment of care issues were abated. This will be followed by monthly inspections beginning in March 2012 and will continue until the Sterile Processing Service moves into its new and permanent renovated space. Inspection findings will be reported to the Environment of Care and RME Committees for oversight, analysis and ongoing monitoring. **Completed March 2012**

Status: Implemented with ongoing monitoring

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Toni Woodard, Team Leader Kathi Shimoda, BSN Victoria Coates, LICSW, MBA

Appendix C

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