Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Reusable Medical Equipment Issues

VA Northern California Health Care System Sacramento, California

Report No. 12-02098-11

October 16, 2012

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection at the VA Northern California Health Care System (the system), Sacramento, California, at the request of Senator Richard Burr, Ranking Member of the Senate Committee on Veterans' Affairs. The purpose of the review was to determine the validity of multiple allegations regarding improper reusable medical equipment practices at Sacramento VA Medical Center, Martinez Outpatient Clinic, and McClellan and Redding community based outpatient clinics.

We found that the system generally complied with the manufacturer's instructions (MI) regarding sterilization parameters for selected Olympus and Padgett Dermatome devices. However, we found that the system's sterilization processes for the Phaco Alcon and Midwest dental handpieces were inconsistent with the MI. Nevertheless, these devices were sterilized using the Centers for Disease Control and Prevention's minimum exposure recommendations.

We concluded that the system's standard operating procedures and sterilization logs were generally inconsistent with the MI. We substantiated the allegations related to bioburden testing, delayed reprocessing, endoscope reprocessing documentation, and staff competencies. We also found improvement opportunities regarding proper use and care of suction canisters and other accessories.

We recommended that the System Director review all findings in this report and take steps to correct the identified deficiencies.

The Veterans Integrated Service Network and System Directors agreed with our findings and recommendation and provided acceptable improvement plans.

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

TO: Director, VA Sierra Pacific Network (10N21)

SUBJECT: Healthcare Inspection – Reusable Medical Equipment Issues, VA Northern California Health Care System, Sacramento, California

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections reviewed allegations regarding reusable medical equipment (RME) practices at the VA Northern California Health Care System (the system). The review was requested by Senator Richard Burr, Ranking Member of the Senate Committee on Veterans' Affairs. The purpose of the review was to determine whether the allegations had merit.

Background

The system consists of two divisions. The Sacramento Valley Division consists of a medical center in Sacramento (Sacramento VAMC) and community based outpatient clinics (CBOCs) in Chico, McClellan, and Redding, CA. The East Bay Division is comprised of a rehabilitation and extended care facility and outpatient clinic (OPC) in Martinez and CBOCs in Fairfield, Vallejo, Mare Island, and Oakland, CA. The system offers a full range of services, including medical, surgical, outpatient, and mental health. It is part of Veterans Integrated System Network (VISN) 21.

RME reprocessing is performed at Sacramento VAMC, Martinez OPC, and Redding CBOC. Reprocessing was also performed at McClellan CBOC until October 2011.

RME refers to devices that are designed for use on multiple patients and are made of materials that can withstand repeated reprocessing. These devices must be properly cleaned, disinfected and/or sterilized between patients to ensure safe use. If these devices are not adequately reprocessed, they may remain contaminated and compromise patient safety.

RME Reprocessing Overview

RME can be grouped into one of three categories according to the degree of risk of infection associated with its use and the level of cleaning required to prevent infection. These categories are:

Critical. Devices in this category enter sterile body areas, such as joints and the vascular system. They carry a high risk for infection if they are contaminated with microorganisms (germs) and require ***sterilization*** to eliminate all forms of microorganisms. Examples include surgical instruments and implants.

Semicritical. Devices in this category examine intact mucous membranes but do not ordinarily penetrate sterile tissue. Examples include many endoscopes[1] and respiratory therapy equipment. These devices need to be cleaned and then undergo ***high-level disinfection*** (***HLD***) to destroy all microorganisms except for small numbers of spores[2] which are inconsequential.

Noncritical. Devices in this category come in contact with intact skin but not mucous membranes. Since intact skin acts as an effective barrier to most microorganisms, it is not necessary to sterilize these items or use HLD. Nevertheless, these devices must be ***disinfected*** between each patient use.

Adequate reprocessing of RME is a critical step in ensuring patient safety. Reprocessing is intended to remove blood, tissue, and other debris, and to inactivate infectious microorganisms to ensure that devices are safe for the next patient.

In general, RME reprocessing involves three steps: (1) initial decontamination and cleaning at the point of use; (2) thorough cleaning in the reprocessing area; and (3) low-intermediate-level disinfection, HLD, or sterilization, depending on the intended use of the device, its risk of infection transmission, and the materials from which it is made.

Cleaning is the most essential step in reprocessing. It usually involves the use of water and detergents or enzymatic[3] presoak solution to remove foreign material such as blood, tissue, and microorganisms. Decontamination uses physical or chemical means to remove, destroy, or inactivate infectious microorganisms (pathogens) to the point where they are no longer capable of transmitting infections and the device is rendered safe for handling.

Disinfection is any process, chemical or physical, that destroys most pathogens so that the device is safe to handle for its intended use. Disinfection may be subdivided into

[1] Endoscopic equipment is used to look into a body cavity, such as the colon. Examples include colonoscopes, bronchoscopes, and cystoscopes.
[2] Spores are reproductive cells produced by fungi and bacteria.
[3] Agents used to break down and remove the foreign material.

HLD, intermediate-level disinfection, and low-level disinfection according to the anti-microbial activity of the disinfectant.

Sterilization removes or destroys all forms of microorganisms, including bacterial spores. Steam sterilization (moist heat in the form of saturated steam under pressure) is the most widely used type of sterilization and is the most dependable. The basic principle is to expose each piece of RME to direct steam for the time specified by the manufacturer's instructions (MI). The higher the temperature, the shorter the time needed for sterilization.

There are two types of steam sterilizers, and each type utilizes different temperature and pressure exposure parameters. In a gravity displacement sterilizer, steam is admitted at the top or side of the chamber, forcing air out of the bottom of the chamber. In a pre-vacuum sterilizer, the air is removed from the chamber before the steam is admitted.

The Centers for Disease Control and Prevention (CDC) recognizes two common exposure parameters for steam sterilization: 30 minutes at 250 degrees (°) Fahrenheit (F) or 15–25 minutes at 270°F in a gravity displacement sterilizer, or 4 minutes at 270°F in a pre-vacuum sterilizer.[4] Table 1 below summarizes the required exposure or cycle time for the two types of sterilizer.

Sterilizer Type	Item	Exposure time at 250°F	Exposure time at 270°F
Gravity Displacement	Wrapped instruments	30 minutes	15 minutes
	Textile packs	30 minutes	25 minutes
Pre-Vacuum	Wrapped instruments	Not applicable	4 minut**es**
	Textile packs		

Table 1. Minimum cycle times for steam sterilization cycles.

[4] CDC, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008.

The Veterans Health Administration (VHA) has established requirements for the proper reprocessing of RME to ensure patient and staff safety. Requirements include the development of device-specific standard operating procedures (SOPs) for reprocessing RME according to MI, staff competency assessments, and a quality assurance program that ensures appropriate and safe reprocessing.

Allegations

A complainant made multiple allegations pertaining to RME practices at the Sacramento VAMC, Martinez OPC, and McClellan and Redding CBOCs. The complainant alleged that:

- Several critical pieces of RME (endoscopes, telescopes, accessories for the video colonoscope, and KV-5 suction machine) from the Olympus company were sterilized incorrectly at Sacramento VAMC and Martinez OPC.
- The Phaco Alcon handpiece was sterilized for 4 minutes at 270°F at Sacramento VAMC and Martinez OPC although the SOP and competency required 5 minutes at 273°F.
- The Midwest dental handpiece was not sterilized according to the MI at Martinez OPC and McClellan and Redding CBOCs.
- The Padgett Dermatome was not sterilized according to MI at Sacramento VAMC and that a sticker attached to the Padgett Dermatome inhibited proper sterilization.
- Bioburden[5] testing was not conducted on 100 percent of gastroenterology (GI) endoscopes and Sterile Processing Service (SPS) failed to order sufficient supplies to test the amount of organic material remaining on the surface of the endoscopes after cleaning and HLD.
- Four GI endoscopes used on October 29, 2010, were not soaked for 10 hours at the correct temperature and concentration of enzymatic solution and that these endoscopes were not properly identified.
- The delayed reprocessing of bronchoscopes used during mid-December 2010 in the intensive care unit was not consistent with MI and that Sacramento VAMC staff failed to maintain the required records of the use of each endoscope, which should have included patient identifying information, the type of procedure performed, the temperature of the enzymatic solution, and procedure consent forms for non-emergent procedures. The complainant further stated that an Administrative Investigation Board (AIB)[6] was convened to address the bronchoscope issues but this AIB was later cancelled with no actions taken.

[5] Number of viable microorganisms of organic material (blood, body fluids) found on an object.
[6] VHA Handbook 0700 establishes requirements and procedures for AIBs.

- The system SPS Chief failed to ensure that logs of all testing procedures contained complete information.
- Suction canisters (used during endoscopic procedures to collect blood and body fluids removed from the patient) and tubing were only changed when the canisters were full or at the end of the day, contrary to best practice.
- Basins (used in the procedure room to allow immediate pre-cleaning of endoscopes) were used for multiple procedures during the day and discarded at the end of the day, contrary to best practice.
- The KV-5 suction machine (used on endoscopes during the pre-cleaning step) received in May 2010 at Sacramento VAMC was immediately placed into use in the GI department. However, there were delays in early December 2010, in placing a second suction machine into use at Sacramento VAMC's SPS department, as well as placing a suction machine into use at Martinez OPC and Redding CBOC.
- Three SPS staff at Martinez OPC completed more than 25 staff competencies in 1 day in 2010.
- The system SPS Chief did not complete any competencies after assuming the position.
- The system Associate SPS Chief did not complete competencies for fiscal year (FY) 2011.
- RME reprocessing staff were consistently asked to sign blank competency forms.
- Many of the competencies had erroneous or incomplete information.
- Competency forms contained three types of sterilization, allowing technicians to determine the method of sterilization, thereby promoting unnecessary or potentially confusing variations in practice.
- The RME Locator List did not identify critical pieces of RME at Martinez OPC.
- The system SPS Chief's selection and promotion were inappropriate.

Scope and Methodology

We reviewed VHA directives, handbooks, and memoranda, and CDC recommendations, including:

- VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities,* February 9, 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.

- Acting Deputy Under Secretary for Health for Operations and Management and Chief Patient Care Services Officer, "Clarification of Organizational Hierarchy for Supply, Processing and Distribution (SPD) Line Authority and Clarification of Some Terminology," Memorandum, July 10, 2009.
- Deputy Under Secretary for Health for Operations and Management, "Use of Enzymatic Foams and Gels for the Processing of Reusable Medical, Surgical, and Dental Instruments," Memorandum, July 23, 2010.
- Assistant Deputy Under Secretary for Health for Clinical Operations, "Change in Format and Structure for FY 2012 SPD Inspections," Memorandum, October 25, 2011.
- Assistant Deputy Under Secretary for Health for Clinical Operations, "Review of Standard Operating Procedures in Sterile Processing Services," Memorandum, January 23, 2012.
- CDC, *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.*

We also reviewed the following documents:

- SOPs and MI for selected pieces of RME.
- Steam sterilization logs.
- Automatic endoscope reprocesser logs.
- GI endoscope bioburden test results.
- RME policies.
- Infection Control (IC) Committee minutes.
- RME Committee minutes.
- Executive-level committee minutes related to RME issues.
- Reports of contact involving RME issues.
- Root cause analysis reports involving RME issues.
- Patient safety/incident reports involving RME issues.
- IC documentation involving RME-related infections.
- Training and competency records for FYs 2010 and 2011.
- System and VISN SPS inspection reports.

We interviewed the complainant prior to performing a site visit. We visited the Sacramento VAMC, Martinez OPC, and the McClellan and Redding CBOCs April 9–12, 2012. We toured the SPS and endoscopy areas at each location and interviewed the following individuals:

- System leadership.
- System infectious diseases staff, the system patient safety manager, and the system quality manager.
- System SPS Chief and Associate Chief.
- Sacramento VAMC operating room nurse manager.
- System endoscopy unit managers.

- System staff engaged in RME reprocessing activities.

We communicated extensively with RME manufacturers to clarify their recommendations for proper cleaning, disinfection, and sterilization of specific devices between patient use. We also communicated with a VHA program manager[7] regarding the requirement for competency validations and with a subject matter expert[8] regarding sterilization parameters.

The allegation regarding the selection and promotion of the system SPS Chief is outside the scope of this review. The Office of Personnel Management and VHA have specific regulations governing employee recruitment and selection process.

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

A: Sterilization Practices for Selected RME

Olympus Endoscopes, Telescopes, and Accessories

We did not substantiate the allegation that several critical pieces of RME from the Olympus company were sterilized incorrectly in a pre-vacuum sterilizer for 4 minutes at 270°F at Sacramento VAMC and Martinez OPC.

Prior to March 2009, Olympus MI required that endoscopes be sterilized for 5 minutes at 273°F. On March 16, 2009, Olympus announced that sterilization parameters of 4 minutes at 270°F and 3 minutes at 275°F were acceptable for all Olympus autoclavable[9] products (including endoscopes). The sterilization logs we reviewed indicated that the endoscopes were sterilized for 4 minutes at 270°F. On November 21, 2011, Olympus added yet another sterilization parameter of 4 minutes at 275°F for pre-vacuum sterilizers but maintained the parameters of 4 minutes at 270°F and 3 minutes at 275°F for autoclavable products.

Olympus KV-5 Suction Machine

We could neither confirm nor refute the allegation that the device was incorrectly sterilized because none of the sterilization logs we reviewed documented the KV-5 suction machine's sterilization.

[7] The Deputy Director, VHA National Office for Sterile Processing Services.
[8] Hospital epidemiologist, University of North Caroline Health Care System, and co-author of the CDC *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008.
[9] Devices that are designed to withstand high-temperature steam under pressure.

Phaco Alcon Handpiece, Midwest Dental Handpiece, and Padgett Dermatome

We substantiated the allegation that the Phaco Alcon handpiece was sterilized for 4 minutes at 270°F at Sacramento VAMC and Martinez OPC although the SOP and competency required 5 minutes at 270°F and the MI required 5 minutes at 273°F.

We substantiated that the Midwest dental handpiece was not sterilized according to the MI of 15 minutes at 275°F at Martinez OPC and McClellan and Redding CBOCs.

Despite multiple attempts, we were unable to obtain guidance from the manufacturers to clarify any additional sterilization parameters for the Phaco Alcon handpiece and Midwest dental handpiece.

We did not substantiate that the Padgett Dermatome was not sterilized according to MI at Sacramento VAMC. The complainant stated that the MI required that this device be sterilized for 30 minutes at 250°F; however, we found that this requirement is for a gravity displacement sterilizer. We obtained additional information from the manufacturer which also allowed sterilization for 4 minutes at 270°F in a pre-vacuum sterilizer. Sacramento VAMC's sterilization logs indicated that the latter method was used.

We could neither confirm nor refute the allegation that a sticker attached to the Padget Dermatome inhibited proper sterilization. At the time of our site visit, there was no sticker on the device.

In addition to the sterilization practices identified for the subject RME above, we found inconsistent information between MI, SOPs, and sterilization logs. Table 2 on the next page describes these inconsistencies. (Sterilization parameters are for a pre-vacuum sterilizer except where indicated. As of March 16, 2009, additional sterilization parameters from Olympus apply to all Olympus autoclavable devices.)

RME	MI	SOP	Sterilization logs
Olympus endoscopes and telescopes	5 minutes, 273°F (before March 2009) 4 minutes, 270°F and 3 minutes, 275°F (as of March 16, 2009) 4 minutes, 275°F (as of November 2011)	5 minutes, 273°F	4 minutes, 270°F
Olympus device accessories	5 minutes, 270–274°F (before March 2009)	4 minutes, 270°F	5 minutes, 270°F
Olympus KV-5 suction machine	Not to exceed 279°F (no time) (before March 2009)	4 minutes, not to exceed 279°F	Logs reviewed did not contain this device
Phaco Alcon handpiece	5 minutes, 273°F	5 minutes, 270°F	4 minutes, 270°F
Midwest dental handpiece	15 minutes, 275°F	15 minutes, 270°F	4 minutes, 270°F
Padgett Dermatome	4 minutes, 270°F 30 minutes, 250°F (gravity displacement)	30 minutes, 250°F (gravity displacement)	4 minutes, 270°F

Table 2. Sterilization parameters based on MI, SOPs, and sterilization logs for the subject RME.

B: Bioburden Testing of GI Endoscopes

We substantiated the allegation that bioburden testing of GI endoscopes was not conducted on all endoscopes and that SPS failed to order sufficient testing supplies to test all of the endoscopes. However, we determined that system leadership was aware of this allegation prior to our review and had already taken the necessary steps to correct these deficiencies.

VHA policy highly recommends that bioburden testing be conducted on endoscopes that have been used for biopsy.[10] Although VHA policy does not address the extent of testing, local policy requires that all (100 percent) endoscopes be tested for the presence of bioburden prior to HLD.[11] System leadership clarified that the requirement to test all endoscopes is a system goal and that it exceeds VISN 21 requirement of 10 percent

[10] VHA Directive 2009-031.
[11] Chief of SPD, Northern California Health Care System, *Clarification Memo of the Ruhof ATP Testing Procedure*, October 20, 2010.

testing per month. We confirmed that VISN 21 SPS Management Board accepted and implemented this threshold on January 12, 2010.

We reviewed the GI monthly Quality Assurance records for calendar year 2011. We found that staff did not consistently test all GI endoscopes at the Sacramento VAMC and Redding CBOC. System managers told us that these deficiencies occurred because of technical difficulties with the hand held devices and the lack of a back-up device at the CBOC. We found several emails between system managers and the manufacturer demonstrating joint efforts to correct the problems with the testing devices.

At Redding CBOC, GI department construction was started on August 24, 2011. While under construction, no endoscopes were used and no reprocessing or testing of GI endoscope occurred. Endoscope reprocessing and testing was resumed in December 2011. Table 3 below shows percentage of endoscopes tested at the system.

Calendar Year 2011	**Percent of Endoscopes Tested**		
	Sacramento	**Martinez**	**Redding**
January	52	98	100
February	62	100	100
March	86	100	91
April	89	100	100
May	70	100	100
June	98	100	100
July	100	100	35 (no back up device)
August	100	100	100 (August 1 thru 23)
September	100	100	Under construction
October	100	100	Under construction
November	100	100	Under construction
December	100	100	100

Table 3. Endoscope testing rates.

C: Delayed Reprocessing of Endoscopes and Documentation

Reprocessing of GI Endoscopes

Due to conflicting information between the records we reviewed and the information from a report of contact (ROC)[12] submitted by a GI staff member, we could neither confirm nor refute the allegation that four GI endoscopes used on October 29, 2010, were not soaked for the required 10 hours at the correct temperature and concentration of enzymatic solution, and that these endoscopes were not properly identified.

MI require endoscopes to undergo initial cleaning immediately after use to remove bioburden. In the event of a reprocessing delay, MI require that endoscopes be soaked in an enzymatic solution for 10 hours.

In late November 2010, a GI staff member submitted the above mentioned ROC documenting performing the manual cleaning of the subject endoscopes and soaking them in water because the enzymatic solution "eats away at the lining of the scopes." The endoscopes were then placed in a sink in which the temperature was not monitored. There was a delay of unknown duration prior to soaking the endoscopes. After the delay, according to ROC, the processing soak times ranged from 3 hours and 47 minutes to 4 hours and 4 minutes. This information was inconsistent with the endoscope tracking records provided to us, which stated that each endoscope was soaked for 10 hours. These records also documented patient identification, endoscope identifiers, reprocessor identification, cycle count, and operator initials on the endoscope reprocessing tracking records, as required.[13] However, we could not determine the temperature and concentration of the enzymatic solution because these were not documented.

Reprocessing of Bronchoscopes

We substantiated the allegation that the delayed reprocessing of bronchoscopes used during mid-December 2010 at Sacramento VAMC intensive care unit was inconsistent with the MI and that staff did not consistently record patient identifying information. However, we did not substantiate the allegation that the procedure type was not documented. We also substantiated the allegation that an AIB scheduled to investigate GI staff failure to follow MI was cancelled with no actions taken. We found that recording the presence of procedure consent forms and temperature of the enzymatic solution were not required for RME reprocessing documentation.

MI requires that bronchoscopes be soaked in an enzymatic solution for 1 hour in the event of a reprocessing delay. Records we reviewed showed that bronchoscopes were soaked for 10 hours. The reprocessing tracking records we reviewed had no patient

[12] The ROC documented the elapsed time when the endoscopes were last used and when a GI staff was notified that the endoscopes required reprocessing.
[13] VHA Directive 2009-031.

identifying information; however, the bronchoscope serial number, cycle count, time the cycle started, and date and time of initiation of delayed soak time were appropriately documented.

In January 2011, the VISN chartered an AIB consisting of subject matter experts from the VHA National Infectious Disease to assess GI staff RME reprocessing competencies. On January 27, 2011, the AIB leader recommended suspending the AIB because the team did not find evidence of malicious intent or criminal activity. The team identified system issues but concluded that "steps have been developed to surpass all processing requirements."

D: Ambulatory Endoscopy Unit Documentation and Practices

Oversight of Endoscopy Reprocessing Documentation

We substantiated the allegation that the SPS Chief failed to ensure that reprocessing logs of all testing procedures contained complete information.

We reviewed the endoscopy reprocessing tracking records for three randomly selected days in 2011: February 2, March 28, and July 20. Our review of 66 records found that 12 (18 percent) had incomplete information. Documentation compliance is described in Table 4 below.

	Sacramento	**Martinez**	**Redding**
Number of records reviewed	41	15	10
Evidence of documentation of the following elements:			
Procedure type	41	15	10
Serial number or endoscope identification	41	15	10
Date	41	15	10
Operator and Time	36	15	10
Time only	38	15	10
Patient identifier	40	12	10
Results of tests	41	15	10
Summary			
Noncompliant records	9	3	0

Table 4. Reprocessing tracking record documentation compliance.

Suction Canisters and Tubings Not Changed Between Patients

We could neither confirm nor refute the allegation that suction canisters (used during endoscopic procedures to collect blood and body fluids) and tubing were only routinely changed when the canisters were full or at the end of the day, contrary to best practice.

The local policy requires staff to change suction containers only "when full." While GI staff we interviewed reported that it has been their practice to change the suction canisters and tubings between patients since 2008, they told us that they were aware of instances when the suction canisters and tubings were not changed between patients.

Basins for Pre-Cleaning GI Endoscopes Not Changed Between Each Patient Use

We substantiated that basins (used in the procedure room to perform immediate pre-cleaning of endoscopes) were not changed between each patient use and were only discarded at the end of the day, contrary to best practice. However, we did not find evidence that this practice compromised patient safety.

We noted that in April 2012, the system implemented single-use disposable kits for endoscope pre-cleaning. This new process eliminates the use of basins for pre-cleaning.

System Placement of KV-5 Suction Machines

Although we substantiated the allegation that the KV-5 suction machines were not placed into use simultaneously at Sacramento VAMC's SPS department, Martinez OPC, and Redding CBOC, the system leadership took appropriate action and reported the delay to VHA.

The KV-5 suction machine (used on endoscopes during the pre-cleaning phase) provides a second flushing to reduce the amount of bioburden inside the endoscopes. In an Issue Brief on December 16, 2010, system leadership reported to VHA that there was a distribution delay for the KV-5 suction machines ordered in July 2009. The machines were reportedly placed into use "in GI" on October 29, 2010. However, it was not clear if the units were distributed to all locations simultaneously. The Issue Brief stated that prior to receiving the machines, staff increased flushing time using another device to increase the pressure for flushing and aid in the removal of bioburden from the interior surfaces of the endoscopes.

E: Competencies

Staff Competencies

We substantiated the allegation that SPS staff at Martinez OPC completed more than 25 competencies in 1 day in 2010.

We found that two of the three SPS staff completed competencies for 24–26 pieces of RME on January 26, 2010. Staff told us the VISN advised SPS management to discontinue this practice on April 11, 2010.

SPS Chief and Associate Chief Competencies

We substantiated the allegations that the SPS Chief had not completed any competencies since assuming the position and that the Associate SPS Chief had not completed competencies for FY 2011. However, system leadership clarified that technical competencies, such as reprocessing of RME, are not required for the SPS Chief because the position is strictly administrative.

VHA defines "competency" 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 task or responsibility." VHA requires the System Director to ensure that there is a process and accountability for validating continued staff competency at least annually.[14]

We found that the Associate SPS Chief and the supervisory GI technician did not have any competencies documented for FY 2011. While we were onsite, system staff told us that VHA had not provided guidance on who should validate the competencies of the Associate SPS Chief, and supervisory GI technician. According to the Deputy Director, VHA National Office for SPS, competency assessments must be done by SPS staff familiar and experienced with the competency being assessed. They can be done by a supervisor, director, educator, or any competent and motivated technician.

Signing of Blank Competency Forms

We did not substantiate the allegation that RME reprocessing staff were consistently asked to sign blank competency forms. Although 1 of the 12 staff interviewed acknowledged signing blank competency forms "because of the 'employee's Operating Room' experience," we found no evidence that staff were consistently asked to sign blank competency forms.

[14] VHA Directive 2009-004.

Erroneous or Incomplete Information on Competency Forms

We could neither confirm nor refute the allegation that many of the competencies had erroneous or incomplete information. We did not substantiate that competency forms contained three options for sterilization, allowing staff to determine the method of sterilization, promoting an unnecessary variation in practice.

F: RME Locator List

RME Locator List Did Not Identify Critical Pieces of RME at the Martinez OPC

We did not substantiate this allegation. Local policy requires the RME locator list to include items listed by department and location and to include the type of RME, manufacturer, and model number.[15] The RME locator list provided by the facility contained the required information.

Conclusions

We concluded that the system generally complied with the MI sterilization parameters for the Olympus and Padgett Dermatome devices.

However, we found that the system's sterilization processes for the Phaco Alcon and Midwest dental handpieces were inconsistent with the MI. Nevertheless, these devices were sterilized using the CDC's minimum exposure recommendations of 4 minutes at 270°F in a pre-vacuum sterilizer.

We determined that the system's SOPs and sterilization logs were generally inconsistent with the MI. We substantiated the allegations related to bioburden testing, delayed reprocessing, endoscope reprocessing documentation, and staff competencies. We also found improvement opportunities regarding proper use and care of suction canisters and other accessories. We concluded that these issues were primarily due to the lack of effective oversight by supervisory staff.

Recommendation

The VISN Director requires the System Director to review the findings in this report and take steps to correct all identified deficiencies

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our findings and recommendation and provided acceptable improvement plans. (See

[15] VANCHCS Policy 118-34, September 20, 2010.

Appendixes A and B, pages 17–21, for the full text of 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 21 Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 2, 2012

From: Director, VA Sierra Pacific Network (10N21)

Subject: Reusable Medical Equipment Issues, VA Northern California Health Care System, Sacramento, CA.

To: Director, Los Angeles Office of Healthcare Inspections (54LA)

Thru: Director, VHA Management Review Service (VHA 10AR MRS)

1. Thank you for the opportunity to review the draft OIG Hotline report for VA Northern California Health Care System regarding various RME issues.

2. Attached is the action plan the facility developed. I am sure the actions they have put into place will prevent any reoccurrences in the future.

3. Should you have any questions, please contact Terry Sanders, Associate Quality Manager at (707) 562-8370.

(original signed by:)

Sheila M. Cullen

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 1, 2012

From: Director, VA Northern California Health Care System (612/00)

Subject: Reusable Medical Equipment Issues at the VA Northern California Health Care System, Sacramento, CA.

To: Director, VA Sierra Pacific Network (10N21)

1. Thank you for the opportunity to review the OIG report on the Reusable Medical Equipment issues at Northern California Health Care System. We concur with the recommendations, and will ensure completion as described in the implementation plan.

2. Please find attached our responses to recommendation provided in the attached implementation plan.

3. If you have any questions regarding the response to the recommendations in the report, feel free to call me at (916) 843-9058.

(original signed by:)

Brian J. O'Neill, M.D.
Director, Northern California Health Care System

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

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendation

The VISN Director requires the System Director to review the findings in this report and take steps to correct all deficiencies identified in this report.

Concur

Target Completion Date: January 31, 2013

Response: VA NCHCS has implemented corrective actions and monitors to ensure improvements and compliance with report findings and recommendation. See attached action plan**.**

OIG RME Action Plan Response 2012 10-02

Findings	Facility Actions	Target date
The Phaco Alcon hand piece was sterilized for 4 minutes at 270°F at Sacramento VAMC and Martinez OPC although the SOP and competency required 5 minutes at 273°F.	***Corrective Action*** - 1. Replacement Steam Sterilizer May 2012. Replacement sterilizer allows for temperature settings at 273°F and 275°F. 2. NCHCS SPS staff re-trained April 6 & 20, 2012, in the proper reprocessing of complex surgical instruments. 3. Instituted daily inspections of reprocessing documentation for Phaco Alcon Hand pieces to ensure sterilization according to the MI. 4. SPS Chief will continue to monitor compliance and report findings to the Infection Control Committee for 4 months.	1/15/2013
The Midwest dental hand piece was not sterilized according to the MI at Martinez OPC and McClellan and Redding CBOCs.	***Corrective Action*** - 1. Replacement Steam Sterilizer May 2012. Replacement sterilizer allows for temperature settings at 273°F and 275°F. 2. NCHCS SPS staff re-trained April 6 & 20, 2012, in the proper reprocessing of complex surgical instruments. 3. Instituted daily inspections of reprocessing documentation for Midwest Dental Hand pieces to ensure sterilization according to the MI. 4. SPS Chief will continue to monitor compliance and report findings to the Infection Control Committee for 4 months.	1/15/2013
The delayed reprocessing of bronchoscopes used during mid-December 2010 in the intensive care unit was not consistent with MI and that Sacramento VAMC staff failed to maintain the required records of the use of each endoscope, which should have included patient identifying information, the type of procedure performed, the temperature of the enzymatic solution, and procedure consent forms for non-emergent procedures. The complainant further stated that an Administrative Investigation Board (AIB) was convened to address the bronchoscope issues but this AIB was later cancelled with no actions taken.	1. SOP and for Autoclavable Bronchoscope RME Olympus 600 Reprocessing has been revised to reflect manufactures instruction parameters and instructions on delayed reprocessing. 2. Reinforcement education provided to ensure understanding of documentation requirements and expectations for delayed reprocessing procedures, in accordance with VHA Directive 2009-031, the following is required for reprocessing records: testing procedure(s), locations, the serial number or unique identifier for scopes, solution lot numbers, identification of automated washer or disinfectors, the results of the testing, and any actions taken. 3. Patient identifying information is documented by clinical staff in the CPRS record, which captures the unique identifier for scopes for procedures. Bronchoscopy procedure note template will be revised to include a field to capture the scope information into the procedure note as a forced function which must be completed to sign the note. 4. April 20, 2011, SPS purchased devices that provides pre-measured enzymatic solution and monitors water temperature. 5. SPS Chief will continue to monitor compliance with delayed reprocessing and documentation and report findings to the Infection Control Committee for 4 months.	1/15/2013

Findings	Facility Actions	Target date
The system SPS Chief failed to ensure that logs of all testing procedures contained complete information.	1. Staff re-educated on documentation requirements for reprocessing in accordance with VHA Directive 2009 031. 2. Reinforcement education will be provided initially and as needed for new staff to ensure understanding of documentation requirements and expectations. 3. Institute daily reviews of documentation to ensure requirements are complete. 4. SPS Chief will monitor compliance and report findings to the Infection Control Committee for 4 months.	1/15/2013
The system Associate SPS Chief did not complete competencies for fiscal year (FY) 2011.	1. SPS Associate Chief competencies will be reviewed to ensure competency requirements are complete. 2. Competency training plan developed for with a target completion date of 01/31/2013.	1/15/2013

Appendix C

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	George Wesley, MD, Project Leader Kathi Shimoda, RN, BSN Team Leader Stephanie Hensel, RN, JD Deborah Howard, RN, MSN Mary Toy, RN, MSN

Appendix D

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