Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-02634-397

Healthcare Inspection

Alleged Improper Maintenance of Reprocessing Equipment Huntington VA Medical Center Huntington, West Virginia

June 25, 2015

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to complaints concerning responsibility for and proper maintenance of the MEDIVATORS Advantage Plus Endoscope Reprocessing System® at the Huntington VA Medical Center (facility), Huntington, WV.

We did not substantiate the allegation that staff responsible for cleaning gastrointestinal endoscopes failed to perform required maintenance on reprocessing equipment by not replacing filters. We did not find documentation to support that the reprocessing equipment became clogged and potentially created a patient safety risk.

We did not substantiate the allegation that replacing filters on the reprocessing equipment is the responsibility of Sterile Processing Service staff rather than Biomedical Engineering staff. Facility policy states that reprocessing equipment filters will be changed by Biomedical Engineering staff.

We made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report. (See Appendixes A and B, pages 5–6 for the Directors' comments.) No further action is required.

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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection in response to allegations concerning responsibility for and proper maintenance of the MEDIVATORS Advantage Plus Endoscope Reprocessing System® (reprocessing equipment)[1] at the Huntington VA Medical Center (facility), Huntington, WV. The purpose of this review was to determine the merit of the allegations.

Background

The facility is a fully accredited 80-bed acute care facility providing medical and surgical inpatient care, in addition to primary and specialized outpatient care. The facility has VA-staffed community based outpatient clinics in Prestonsburg, KY, serving eastern Kentucky veterans, and Charleston, WV, serving Kanawha County veterans. The facility is part of Veterans Integrated Service Network (VISN) 9.

Allegations. The complainant alleged that:

- Staff responsible for the cleaning of gastrointestinal (GI) endoscopes failed to perform required maintenance on the reprocessing equipment by not replacing filters, causing the reprocessing equipment to become clogged and preventing the final rinse cycle from being performed for an unknown period of time and potentially creating a patient safety risk.

- Replacing filters on the reprocessing equipment is the responsibility of Sterile Processing Service (SPS) staff rather than Biomedical Engineering (BME) staff, and by not requiring SPS staff to perform and document routine maintenance, proper functioning of equipment could not be ensured.

Scope and Methodology

The period of our review was April 2014 to March 2015. We conducted telephone interviews April–June 2014 and a site visit in August 2014. We interviewed the complainant, Facility Director, Associate Director for Patient Care Services, Chief of Sterile Processing Service, and Chief of Engineering. We reviewed relevant Veterans Health Administration (VHA) and facility policies, the MEDIVATORS Advantage Plus Endoscope Reprocessing System® Service Manual (manufacturer's guidelines), standard operating procedures, filter change logs, water line disinfect cycle logs, employee training records/competencies, and other relevant documents.

[1] Specialized medical equipment used to disinfect and sterilize endoscopic equipment. Product information available at: www.medivators.com. Accessed January 15, 2015.

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

Inspection Results

VHA Directive 2009-031*, Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements* (June 26, 2009), states that reprocessing of reusable medical equipment is a key component to ensuring patient and staff safety and therefore must be performed to exacting standards.[2]

Reprocessing equipment is intended for the washing and high level disinfection of endoscopes after GI procedures. The facility has four MEDIVATORS Advantage Plus Endoscope Reprocessing Systems®—two in SPS and two in the GI Suite. The reprocessing equipment located in the SPS department was installed in August 2011. The reprocessing equipment located in the GI Suite was installed in August 2013 and first used in October 2013.

The manufacturer's guidelines recommend that the facility conduct regular training for all personnel who will operate and maintain the reprocessing equipment. Training should include emergency procedures for toxic, flammable, or pathogenic material released into the environment. Records of attendance at training sessions should be maintained and evidence of understanding documented.

Issue 1: Maintenance

Patient Safety Risk

We did not substantiate the allegation that patients were placed at risk by filters being clogged for an unknown period of time. According to the manufacturer's guidelines, if an error occurs during a disinfection cycle, the program ends and fluids are drained from the basin. A recovery program runs until a safe state is reached and the endoscope can be removed. The recovery program cannot be stopped by the operator. Additionally, when an error occurs, an alarm sounds and the reprocessing equipment cannot be restarted until all errors are corrected.

Filter Replacement

We did not substantiate the allegation that reprocessing equipment filters were not replaced. The manufacturer's guidelines and local policy require that the filters are replaced every 3 to 6 months. Local policy dictates that BME staff is responsible for replacing the filters. A water line and water filtration disinfection process must be performed whenever a water filter is replaced. We found documentation indicating the filters were being changed at appropriate intervals.

[2] VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements*, June 26, 2009. This Directive expired February 28, 2014 and has not yet been updated.

Clogged Filters

We did not substantiate that the reprocessing equipment had clogged filters. The complainant provided no specific information on which piece of reprocessing equipment was clogged or dates when the clogs occurred. A facility review of engineering work orders submitted for the last year did not reveal any work orders submitted for repair or replacement of reprocessing equipment filters.

Issue 2: Staff Responsibility To Change Filters

We did not substantiate the allegation that SPS staff failed to change filters as required. We found that there was disagreement between SPS and BME staff over who was responsible for changing the filters. Before the installation of new reprocessing equipment, SPS staff changed filters on the old reprocessing equipment they used because no tools were needed to change the filters. When the new reprocessing equipment was received by the facility in 2011, BME staff were given the responsibility to change all filters since the process required more technical skill and the use of tools. Facility leadership told us that a vendor representative trained BME staff on how to change the filters. Despite this training, BME staff consistently refused to change the filters. This refusal led to a 9-day delay in changing the filters.

In December 2013, facility leadership directed that BME staff would be responsible for changing reprocessing equipment filters. The Chief of Engineering verbally informed BME supervisors that it was a BME staff responsibility to change the filters. The issue resurfaced in April 2014, and the Chief of Engineering sent an e-mail to BME supervisors giving detailed expectations that BME staff would change the filters. These issues were discussed with facility leadership, and corrective actions have been addressed. Facility policy states that BME staff will change the filters. The Chief of Engineering produced explicit written guidelines in April 2014 for BME staff responsible for changing the reprocessing equipment filters, and detailed in-service training on how to change the filters was conducted in June 2014. During an August 2014 site visit, we inspected the area where reprocessing equipment is located. Review of the filter change log showed that filters were changed and the process was adequately documented.

Conclusions

We did not substantiate that staff responsible for cleaning the GI scopes failed to perform required maintenance on reprocessing equipment by not replacing filters. We did not find evidence to support that reprocessing equipment became clogged and potentially created a patient safety risk.

We did not substantiate that replacing filters on the reprocessing equipment is the responsibility of SPS staff and not BME staff. Facility policy states that reprocessing equipment filters will be changed by BME staff.

We made no recommendations.

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: May 27, 2015

From: Director, VA Mid South Healthcare Network (10N9)

Subj: Healthcare Inspection—Alleged Improper Maintenance of Reprocessing Equipment, Huntington VA Medical Center, Huntington, West Virginia

To: Director, Washington DC Office of Healthcare Inspections (54DC)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the draft report and concur with the report's findings. Attached is the facility's response for the report's findings.

2. If you have any questions or need additional information, contact Shellena Storey, Deputy Quality Management Office, VISN 9 at 615-695-2206.

(*original signed by*:)
John E. Patrick
Network Director

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: May 19, 2015

From: Director, Huntington VA Medical Center, Huntington, WV (581/00)

Subj: Healthcare Inspection—Alleged Improper Maintenance of Reprocessing Equipment, Huntington VA Medical Center, Huntington, West Virginia

To: Director, VA Mid South Healthcare Network (10N9)

Thank you for the OIG Healthcare Inspection related to the alleged improper maintenance of reprocessing equipment at the Huntington VA Medical Center. We appreciate the thorough review and concur with the findings in the report.

(original signed by:)

J. Brian Nimmo
Medical Center Director

OIG Contact and Staff Acknowledgements

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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Appendix D

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