Department of Veterans Affairs
Office of Inspector General

Combined Assessment Program Summary Report

Evaluation of Reusable Medical Equipment Practices in Veterans Health Administration Facilities

Report No. 10-00135-121

March 14, 2011

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections completed an evaluation of Veterans Health Administration (VHA) facilities' reusable medical equipment (RME) practices. The purposes of the evaluation were to determine whether facilities: (1) complied with local and selected VHA standards for RME sterilization and high-level disinfection, (2) provided and documented annual training for employees who perform RME reprocessing activities, and (3) assessed and documented annual competencies for employees who perform RME reprocessing activities.

Inspectors evaluated RME practices at 45 facilities during Combined Assessment Program reviews conducted from January 1 through September 30, 2010.

VHA facilities recognized the importance of maintaining consistent RME practices to ensure patients' safety. Despite VHA's efforts to fully comply with proper reprocessing procedures, problems in RME practices continue to occur. It is appropriate at this time to consider changes to the current management approach to ensure that RME is properly reprocessed. The identification of technology needs, changes in personnel policies, and changes in procurement strategies are among the areas that VA should review. We identified six areas where compliance with RME requirements needs to improve. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that:

- Standard operating procedures (SOPs) are current, consistent with manufacturers' instructions, and located within the reprocessing areas.
- Employees consistently follow SOPs, supervisors monitor compliance, and annual training and competency assessments are completed and documented.
- Flash sterilization is used only in emergent situations, supervisors monitor compliance, and managers assess and document annual competencies for employees who perform flash sterilization.
- Appropriate personal protective equipment is donned before entering and worn in decontamination areas.
- Ventilation systems are inspected and filters are changed quarterly in all reprocessing areas and that temperature and humidity are monitored and maintained within acceptable ranges in sterile storage areas.
- Processes for consistent internal oversight of RME activities are established to ensure senior management involvement.

The Under Secretary for Health concurred with the findings and recommendations. The implementation plan is acceptable, and we will follow up until all actions are complete.

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

TO: Under Secretary for Health (10)

SUBJECT: Combined Assessment Program Summary Report – Evaluation of Reusable Medical Equipment Practices in Veterans Health Administration Facilities

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) evaluated Veterans Health Administration (VHA) facilities' practices related to the cleaning, disinfecting, and sterilization of reusable medical equipment (RME). The purposes of the evaluation were to determine whether facilities: (1) complied with local and selected VHA standards for RME sterilization and high-level disinfection, (2) provided and documented annual training for employees who perform RME reprocessing activities (cleaning, disinfecting, and sterilizing), and (3) assessed and documented annual competencies for employees who perform RME reprocessing activities.

Background

In 2009, the Secretary and the Chairmen of VA oversight committees requested the OIG to assess the extent of problems related to reprocessing of endoscopic equipment within VHA facilities. OHI's inspection[1] determined that facilities had not complied with VA directives regarding the reprocessing of endoscopes, resulting in a risk of infectious disease to patients. OHI also performed an inspection on colonoscope reprocessing[2] to determine compliance with requirements for standard operating procedures (SOPs) and employee competency assessment. We determined that all 129 facilities inspected were compliant with respect to SOPs and that 128 facilities had adequate documentation of demonstrated competence for reprocessing staff. Because of identified problems with

[1] *Healthcare Inspection – Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, Report No. 09-01784-146, June 16, 2009.
[2] Healthcare *Inspection – Follow-Up Colonoscope Reprocessing at VA Medical Facilities*, Report No. 09-02848-218, September 17, 2009.

endoscope reprocessing in these reports and because of other OHI inspections identifying RME issues, we identified a need for further evaluation of reprocessing practices at VHA medical facilities.

Definitions

1. **RME:** Any piece of medical equipment designed by the manufacturer to be reused for multiple patients.

2. **High-level disinfection:** A process that eliminates many pathogenic microorganisms, except bacterial spores, on inanimate objects.

3. **Sterilization:** A process that destroys or eliminates all forms of microbial life.

4. **Decontamination:** A process of cleaning and disinfecting medical supplies and equipment.

5. **Flash sterilization:** An abbreviated sterilization process to be used during surgical procedures only in emergent situations, such as when a sterilized instrument is dropped.

6. **Personal protective equipment (PPE):** Special attire, such as masks, gloves, gowns, and head and shoe coverings, used to protect employees from exposure to contaminates during RME cleaning.

7. **SOP:** A written document containing the specific steps in completing a task. SOPs are important as a reference for staff who reprocess RME. They should be located in reprocessing areas for quick reference.

8. **Manufacturers' instructions:** Tested and validated instructions developed by the manufacturer to prepare the device for reuse.

Scope and Methodology

Inspectors evaluated RME processes at 45 facilities during Combined Assessment Program (CAP) reviews conducted from January 1 through September 30, 2010. The facilities reviewed represented a mix of size, affiliation, geographic location, and Veterans Integrated Service Networks (VISNs). We interviewed selected program managers and reviewed documents, including facility self-assessments, RME-related policies and SOPs, manufacturers' instructions, meeting minutes, employee training records and competency folders, and other documentation related to RME reprocessing. We also observed employees clean the following RME:

- Bronchoscopes
- Colonoscopes
- Cystoscopes

- Laparoscopes
- Gastroenterology (GI) biopsy forceps
- Biopsy probes
- Dental instruments
- Orthopedic instruments
- Surgical instruments
- Transesophageal echocardiography probes
- Bladder scanners
- Echo ultrasound scanners
- Hemodialysis machines (internal pathways)

Additionally, we conducted inspections of the following RME reprocessing areas:

- Supply, Processing, and Distribution (SPD)
- Operating Room (OR)
- Bronchoscopy
- GI/Endoscopy
- Genitourinary (GU)/Urology

We generated an individual CAP report for each facility. For this report, we analyzed the data from the individual facility CAP reviews to identify system-wide trends.

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

Inspection Results

Issue 1: SOPs

VHA requires that SOPs be current and consistent with manufacturers' instructions.[3] It is important that SOPs mirror manufacturers' instructions because improper reprocessing could result in transmission of pathogens to patients and affect the functionality of the RME item. We reviewed 300 SOPs and determined that 279 (93 percent) were current and that 261 (87 percent) were consistent with manufacturers' instructions.

VHA also requires that SOPs be located within reprocessing areas for easy reference by employees.[4] Of the 300 SOPs reviewed, 276 (92 percent) were located within reprocessing areas.

[3] VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements,* June 26, 2009.
[4] VHA Directive 2009-031.

We recommended that SOPs be current, consistent with manufacturers' instructions, and located within the reprocessing areas.

Issue 2: Training and Competency Assessment

VHA requires that staff be trained and follow RME reprocessing SOPs.[5] Additionally, annual competency assessment is required for all employees who reprocess RME.[6]

We made 294 observations of the cleaning step of RME reprocessing and determined that employees followed SOPs in 255 (87 percent) cases. We reviewed training records associated with each observation and found documented annual training in 241 (82 percent) records. Competencies were completed for 255 (87 percent) of the 294 RME items cleaned.

We recommended that employees consistently follow SOPs, that supervisors monitor compliance, and that annual training and competency assessments be completed and documented.

Issue 3: Flash Sterilization

VA requires that flash sterilization only be used in emergent situations during surgical procedures, such as when a sterile instrument is dropped yet still needed, or when there are unplanned emergency procedures requiring the same piece of equipment.[7]

Flash sterilization was used at 34 of the facilities we reviewed. Of these, 19 facilities (56 percent) demonstrated appropriate use of flash sterilization. At the remaining facilities, items that were inappropriately flash sterilized included suction tubes, instrument sets, and forceps.

Employees who perform flash sterilization must have an annual competency assessment for this activity. We reviewed 180 competency folders of employees who performed flash sterilization and found that 147 (82 percent) had documented annual competency assessments.

We recommended that VHA ensure that flash sterilization is used only in emergent situations, that supervisors monitor compliance, and that managers assess and document annual competencies for employees who perform flash sterilization.

[5] VHA Directive 2009-031.
[6] VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities,* February 9, 2009.
[7] VA Handbook 7176, *Supply, Processing and Distribution (SPD) Operational Requirements,* August 16, 2002.

Issue 4: Environment

VA requires that PPE be donned prior to entering and worn while in the decontamination area to protect employees from exposure to contaminates.[8] We inspected 123 decontamination areas and observed that employees in 110 (89 percent) areas appropriately donned PPE prior to entering and wore all required PPE while in the decontamination areas.

VA requires that ventilation systems be inspected and that filters be changed at least quarterly in RME reprocessing areas.[9] The following table shows RME reprocessing areas inspected and compliance rates:

Location	Ventilation System Inspections (percent compliance)	Filter Changes (percent compliance)
SPD	87 (39/45)	87 (39/45)
OR	88 (30/34)	88 (30/34)
Bronchoscopy	65 (11/17)	71 (12/17)
GI/Endoscopy	77 (24/31)	81 (25/31)
GU/Urology	83 (5/6)	83 (5/6)

VA requires that sterile items be stored in controlled conditions that protect against extreme temperatures and humidity. Temperatures must be maintained between 65 and 72 degrees Fahrenheit, and humidity must be 35 to 75 percent.[10] Of the 61 sterile storage areas inspected, 53 (87 percent) were maintained within the acceptable temperature range, and 41 (67 percent) were within acceptable humidity levels.

We recommended that appropriate PPE be donned before entering and worn in decontamination areas. We also recommended that ventilation systems be inspected and filters be changed quarterly in all reprocessing areas and that temperature and humidity be monitored and maintained within acceptable ranges in sterile storage areas.

Issue 5: Reporting to Executive-Level Committee

VHA requires that RME activities, such as validation of staff competency, compliance with established SOPs, results of infection prevention and control monitoring, and risk management activities, be reported to the Executive Committee of the Medical Staff (ECMS).[11] Senior managers must have oversight of RME practices to address identified problems expediently. Without appropriate oversight, patients' safety may be compromised. Of the 45 facilities inspected, 37 (82 percent) had documented ECMS discussions of all required elements.

[8] VA Handbook 7176.
[9] VA Handbook 7176.
[10] VA Handbook 7176.
[11] VHA Directive 2009-004.

We recommended that processes for consistent internal oversight of RME activities be established to ensure senior management involvement.

Conclusions

VHA facilities recognized the importance of safe and consistent RME practices and had taken steps to improve compliance. Despite VHA's efforts to fully comply with proper reprocessing procedures, problems in RME practices continue to occur. It is appropriate at this time to consider changes to the current management approach to ensure that RME is properly reprocessed. The identification of technology needs, changes in personnel policies, and changes in procurement strategies are among the areas that VA should review. Compliance with applicable RME requirements needs to improve in the following areas: (1) SOPs, (2) training and competency assessment, (3) flash sterilization, (4) environment, and (5) reporting to the ECMS.

Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that SOPs are current, consistent with manufacturers' instructions, and located within the reprocessing areas.

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that employees consistently follow SOPs, that supervisors monitor compliance, and that annual training and competency assessments are completed and documented.

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that flash sterilization is used only in emergent situations, that supervisors monitor compliance, and that managers assess and document annual competencies for employees who perform flash sterilization.

Recommendation 4. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that appropriate PPE is donned before entering and worn in decontamination areas.

Recommendation 5. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that ventilation systems are inspected and filters are changed quarterly in all reprocessing areas and that temperature and humidity are monitored and maintained within acceptable ranges in sterile storage areas.

Recommendation 6. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that processes for consistent

internal oversight of RME activities are established to ensure senior management involvement.

Comments

The Under Secretary for Health concurred with the findings and recommendations. The implementation plan is acceptable, and we will follow up until all actions are complete.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: Mar 03, 2011

From: Under Secretary for Health (10)

Subject: **OIG Healthcare Inspection Draft Report – Evaluation of Reusable Medical Equipment Practices in Veterans Health Administration Facilities (VAIQ 7068652)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with all six of the report's recommendations. Attached is the Veterans Health Administration's (VHA) corrective action plan for the report's recommendations.

2. Thank you for the opportunity to review the draft report. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10B5) at (202) 461-7014.

(original signed by:)
Robert A. Petzel, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report: Healthcare Inspection, Evaluation of Reusable Medical Equipment Practices in Veterans Health Administration Facilities

Date of Draft Report: December 20, 2010

Recommendations/ Actions	Status	Completion Date

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that SOPs are current, consistent with manufacturers' instructions, and located within the reprocessing areas.

VHA Comments

Concur

VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements, dated June 26, 2009, requires that standard operating procedures (SOP) be current and consistent with manufacturers' instructions. To ensure compliance with this directive, as well as to ensure that these SOPs are located in the reprocessing areas, the Deputy Under Secretary for Operations and Management (DUSHOM) sent a memo to all Veterans Health Administration (VHA) facilities in October 2010 requiring that facilities perform self-inspections of Sterile Processing Departments (SPD) six times per year and all Veterans Integrated Service Networks (VISNs) to perform inspections three times per year. After reviewing initial facility inspections, SPD Operations identified best practices and compiled these into a standardized data collection tool. This tool was sent to the field on February 14, 2011, and will be used from that date forward for all VISN and facility inspections. This tool requires inspectors to verify that SOPs are in place. The DUSHOM will monitor compliance by reviewing its SharePoint database

to check both for completion of the inspections, as well as to identify systemic issues and trends.

Completed February 14, 2011

In addition, although not required by the Office of Inspector General (OIG), VHA is not only ensuring compliance with existing directives, but is also moving towards standardization of all SOPs for the reprocessing of reusable medical equipment (RME). The National Program Office for Sterile Processing Department (SPD Operations) has contracted with Best Practice Professionals to provide access to the One Sourcedocs database to obtain manufacturers' instructions for use (IFU). This database also provides Tech Ready documents that can be used as the basis for developing SOPs based on the IFUs. VHA will implement the use of these Tech Ready documents as the basis for development of standardized SOPs, beginning no later than June 1, 2011. The use of standardized SOPs is a step toward conformance with the International Organization for Standardization (ISO) 9001-2008 Quality Management Systems (QMS) requirements related to sterile processing. The availability of current IFUs to all facilities enhances efforts to attain standardization. Three (3) training sessions on how to use One Sourcedocs were conducted via webinar with approximately 300 VHA SPD personnel and Nurse Executives attending. Additional training sessions will be scheduled as needed.

For targeted groups of instruments without Tech Ready documents, SPD Operations workgroups have convened to write SOPs. For dental instruments, for example, these SOPs have been drafted and are pending manufacturers' approval prior to deployment to the field.

The Veterans Engineering Resource Centers (VERC) are engaged in many efforts to promote quality reprocessing through technological innovation and process improvement. In particular, VERCs are exploring innovative ways to improve existing SOPs by identifying steps critical to the outcome that require special quality controls and by simplifying and error-proofing SOPs to include novel ways to display processes and make explanations more accessible to the employees who use them.

In process — Use of Tech Ready documents to begin June 1, 2011

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that employees consistently follow SOPs, that supervisors monitor compliance,

and that annual training and competency assessments are completed and documented.

VHA Comments

Concur

The VISN and facility inspection processes described in the response to Recommendation 1 will be used to ensure that employees consistently follow SOPs and that annual training and competency assessments are complete and documented. In addition, staff from SPD Operations within the DUSHOM will perform site visits to provide additional oversight to ensure that annual training and competency assessments are complete. During Fiscal Year (FY) 2010 a total of 22 site visits were performed. To date in FY 2011, a total of eight site visits have been performed with a total of 18 pending visits prior to the end of FY 2011.

In addition, although not required by the OIG, staff in SPD Operations have made numerous improvements to the educational requirements for SPD staff. SPD Operations has partnered with the VHA Office of Clinical Consultation and Compliance (OCCC) to conduct a standardized, extensive educational program and maintain records of attendance through the International Association of Healthcare Central Services Material Management (IAHCSMM). During FY 2010, VHA's own Level 2 training was revised to include a standardized curriculum and certification examination. During FY 2010, four Level 2 classes were offered and attended by more than 200 SPD professionals and managers.

The IAHCSMM recognizes Level 2 certification within VHA as an alternate means of certification. IAHCSMM is an internationally recognized professional organization dedicated to the education and certification of SPD personnel. VA staff are being encouraged to apply for this alternate IAHCSMM certification. In addition, VHA contracted with IAHCSMM to train 71 attendees at a course held on September 24, 2010, and 91 attendees on October 8, 2010.

During FY 2011, VHA has continued to expand its extensive commitment to professional certification and education of its SPD workforce. SPD Operations and OCCC offered two Level 2 classes with two additional classes scheduled for the remainder of FY 2011. One additional IAHCSMM training is being offered by SPD Operations in collaboration with OCCC during the first quarter of FY 2011.

Completed January 2011

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that flash sterilization is used only in emergent situations, that supervisors monitor compliance, and that managers complete and document annual competency assessments for employees who perform flash sterilization.

VHA Comments

Concur

The use of flash sterilization and competencies of employees performing flash sterilization are being monitored during the VISN and facility inspection processes described in the response to Recommendation 1.

Completed February 14, 2011

Recommendation 4: We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that appropriate PPE is donned before entering and worn in decontamination areas.

VHA Comments

Concur

The DUSHOM will clarify the requirements for use of personal protective equipment (PPE) in decontamination areas to implement Code of Federal Regulations (CFR) 1910.1030, Blood Borne Pathogens Standard. This will include initial and annual training about hazards in SPD decontamination arising from blood and body fluids, guidance on what PPE is required to address various exposures and activities, information on appropriate care for injuries from using sharps, and information on the Hepatitis B vaccination requirements.

During its site inspections, SPD Operations will evaluate and enforce these requirements through documentation of the appropriate use of PPE. The VISN and facility inspections, totaling nine per year, will also ensure that employees wear appropriate PPE. Also, training sessions will reinforce the need to wear PPE.

Completed September 30, 2011

Recommendation 5: We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that ventilation systems are inspected and filters are changed quarterly in all

reprocessing areas and that temperature and humidity are monitored and maintained within acceptable ranges in sterile storage areas.

VHA Comments

Concur

To assess the heating, ventilation, and air conditioning (HVAC) needs at the facility level, SPD Operations will survey each VISN about what, if any, HVAC equipment is required to meet the temperature and humidity requirements in SPDs and other areas in the facilities. The DUSHOM will develop an action plan to address any deficiencies noted from the surveys.

In process	Surveys and action plans to be completed by September 30, 2011

Recommendation 6: We recommended that the Under Secretary for Health, in conjunction with VISN and facility senior managers, ensures that processes for consistent internal oversight of RME activities are established to ensure senior management involvement.

VHA Comments

Concur

As described above, a standardized template has been developed and deployed to the field requiring facilities to conduct six inspections per year and VISNs to conduct three unannounced inspections per year (see Recommendation 1). This template may be revised based upon field input and utilization. These inspections are being reviewed, with results tracked and trended at the VA Central Office (VACO) level to refine future oversight methods. Facility and VISN leadership will remain responsible for remedying issues identified during these inspections. Results of the inspections will be reported quarterly, beginning in the third quarter of FY 2011, to senior managers at the local, VISN, and VACO levels. The results will be used to target future RME initiatives. SPD Operations will provide this information to OCCC.

Completed February 14, 2011

Although not required by OIG, OCCC has been charged with ensuring that SPDs meet the ISO 9001-2008 QMS requirements to reduce variation and increase standardization of processes to the maximum extent possible throughout VHA. OCCC will begin consultative visits in FY 2011 to

provide assistance and guidance to facilities in reaching compliance with the ISO-9001-2008 QMS principles in SPD departments. OCCC will provide facilities with consultative resources regarding ISO 9001 standards and follow-up visits to help them achieve these goals.

In process Throughout FY 2011

Veterans Health Administration
March 2011

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Deborah Howard Director, San Diego Office of Healthcare Inspections
Acknowledgments	Lisa Barnes Jennifer Christensen Donna Giroux Kathy Gudgell Douglas Henao Stephanie Hensel Tishanna McCutchen Clarissa Reynolds Kathleen Shimoda Carol Torczon Toni Woodard

Appendix C

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