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Healthcare Inspection

Operating Room Reusable Medical Equipment and Sterile Processing Service Concerns VA New York Harbor Healthcare System New York, New York

September 29, 2016

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to complaints about operating room (OR) reusable medical equipment (RME) and Sterile Processing Service (SPS) at the Manhattan Campus of the VA New York Harbor Healthcare System (facility), New York, NY. Specifically, the allegations included the following:

- RME trays were missing instruments and/or were not properly processed with filters, indicators, or intact wrapping;
- RME trays were heavy and stored above head level, which risked the safety of nurses who had to lift them;
- Nurses sometimes had to leave patients to get supplies because the SPS-OR sterile storage rooms were not consistently staffed with an SPS-OR employee.

Following our first site visit in April 2015, the Veterans Health Administration (VHA) completed external reviews that focused on select components of the OR/SPS program. The facility made some progress in addressing the recommendations; however, on a second visit in October 2015, we found continued unresolved concerns in multiple aspects of the program. Additionally, facility managers did not meaningfully integrate the reviews' recommendations nor develop an overarching plan.

We substantiated the allegation that some of the OR RME trays were missing instruments and/or were not properly processed with filters or indicators. We also found that SPS medical support technicians failed to place external tags on rigid containers or use standardized methods on count sheets. We determined that there was no significant harm to the 14 patients who had SPS-related cancellations or delays of surgeries or other SPS-related concerns during a 5-month period in fiscal year 2015. We also found that the facility was not consistently monitoring the temperature and humidity in the SPS-OR sterile storage rooms.

We substantiated that some of the OR RME containers and packages were heavy and stored above head level, which placed nurses who had to lift them at risk for injury. During our October 2015 site visit, we also did not find documentation of training for proper handling of sterile packages for OR staff or a formal process in place to track and trend issues with packages (such as tears or holes).

We confirmed that SPS staff were not consistently available in the SPS-OR sterile storage rooms and found other SPS staffing concerns. However, we did not substantiate that OR nurses had to leave patients to get supplies and instruments, creating a dangerous patient care situation. We found that SPS staffing levels appeared inadequate and may not support newly expanded hours.

We found the facility did not have an effective SPS quality control program. Specifically, we found that discussion of RME in various committees and service meeting minutes lacked detail, evaluation, and corrective action plans.

We found that OR and SPS staff members did not collaborate or communicate well, which created a contentious culture and interfered with resolving problems.

We recommended that the System Director:

- Charter a team to evaluate the facility's entire process involving RME in accordance with applicable guidelines, integrate reviews' recommendations, and develop an overarching RME management plan.
- Ensure that SPS staff comply with applicable national and local policies and guidelines for the reprocessing of RME and the preparation of trays and instrument lists.
- Ensure that SPS staff comply with applicable guidelines to record daily temperature and humidity levels in SPS areas and act upon and document actions when temperature and humidity levels are out of range.
- Ensure that an ergonomic assessment be made of the physical access and weight of items stored in the OR SPS storage area and determine the appropriate equipment needed to ensure staff safety and compliance with applicable Occupational Safety and Health Administration standards.
- Ensure training of OR staff in proper handling of sterile packages and establish a formal process to track and trend issues with packages.
- Ensure adequate staffing to manage the operational requirements of SPS.
- Ensure that the OR and SPS staff implement an RME quality control program consistent with VHA guidelines.
- Implement measures to improve collaboration and communication within and between OR and SPS staff.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 18–23 for the Directors' comments.) We will follow up on the planned actions until they are completed.



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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations regarding operating room (OR) reusable medical equipment (RME) and Sterile Processing Service (SPS) at the Manhattan Campus of the VA New York Harbor Healthcare System (facility), New York, NY.

Background

The VA New York Harbor Healthcare System (system), comprising three campuses located in Manhattan, Brooklyn, and Queens, NY, oversees four community based outpatient clinics and in 2015, was part of Veterans Integrated Service Network (VISN) 3.¹ The facility is a 171-bed tertiary care teaching facility affiliated with New York University School of Medicine and other medical institutions. The facility has seven active ORs and performs multiple types of surgeries, including general, cardiac, orthopedic, neurologic, and other surgeries. The facility has 11 surgical subspecialties that use multiple RME instruments.

RME Reprocessing and Monitoring

RME refers to surgical instruments and other devices made of materials that can withstand reprocessing² to enable safe reuse on multiple patients. The Veterans Health Administration (VHA) requires that in reprocessing, RME be properly cleaned,³ disinfected,⁴ and sterilized between patients. If contaminated devices are not adequately reprocessed, they may compromise patient safety. RME reprocessing generally involves three steps: (1) initial decontamination and cleaning at the point of use; (2) thorough cleaning in a central processing area; and (3) low-intermediate-level disinfection, high-level disinfection, or sterilization.

¹ In June 2015, Secretary McDonald announced an integration plan that would decrease the number of VISNs from 21 to 18. The plan included a merger of VISN 2 and 3 which was initiated in October 2015.

² VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009. VA website.

http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1824. Accessed December 23, 2015. VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016 rescinded and replaced several VHA Directives including Directive 2009-004.

³ Cleaning is the removal of visible soil (for example, organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008. Centers for Disease Control and Prevention (CDC) website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed December 10, 2015.

⁴ Disinfection is any process, chemical or physical, that destroys most pathogens (infectious microorganisms).

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC website.

http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed December 10, 2015.

Once surgical instruments are decontaminated and cleaned, SPS staff may place individual surgical instruments into peel-pouches⁵ or assemble a set of instruments into trays and place the trays into packages enclosed in multi-ply disposable sterilization wraps (wrappers) and taped or rigid containers to maintain sterility. The containers and packages include indicators⁶ and, on the outside, paper instrument list(s) showing the types and numbers of instruments included within. Containers also include filters.⁷

VHA requires that a quality management program is in place to ensure appropriate and safe reprocessing.⁸ A combination of biological, chemical, and mechanical indicators is used to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items.⁹ Biological indicators are placed inside the sterilizer with a load of instruments. Chemical indicators are usually used on the outside of the package and container. Mechanical indicators monitor cycle time and temperature. Used in conjunction with one another, the indicators create a check and balance for the sterilization process designed to eliminate the potential use of non-sterile instruments.

SPS and OR Sterile Storage Responsibilities

SPS provides the cleaning, disinfection, and sterilization for surgical instruments and other RME. Facility SPS employees perform RME reprocessing for multiple Services, including Surgical Services. SPS purchases most RME, but also inventories, cleans, and sterilizes “loaner” trays and instruments leased from vendor(s).¹⁰

⁵ A peel pouch is a plastic or paper packet that is self-sealed or heat-sealed and is one method for maintaining sterility of surgical instruments. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed December 10, 2015.

⁶ Indicators are devices used to monitor exposure to one or more sterilization parameters. Association of periOperative Registered Nurses. <http://www.aornstandards.org/content/1/SEC37.body?sid=4ab0fd61-e385-453a-8b1e-84e76c9307fc>. Accessed April 6, 2016.

⁷ Rigid containers use filters to create a barrier that allows for the sterilization process to reach the RME in the container while preventing microorganisms from penetrating the container. Flynn S. Considerations for Use of Rigid Sterilization Containers. Healthcare Purchasing News. October 2010. <http://www.hponline.com/ce/pdfs/1010cetest.pdf>. Accessed January 5, 2016.

⁸ 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 was replaced with VHA Directive 1116, Sterile Processing Services (SPS) on March 23, 2016. Both Directives include requirements for a quality management program.

⁹ Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed December 10, 2015.

¹⁰ “Healthcare facilities often have a need to borrow instrumentation and surgical implants for a surgical or invasive procedure from a specific vendor or neighboring healthcare facility.” from https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2014-04274-HI-367/Standards/IAHCSMM_Position_Paper-Management_of_Loaner_Instrumentation.pdf, The International Association of Healthcare Central Service Materiel Management (IAHCSMM) Position Paper on the Management of Loaner Instrumentation. Accessed December 10, 2015.

To protect sterilized RME, all SPS and OR staff must take care with placement and not bend, drag, slide, crush, compress, or puncture the packaging.¹¹ At the facility, staff use large metal carts to deliver sterile RME from the mobile SPS trailer to the SPS-OR sterile storage rooms. Upon receipt of the sterile RME, the OR SPS sterile storage medical supply technician (MST) inspects each container and package and places them onto wire shelves and into case carts outside of each OR, determined by the OR schedule. In preparation for surgery, the OR staff member removes the sterile containers and packages from the case cart and places them on a rolling table for use during surgery. Immediately before the surgical procedure, the OR staff member unwraps the sterile package(s) or opens the instrument tray(s), inspects the container or wrapper that covered the instruments, and inventories the contents of the tray. Following surgery, an OR staff member moves the contaminated instruments on the rolling tables to a soiled utility room for pick up and reprocessing by SPS.

Allegations. On June 20, 2014, OIG Hotline Division received a letter from OR staff that included the following allegations:

- RME trays were missing instruments and/or were not properly processed with filters, indicators, or intact wrapping;
- RME trays were heavy and stored above head level, which risked the safety of nurses who had to lift them;
- Nurses sometimes had to leave patients to get supplies because the SPS-OR sterile storage rooms were not consistently staffed with an SPS-OR employee.¹²

On August 4, 2014, OIG requested that the system director respond to the allegations. After receiving and reviewing the system director's response, OIG determined further inspection was warranted.

This review addressed the allegations above and also followed up on SPS quality control and SPS-OR communication deficiencies identified in June 2015 by VHA's National Program Office for Sterile Processing (NPOSP).

We did not address allegations related to timeliness of trays reprocessed by the Brooklyn SPS because the facility, after Superstorm Sandy, had already abandoned this practice.

Scope and Methodology

We conducted our review from October 27, 2014, through January 7, 2016.

¹¹ Jefferson J, Young M. Chapter 106 – Sterile Processing. In: The Association for Professionals in Infection Control and Epidemiology, Basic Principles APIC Text Online. <http://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/sterile-processing>. Accessed October 2, 2015.

¹² For this allegation, we interpreted the meaning of needing to “leave patients” as leaving patients alone and creating a dangerous patient care situation.

We interviewed some OR nurses by telephone in advance of an unannounced site visit April 22–23, 2015. Additionally, we conducted an announced site visit October 19–20, 2015. We toured the OR and SPS areas. We interviewed OR nursing staff, SPS staff and managers, surgeons, and facility leadership. We reviewed relevant VHA, VISN, and facility policies, standard operating procedures, directives, handbooks, memoranda on SPS, and Employee Assessment Review (EAR) survey results.

In the absence of current VA/VHA policy, we considered previous guidance to be in effect until superseded by an updated or re-certified Directive, Handbook, or other policy document on the same or similar issue(s).

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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.

Sequence of Events

Superstorm Sandy (October 2012)

During Superstorm Sandy in October 2012, a storm surge of seawater of historic proportion flooded the facility's basement and grounds. After the storm, the facility was not able to reopen the building immediately because of flood damage to several clinical spaces and SPS.

By May 2013, the facility replaced a large portion of the water-damaged RME inventory and reopened using an independent contractor to provide sterilization services. However, because of performance failures by the contractor, SPS at the Brooklyn campus assumed responsibility for providing RME services to the facility from December 2013 until July 2014. On July 18, 2014, SPS was restored to the facility's campus by leasing a temporary SPS trailer.

OIG Combined Assessment Program Review (June 2014)

The OIG conducted a Combined Assessment Program (CAP) review at the system the week of June 9, 2014. As part of the CAP review, we surveyed all employees via an online EAR survey. EAR survey results reflected RME and SPS-related concerns; those results were provided to the System Director for review and action, as indicated.

OIG Hotline Complaint (June 2014) and System Response (September 2014)

Shortly after our CAP review, the OIG Hotline Division received allegations about ongoing RME and SPS problems. The OIG requested that the facility respond to the allegations.

On September 26, facility leaders sent a response to the OIG Hotline Division, indicating that the installation of a dedicated SPS trailer would address the failures encountered previously. Data at the time did not conclude the facility to be a significant outlier in the rates of RME-related surgery cancellations, immediate use steam sterilization (IUSS), surgical site infections, or events related to sterile RME package tears or holes. However, OIG determined that an additional review was warranted due to potential patient safety concerns.

OIG Unannounced Site Visit (April 2015)

Prior to our initial site visit, OIG made a SPS Services survey available to facility OR staff from January 30, 2015, through February 17, 2015, to determine whether the concerns alleged were resolved or ongoing. Of the 26 OR staff, 20 completed the SPS Services survey, which revealed that the concerns were ongoing.

During our initial site visit, we interviewed multiple employees, many of whom reported that deficient OR, SPS, and RME conditions continued unabated. OR nurses gave us copies of two instrument lists from February and April 2015, respectively, which showed missing or otherwise incorrect RME. The February list showed a surgery was delayed

for 8 hours while awaiting an MST to sterilize 6 trays (including loaner trays). Other than these lists, facility managers were unable to provide us with basic data regarding the number and type of SPS and RME-related concerns. We encouraged facility managers to formally track this information.

Following our initial site visit, system leaders requested external VHA reviews of SPS at all campuses.

VISN SPS Site Visit (May 2015)

A VISN SPS inspector conducted a site visit on May 27, 2015 and found that the facility was generally compliant with OR SPS safety, quality, record keeping, and policy elements.

NPOSP Site Visit (June 2015)

Following a June 3–4, 2015 visit, the NPOSP issued a report outlining 25 findings and 20 corrective actions and recommendations for SPS administration, decontamination, and OR operations. Facility managers created an action plan to address the NPOSP findings and recommendations; under the Status of Actions column, most of the action items were annotated as “closed.” For action items that were “in progress,” target dates for completion were generally no later than September 30, 2015.

OIG Announced Visit (October 2015)

During our second site visit dates, we interviewed additional staff members, reviewed data that had been collected over the previous 6 months, toured the OR-SPS storage area, and reviewed the status of the NPOSP corrective action plan and resolution of identified issues.

Inspection Results

Many of the deficient conditions reported in June 2014 still existed 16 months later in October 2015. Despite reporting on improvements and quality control measures, developing corrective action plans and documenting completion of action items, facility managers had not implemented some corrective actions and did not track and periodically evaluate the status and effectiveness of actions.

We spoke with surgeons and heard differing reports of SPS concerns, as some reported frequent problems and others none. However, OR staff consistently described persistent problems and told us they were frustrated with SPS, believed there was no accountability with MSTs, and felt a lack of support from leadership. Nurses told us they “used to write up problems with the SPS staff” but stopped because it “went nowhere.” Employees we interviewed reported concerns that had a cascade effect on SPS-OR operations and, potentially, the OR schedule and timeliness of surgeries. For example, vendor-supplied loaner trays were sometimes requested later than policy permitted, which affected timely reprocessing by SPS, and surgeries that used the same unique instrument trays were scheduled close in time to each other, which challenged SPS staff to reprocess specialty or loaner trays timely. In this report, we addressed the most significant concerns raised during interviews. We briefed the System Director on the other concerns.

To promote reader understanding of the scope and breadth of the identified issues, each section of this report includes:

- NPOSP’s findings and recommendations that are specific to, or related to, the allegations;
- Facility managers’ corrective action plan(s) responding to the NPOSP’s recommendations, if applicable;
- Our observations and findings of the current statuses (as of October 2015) of the identified issues; and
- The effect(s) of facility managers’ failure to adequately address the deficiencies, as verbalized by staff we interviewed, if applicable.

Issue 1: Sterile RME Packaging and Storage

We substantiated the allegations that some of the RME trays (in rigid containers and packages) were missing instruments and/or were not properly processed with filters or indicators. The concern about the lack of intact wrapping is addressed under Issue 2 (RME Package Integrity) of this report.

Missing Instruments

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p>FINDING: Missing instrumentation from sets was not easily identifiable to OR staff.</p> <p>RECOMMENDATION: Mark the outside of the sterilization container/paper wrapped RME with easily identifiable label indicating what instruments are missing.</p>	<p>Closed.</p> <ul style="list-style-type: none"> • SPS no longer releases incomplete set(s) to the OR. • Count sheets will be revised so that they no longer include items that are not needed, and as such, are not “missing.”

OIG Observation/Finding: During our October 2015 site visit, we observed:

- Twelve of 27 rigid containers and packages were missing count sheets.¹³
- Nine of 15 count sheets were prepared with 1 or more missing instruments.
- On the 9 count sheets, 51 of 440 individual instruments were missing.

We also found that SPS MSTs failed to: (1) use external red tags on rigid containers to alert users of missing instruments, (2) use methods to note missing instruments on the count sheets, and (3) date two count sheets and initial one of those two count sheets.

Following our initial site visit, a staff member initiated a detailed record to track OR case start times and other concerns, including SPS and other reasons for delays or cancellations encountered during her tour. Of the 494 scheduled surgeries tracked from April 24, 2015 through October 16, 2015, the nurse documented 20 surgeries (4 percent) with SPS and/or RME-related concerns. Specifically, we found:

- Of 41 cancelled surgeries, 2 resulted from SPS not having the necessary RME processed and available to the OR.
- Of 189 delayed surgeries, 6 were delayed solely as a result of RME being missing or not processed; an additional 6 delayed surgeries resulted from RME-related concerns and at least 1 other monitored condition (such as high temperature and humidity in the OR).¹⁴
- For six additional surgeries, which were not delayed or cancelled, staff documented SPS concerns, primarily related to loaner tray reprocessing.

¹³ Goldberg, Judith L. and David L. Feldman, Implementing AORN Recommended Practices for Prevention of Retained Surgical Items. *Association of periOperative Registered Nurses Journal* 95 (February 2012), p. 205-216. Count sheets are used to inventory what is in the instrument set and support the efficient post-procedure inventory count.

¹⁴ Seven of the cases involved delays of 10 minutes or less, but one case was delayed nearly 2 hours.

We determined no significant harm occurred to the 14 patients who had SPS-related cancelled or delayed surgeries or other SPS-related concerns.

Filters and Indicators

The NPOSP did not identify specific problems with the use of filters or display of indicators.

During our October 2015 site visit, however, we observed that 3 of 214 containers and packages in the SPS OR sterile storage area did not have 1 or more external indicators. Two OR nurses reported that sometimes the filters were not present, and they were therefore unable to use the trays. During our site visits, we did not validate the presence of filters because to do so would require opening sterile packaging that would then necessitate re-sterilization.

Temperature and Humidity

Although not an allegation, we found that the facility was not consistently monitoring the temperature and humidity in the SPS-OR sterile storage rooms. The Centers for Disease Control and Prevention (CDC) requires that the temperature in sterile storage areas does not exceed 75 degrees Fahrenheit and that humidity levels cannot exceed 70 percent.¹⁵ In work areas, such as the SPS trailer, the CDC has a lower threshold for the humidity, which must be within 30–60 percent.

Of daily temperature and humidity manually-maintained logs from April 1 through September 30, 2015, SPS staff did not:

- Use forms that correctly identified the desired humidity levels¹⁶ for work areas other than SPS storage.
- Record entries for 41 of 128 applicable days (32 percent) in the SPS-OR sterile storage rooms and 26 of 154 applicable days (17 percent) in the SPS trailer.¹⁷
- Document taking action on 6 of the 13 days when temperatures (ranging from 75.3 to 92.4 degrees) were higher than the recommended 75 degrees.¹⁸

¹⁵ CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, states "The sterile storage area should be a limited access area with a controlled temperature (may be as high as 75 degrees) and relative humidity (30–60 percent in all work areas except sterile storage, where the relative humidity should not exceed 70 percent)." Page 73. CDC website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed October 12, 2015.

¹⁶ CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, Page 73. CDC website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed October 12, 2015.

¹⁷ With the exception of Federal holidays, SPS-OR storage is staffed by an SPS employee Monday through Friday, and the SPS mobile unit operates Monday through Saturday. Of the 183 calendar days from April 1 through September 30, 2015, SPS-OR storage was operational for 128 days and the SPS mobile unit was operational for 154 days.

- Document taking action (such as calling Engineering Service or inspecting sterile containers or packages) on 108 of the 109 entries when humidity (ranging from 14.2 to 81.5 percent) was logged as outside the recommended range.

Issue 2: RME Storage Methods

We substantiated the allegations that some OR RME containers and packages were heavy and stored above head level, which placed facility staff who had to lift them at risk for injury.

The Occupational Safety and Health Administration (OSHA) defines the power zone for lifting close to the body as located between mid-thigh and mid-chest height. This area of the body is the area where the arms and back can lift the most with the least amount of effort. To prevent injuries, OSHA recommends minimizing the weight of the item, decreasing the range of motion used for manually lifting and moving items, and minimizing the distance between the person and the object being handled. To reduce reach and overextension, OSHA recommends storing items on shallow shelves as opposed to deep shelves, placing heavier items on shelves located in the best work zone, and storing heavy objects at waist level.

While the NPOSP review team did not make a specific recommendation related to this issue, the facility included in its action plan (related to a different finding) that “stepladders have been placed in the area and heavier instrument trays have been placed on lower shelves. The SPS Chief or designee monitors compliance with placement of heavy trays.”

During our October 2015 site visit, we found that 2-step mobile ladder stands that added a vertical rise of approximately 18 inches were available in the SPS-OR sterile storage rooms; however, they were inadequate for use by short-statured individuals to reach items on high shelves safely. We also observed that the SPS-OR sterile storage rooms had 62-inch-tall shelving units. Many RME rigid containers and packages were stored on the upper shelves and weighed 25 pounds or more. The depths of the shelves contributed to staff overextending to reach and grasp trays with both hands.

While staff reported efforts to limit the weight of RME trays to 25 pounds, the facility did not have a policy to check RME tray weights or store RME trays with weights nearing 25 pounds or more on lower shelves. Further, we found no evidence that the SPS Chief or designee monitored compliance with placement of heavy trays.

Despite inadequate RME storage methods, we found only one reported RME-related injury for the period May 1, 2013 through September 30, 2015, which resulted from a nurse lifting a tray in the OR.

¹⁸ CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, page 73. CDC website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed October 12, 2015.

Because some staff could not lift the instrument trays off the storage shelves, some staff resorted to dragging the trays across the shelving unit, which could unintentionally thin the wrapping or cause tears or holes in the package that surrounds the sterile trays, rendering the RME unsterile.

RME Package Integrity

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p><u>FINDING</u>: Paper wrapped instrument sets on shelves found with tears or holes in the wrapper.</p> <p><u>RECOMMENDATION</u>: Consider putting plastic on all wire shelves to protect the sterilized wrapped products from sharp welding points.</p>	<p>In progress.</p> <ul style="list-style-type: none"> • Plexiglas, to line all shelves, is on order (as of June 2015).

OIG Observation/Finding: During our October 2015 site visit, we found 5 of 100 shelves did not have plastic installed. The facility corrected this during our site visit.

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p><u>FINDING</u>: Following the sterilization process, the SPS team takes the instrument sets to the OR. OR staff receives the instrumentation, stacking the sets 2–4 sets high resulting in tears and pinholes.</p> <p><u>RECOMMENDATION</u>: Consider a strong grade maintenance cover for transport of paper wrapped items from Prep to the OR.</p>	<p>In progress.</p> <p>In-services for OR staff on proper handling of wrapped instruments by the vendor are being planned.</p>

OIG Observation/Finding: During our October 2015 site visit, we did not find documentation of training of OR staff on proper handling of sterile packages. Further, we were told that a formal process was not in place to track and trend issues with packages (such as tears or holes). As such, facility leaders could not be assured that their corrective actions have been effective.

Tears or holes in packaging compromise the sterility of the surgical instruments contained within, rendering the items unusable until they are re-sterilized. OR staff told us that they sometimes had to locate replacement instruments from other trays or wait for the needed items to be re-sterilized.

Issue 3: SPS Staffing and Hours of Operation

We confirmed that SPS staff were not consistently available in the SPS-OR sterile storage rooms; however, we did not substantiate that OR nurses had to leave patients alone to get supplies and instruments.

At the time of our April site visit, SPS had assigned one employee to the SPS-OR sterile storage rooms daily from 6:30 a.m. through 3:00 p.m. but provided no coverage to the SPS-OR sterile storage rooms when the employee left to attend to other duties, took breaks, or left for the day. When SPS-OR sterile storage room employees were absent, OR nurses were responsible for obtaining any needed supplies. Two to three OR nurses staffed each surgical case (one or two circulators and one scrub nurse), so when one nurse left to get supplies from the SPS-OR sterile storage rooms, other nurses and OR staff remained with the patient. The NPOSP identified the need for expanded SPS hours to improve the timeliness of [RME] pick-ups, as follows:

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p>FINDING: Additional pick-up times are needed for the clinics and OR are needed to ensure no soiled critical and semi-critical RME remains overnight.</p> <p>RECOMMENDATION: Consider expanding SPS hours to clean soiled instruments and not leave them overnight to build biofilm.</p>	<p>In progress. Will work with other services (e.g., Logistics, [other services]) to see how additional pick-ups can be arranged.</p> <p>a) NY SPS hours were extended; now open 6:30 a.m. to 10:30 p.m. (June 22, 2015)</p> <p>b) RME from clinics is picked up by SPS staff members after 4P; but a transporter is needed for that and to pick up OR instruments after 7P. Will work with other services to see how additional pick-ups can be arranged</p> <p>c) OR RNs [registered nurses] spray the instruments that cannot be picked up (July 8, 2015)</p> <p>d) SPS staff need access to GU [Urology] after 4P; a key will be requested</p>

OIG Observation/Finding: During our October 2015 site visit, we found:

- No one from the Logistics Department was trained to pick up contaminated trays from late day, overnight, or weekend cases. The supervisor of Logistics was in the training process at the time of our second site visit. The former Logistics technician who picked up trays had switched jobs and was working as an MST in SPS.
- Extended hours were covered by current SPS staff working overtime or adjusting the shift schedule.
- Multiple contaminated trays had not been sprayed by the OR nursing staff and remained after hours in the holding area.

The April 2015 SPS organizational chart showed nine MSTs conduct the SPS work including coverage of non-OR services; the SPS Coordinator informed us that one supervisory position was vacant. We observed the SPS Coordinator to be actively working in the decontamination or other areas covering the duties of an MST. The SPS

Coordinator told us that eight employees are expected to be on duty per day, but one staff member calls off per day, on average.

We confirmed that, as of our October visit and during fiscal year 2015, at least three employees were on official leave restrictions, and the SPS-OR sterile storage room employee was on extended sick leave.

Given the newly expanded hours and other concerns identified within this report, the SPS staffing level appeared inadequate for demand and prevented the SPS Coordinator from adequately managing the Service, conducting quality audits, attending meetings, and providing necessary oversight. Further, when trays are not sprayed with enzymatic solution and are left overnight, bioburden hardens on the instruments, making the cleaning process more time-consuming for SPS employees the next day, and potentially delaying the trays' reprocessing and availability for subsequent surgeries.

Issue 4: SPS Quality Control

The facility did not have an effective SPS quality control program.

VHA requires that each facility have a systematic standardization and oversight plan for reprocessing RME.¹⁹ VHA further requires that facilities implement and report on quality systems and take corrective actions when necessary.²⁰ The facility has had policies in place since 2010, which require the Infection Control Committee to review SPS biological, chemical, mechanical, and other controls, as well as a "generic RME quality monitor."²¹

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p>FINDING: Do a monthly tracer audit for event related sterility.</p> <p>RECOMMENDATION: Reinstigate the tracer report created by the ADNPCS [Associate Director for Nursing and Patient Care Services] to track, trend, and benchmark SPS issues.</p>	<p>Closed.</p> <ul style="list-style-type: none"> • Bi-weekly event-related audits are now taking place (as of July 6, 2015).
<p>FINDING: OR start doing incident reports on tray issues. SPS needs to benchmark and do corrective actions.</p> <p>RECOMMENDATION: Create a quality</p>	<p>In progress.</p> <ul style="list-style-type: none"> • [The] Quality assurance process is currently in place. There is a quality dashboard in eQMS [electronic quality management system] that is

¹⁹ 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 VHA Directive expired on February 28, 2014; it was rescinded by VHA Directive 1116(2), *Sterile Processing Services (SPS)* March 23, 2016. The 2016 Directive contains the same or similar language as the previous one regarding standardization and oversight.

²⁰ Ibid. Both Directives require (d) a Quality Assurance program for RME reprocessing.

²¹ NY Harbor Health Care System. *Healthcare System Policy No 118-32 Reusable Medical Equipment Quality Control and Monitoring Plan*. February 2010; *Healthcare System Policy No 118-32 Reusable Medical Equipment Quality Control and Monitoring Plan*. June 2014.

<p>assurance program to capture the good work that is being done.</p>	<p>used to monitor biological results, early releases, and temperature/humidity. Management tracks for nonconformance, SPS requirements not met, customer complaints & compliments, inspection/audit findings, and the status of corrective actions are in place. Once the customer service section of eQMS is implemented, more feedback re: quality will be available for SPS staff.</p>
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OIG Observation/Finding: During our October 2015 site visit, we found:

- Facility SPS managers had not conducted audits or otherwise assessed the accuracy, completeness, and quality of sterile containers and packages as part of an overall quality management program.
- eQMS was partially implemented at the facility due to the temporary set-up of SPS.
- SPS managers did not track or evaluate complaints from OR staff.

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p><u>FINDING:</u> All SPS/RME issues need to be routed and tracked through the RME committee and elevated to the leadership board. Reviewing attendance records revealed minimal or inconsistent facility participation.</p> <p><u>RECOMMENDATION:</u> Formulate a process by which the RME committee tracks each finding or issue within the SPS/RME program until complete. Ensure facility executive level board reviews/approves RME minutes. This process can be through a subordinate committee or board. [Resources suggested]</p>	<p>Closed.</p> <p>a) Critical & semi-critical RME issues are presented at the RME Committee and tracked to completion. Minutes will be reported to the Infection Control Committee.</p> <p>b) Detail of minutes will provide traceability of issues and resolutions.</p> <p>c) Critical & semi-critical RME issues are also reviewed at the Brooklyn quarterly SPS Management Review Meetings.</p> <p>d) Intractable issues are reviewed at the VISN ISO [International Organization for Standardization] Governing Council (SPS Board).</p>

OIG Observation/Finding: During our October 2015 site visit, we found:

- VHA requires committees to work “...towards understanding the complex environment that results in adverse events, and loss of value and efficiency. The committee must develop prioritized recommendations to aid facility leadership.”²² Additionally, meeting minutes must “track issues to resolution.”²³ ICC, RME, and

²² VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013.

²³ Ibid.

SPS Board Committee minutes during fiscal years 2014 and 2015 did not discuss RME-related issues in meaningful detail. The facility’s RME Committee reviewed sterility testing and the ICC reviewed SPS biological reports and IUSS rates, but did not regularly include mechanical or chemical reports as required. We found these minutes noted brief comments (such as, IUSS required for tear in wrapper) with plans to continue to monitor, but contained no meaningful discussion of evaluation, trending, or corrective actions. Committee minutes lacked important details and the reporting of issues to higher-level committees was inconsistent. As a result, facility leaders could not be assured that critical issues were appropriately and timely communicated to relevant managers and departments for corrective action.

- For the 11 ICC meetings that occurred from September 2013 through September 2015, RME was a standing agenda item. However, we found no attached RME Committee minutes, no report for three meetings, and identical reports for multiple meetings.

Issue 5: Collaboration and Communication

We found that OR and SPS did not collaborate or communicate well, which created a contentious culture among staff and interfered with problem resolution.

NPOSP Finding and/or Recommendation	Facility Response and Action Plan
<p><u>FINDING</u>: OR/SPS relationship appears to be founded on limited communication and a weak quality assurance program.</p> <p><u>RECOMMENDATION</u>: Create a quality assurance program to capture the good work that is being done.</p>	<p>Closed; communication is ongoing.</p> <ul style="list-style-type: none"> • SPS representative will attend the weekly OR staff meeting (beginning week of July 13, 2015). • Daily communication between OR manager and SPS Chief. • SPS-OR liaison is in place (as of June 30, 2015).

OIG Observation/Finding: During our October 2015 site visit, we found:

- An SPS representative attended one OR staff meeting from July through October 2015.
- The SPS-OR liaison was on extended sick leave prior to and after our October 2015 site visit.

During interviews, we were told that:

- After SPS returned to the facility in July 2014, 10 months passed before the facility’s responsible contracting officials learned of, and restored, surgical instrument sharpening services, which resulted in numerous dull instruments and delays in “catching up” on sharpening status.

- The OR Nurse Manager sometimes approved SPS to substitute instruments but failed to communicate the approval to OR staff nurses.
- OR staff sometimes removed and discarded damaged instruments, but failed to communicate to SPS the need to purchase, reorder, and/or replace incorrect or unwanted RME.

The Nurse Executive was aware of some concerns between SPS and OR staff and invited SPS and OR managers to participate in daily teleconferences to facilitate communication. However, minutes and attendance rosters were unavailable for us to confirm participation. Despite these reported efforts, some staff perceived an ongoing lack of support from facility leaders.

Conclusions

Following our first site visit in April 2015, VHA completed external reviews that focused on select components of the SPS-OR program. Facility managers made some progress in addressing the recommendations; however, during our site visit in October 2015, we found that unresolved concerns continued in multiple aspects of the program. Additionally, facility managers did not meaningfully integrate the recommendations nor develop an overarching plan.

We substantiated the allegation that some of the OR RME in rigid containers and packages were missing instruments and/or were not properly processed with filters or indicators. We also found that SPS MSTs failed to place external tags on rigid containers or use standardized methods on count sheets. We determined that there was no significant harm to the 14 patients who had SPS-related cancelled or delayed surgeries or other SPS-related concerns during a 5-month period in fiscal year 2015. We also found that the facility was not consistently monitoring the temperature and humidity in the SPS-OR sterile storage rooms, as required by the CDC.

We substantiated that some of the OR RME containers and packages were heavy and stored above head level, which placed facility staff who had to lift them at risk for injury. During our October 2015 site visit, we did not find documentation of training of OR staff in proper handling of sterile packages or a formal process in place to track and trend issues with packages (such as tears or holes). As such, facility leaders could not be assured that their corrective actions have been effective.

We confirmed that SPS staff were not consistently available in the SPS-OR storage rooms and found other SPS staffing concerns. However, we did not substantiate that OR nurses had to leave patients to get supplies and instruments creating a dangerous patient care situation. We found that SPS staffing levels appeared inadequate for demand and may not support newly expanded hours.

We found the facility did not have an effective SPS quality control program. Specifically, we found that discussion of RME in various committees and service meeting minutes lacked detail, evaluation, and corrective action plans.

We found that OR and SPS staff members did not collaborate or communicate effectively, which created a contentious culture and interfered with problem resolution.

Recommendations

1. We recommended that the System Director charter a team to evaluate the facility's entire process involving reusable medical equipment in accordance with applicable guidelines, integrate reviews' recommendations, and develop an overarching reusable medical equipment management plan.
2. We recommended that the System Director ensure that Sterile Processing Service staff comply with applicable national and local policies and guidelines for the reprocessing of reusable medical equipment and the preparation of trays and instrument lists.
3. We recommended that the System Director ensure that Sterile Processing Service staff comply with applicable guidelines to record daily temperature and humidity levels in Sterile Processing Service areas and act upon and document actions when temperature and humidity levels are out of range.
4. We recommended that the System Director ensure that an ergonomic assessment be made of the physical access and weight of items stored in the operating room Sterile Processing Service storage area and ensure staff safety and compliance with applicable Occupational Safety and Health Administration standards.
5. We recommended that the System Director ensure training of operating room staff in proper handling of sterile packages and establish a formal process to track and trend issues with packages.
6. We recommended that the System Director ensure adequate staffing to manage the operational requirements of Sterile Processing Service.
7. We recommended that the System Director ensure that the operating room and Sterile Processing Service staff implement a reusable medical equipment quality control program consistent with Veteran Health Administration guidelines.
8. We recommended that the System Director implement measures to improve collaboration and communication within and between operating room and Sterile Processing Service staff.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: May 12, 2016

From: Director, VA NY/NJ Veterans Healthcare Network (10N2)

Subj: Healthcare Inspection—Operating Room Reusable Medical Equipment and Sterile Processing Service Concerns, VA New York Harbor Healthcare System, New York, New York

To: Director, Baltimore Office of Healthcare Inspections (54BA)
Director, Management Review Service (VHA 10E1D MRS Action)

Attached please find the response to the draft OIG Healthcare Inspection report of the operating room reusable medical equipment and sterile processing service concerns, VA New York Harbor Healthcare System, New York, New York.

The VISN concurs with the action plan submitted by the facility. If you have any questions, please contact Pam Wright, RN MSN VISN 2 QMO at 718-741-4143.

(original signed by:)
Joan McInerney, MD, MA, MBA, FACEP
VISN 2 Director

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: May 12, 2016
From: Director, VA New York Harbor Healthcare System (630/00)
Subj: Healthcare Inspection—Operating Room Reusable Medical Equipment and Sterile Processing Service Concerns, VA New York Harbor Healthcare System, New York, New York
To: Director, VA NY/NJ Veterans Healthcare Network (10N2)

This is to acknowledge receipt and review of the draft OIG Healthcare Inspection report of the operating room reusable medical equipment and sterile processing service concerns, VA New York Harbor Healthcare System, New York, New York.

Thank you for the opportunity to comment on the recommendations for improvement contained in this report. If you have any questions, please contact Cynthia Caroselli, the Chief Nurse at 212-951-6894.

(original signed by:)
Martina A. Parauda
Director

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the System Director charter a team to evaluate the facility's entire process involving reusable medical equipment in accordance with applicable guidelines, integrate reviews' recommendations, and develop an overarching reusable medical equipment management plan.

Concur

Target date for completion: 11/30/16

Facility response: A management plan is being drafted in accordance with ISO 9001 standards to respond to the issues identified in this report and to ensure that corrective actions regarding recommendations are executed and sustained. As part of this management plan, an ISO Management Review Committee will be created to assess the adequacy, appropriateness and effectiveness of the processes related to the reprocessing and sterile storage of critical and semi-critical reusable medical. Based on this assessment, the Committee will insure the development of corrective action plans and oversee the implementation of action plans and monitor for sustained conformance to standards. The status of completion of corrective actions will be documented in the Committee meeting minutes. The ISO Management Review Committee will meet monthly for six months and then quarterly thereafter. Membership will include Executive leadership, SPS service chiefs, and key stakeholders in clinical and administrative services supporting SPS. Minutes from this Committee's meetings will be communicated to the Clinical Executive Board (CEB), and on to the Executive Council (EC).

Recommendation 2. We recommended that the System Director ensure that Sterile Processing Service staff comply with applicable national and local policies and guidelines for the reprocessing of reusable medical equipment and the preparation of trays and instrument lists.

Concur

Target date for completion: 11/30/16

Facility response: Oversight of the SPS program, including whether reprocessing RME is compliant with national and local policies and guidelines, will occur through the ISO quality management review process. Clinical Services using RME and SPS leadership will collaboratively initiate the ISO quality management review process to insure effective and appropriate count sheet/tray list management which supports SPS intake and outtake inventory management and equipment/tray count sheet reconciliation

during prep & assembly phases of reprocessing. This process redesign will begin with a “count sheet/tray list cleanup” to insure document content accuracy. Any missing items will be removed from those documents. The goal of the ISO count sheet management processes is to eliminate the delivery of an incomplete tray to the using customer. Count sheet nonconformance will be documented, tracked, trended and reported to the ISO Management Review Committee using the SPS Requirements Not Met Reports on the SPS e-QMS. Customer-SPS Service Level Agreements will include defined processes for the frequency and manner in which count sheet/tray list accuracy will be maintained in the future.

Recommendation 3. We recommended that the System Director ensure that Sterile Processing Service staff comply with applicable guidelines to record daily temperature and humidity levels in Sterile Processing Service areas and act upon and document actions when temperature and humidity levels are out of range.

Concur

Target date for completion: 11/30/16

Facility response: In April 2016, the new Chief, SPS re-created the temperature and humidity monitoring logs used in SPS areas to include sections for actions taken and the new temp/humidity after the action was taken. At the end of each month, the temperature and humidity control rates will be tracked and trended on the SPS e-QMS Quality Measurement and Monitoring Dashboard. Uncontrolled/variant temperature and humidity readings and related corrective actions will be documented and tracked through closure using the e-QMS Nonconformance Report. Data will be reviewed at the RME Committee and ISO Management Review Committee meetings for compliance with applicable guidelines for temperature and humidity levels in SPS areas, and to assess the completeness of documentation of corrective actions taken for out of range values. Target for compliance will be that temperature and humidity ranges are monitored 90% of the time (including corrective actions taken for out of range readings).

Recommendation 4. We recommended that the System Director ensure that an ergonomic assessment be made of the physical access and weight of items stored in the operating room Sterile Processing Service storage area and ensure staff safety and compliance with applicable Occupational Safety and Health Administration standards.

Concur

Target date for completion: 11/30/16

Facility response: An ergonomic assessment will be completed by the facility's Industrial Hygienist (IH) to ensure that access to and weight of items stored in the OR SPS storage area complies with applicable OSHA standards. Staff will be informed of the findings and advised re: proper tray weight and placement on shelves. This will ensure that staff injuries are prevented while items are stored in this temporary location until the renovation of the SPS area is complete. After the assessment is complete and

SPS and OR staff have been in-serviced by the IH re: findings, the IH will do a random sampling of trays weighing 25 pounds or more for placement on the shelves once a month.

Recommendation 5. We recommended that the System Director ensure training of operating room staff in proper handling of sterile packages and establish a formal process to track and trend issues with packages.

Concur

Target date for completion: 11/30/16

Facility response: OR staff received an in-service in September 2015 by Medline on the proper wrapping of trays. As part of the SPS Quality Program, sterile package integrity will be regularly monitored using appropriate sampling methods and documented on the SPS Quality Measuring and Monitoring Dashboard. Instances of nonconformance will be documented in the SPS Nonconformance Report with corrective actions. Actions will be tracked through closure. The data will be analyzed, tracked, trended and reported at and reviewed by the RME Committee and the ISO Management Review Committee. Expected sterile package integrity is 90%.

Recommendation 6. We recommended that the System Director ensure adequate staffing to manage the operational requirements of Sterile Processing Service.

Concur

Target date for completion: 11/30/16

Facility response: The Chief, SPS Manhattan will conduct an SPS staffing assessment using the National Program Office for Sterile Processing (NPOSP). Staffing Assessment Tool. The results of that assessment will be reviewed for action by the ISO Management Review Committee and senior leadership.

SPS NY has one Lead Tech vacancy that is currently under recruitment

Recommendation 7. We recommended that the System Director ensure that the operating room and Sterile Processing Service staff implement a reusable medical equipment quality control program consistent with Veteran Health Administration guidelines.

Concur

Target date for completion: 11/7/16

Facility response: As part of the management plan, the ISO Management Review Committee will deploy and oversee the execution of the VISN SPS Quality Measurement and Monitoring Process and the Measurement and Calibration Process. Together, these processes constitute the SPS quality control monitoring indicators and

metrics required by internal and external oversight bodies. Indicators include by are not limited to EOC temperature, humidity air exchanges and filter changes, biologic and chemical monitors, event related sterility, reprocessing equipment PM monitoring indicators, use of IUSS, and service-specific quality concerns. In addition, e-QMS Nonconformance, SPS Requirements Not Met and Customer Feedback Reports, Sterile Storage Tray Weights, and Sterile Package Integrity will be reported at the RME Committee and the ISO Management Review Committee.

Recommendation 8. We recommended that the System Director implement measures to improve collaboration and communication within and between operating room and Sterile Processing Service staff.

Concur

Target date for completion: 11/30/16

Facility response: At the direction of the ISO Management Review Committee, SPS will launch the QMS “customer” service level agreements with the clinical services which use SPS to reprocess critical and semi-critical RME. The Service Level Agreements identify customer expectations/reprocessing requirements and SPS expectations/requirements to effectively achieve the customer’s RME reprocessing requirements. Service Level Agreements are routinely reviewed on an annual basis and can be updated/revised based on new service/equipment requirements. SPS will fully deploy the QMS Customer Feedback process which requires periodic evaluation of customer satisfaction as well as providing customers with ready access to tools to report complaints and compliments. The SPS Chief will follow up with the complaints and will document corrective or preventative actions taken in e-QMS. Analysis of compliment and complaint data will be reported to the RME Committee and the ISO Management Review Committee.

OIG Contact and Staff Acknowledgments

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