RESPONSE TO

OFFICE OF THE MEDICAL INSPECTORS

Supplemental Report to the

Office of Special Counsel

File Number DI-13-2133

Medical Inspector's Supplemental Report, May 14, 2014, TRIM 2014-D-585

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I would like to affirm the continued danger to our Patients and Staff at the Ann Arbor Veterans Affairs Health System (AAVAHS). The VA Office of Inspector General, Office of the Medical Inspectors and the AAVAHS leaderships' continue to ignore patient safety and proper procedures in Medical Supply Distribution (MSD) and Sterile Processing Service (SPS). I have reported unsafe conditions at the AAVAHS starting in mid 2010. The current investigation started with my complaint to the OSC on 3/8/2013 and the OMI has been stonewalling and using delay tactics so the report does not make it to President Obama, acting Secretary Sloan Gibson and the Congressional Oversight Committee. Bottom line is Veterans are in more danger than ever and the VA leadership has had to be pushed and prodded for years to do the next right thing. I have requested the OMI shutdown sterile processing at the AAVAHS during construction. Conditions have deteriorated in sterile processing and sterile storage areas and will continue to deteriorate as the next phases move into sterile processing. As stated in the International Association of Healthcare Central Service Material Management (IAHCSMM), Central Service Technical Manual seventh edition pg. 25 **"Negligence and carelessness in Central Service could cost a patient's life!" (See Attachment 6).**

The following is a short history of meetings, emails and request for investigations at all levels of leadership.

September 2010, in a staff meeting I tried to bring the problems with sterile processing and storage to the attention of my supervisor (Chief of Logistics AAVAHS) and a threat was made.

December 20 2010, a meeting with AAVAHS Associate Director, Medical Supply Distribution (MSD) Lead Technician to discuss sterile processing and storage problems.

January 6, 2011, a meeting with the AAVAHS Associate Director, Chief of Logistics and the Medical Supply Distribution (MSD) Supervisor to discuss sterile processing and storage problems.

February 2, 2011 a Complaint to Veterans Affairs Office of Inspector General (VAOIG).

June 28-30, 2011 VAOIG inspection. The sterile processing and storage areas were identified as substandard and a redesign plan was developed. **(No further action other than a plan).**

July 5, 2011 in a meeting with AAVAHS Director about the VAOIG inspection. This meeting happened eight days after the inspection. A veiled threat was made by the AAVAHS Director. It was made clear that I would not have a job if I continued to cause problems.

May 6, 2012 a complaint in an email VISN 11 Director.

July 11, 2012, Office of Special Council Complaint (MA-12-3972) with the same discrepancies from the VAOIG complaint of February 2, 2011. No action taken. I was told I did not have new evidence and the VAOIG had done an inspection.

July 24, 2012, Office of Special Council Complaint (MA-12-3970). No action taken.

March 8, 2013, Office of Special Council complaint with new evidence. (Case #DI-13-2133)

June 25, 2013 OMI's AAVAHS Site Visit (June 25-26 2013)

July 24, 2013 OMI's AAVAHS site visit report. Funding approved to renovate Sterile Processing and Sterile Storage.

September 26, 2013 VA Chief of Staff Response to OMI's site visit report.

February 28, 2014 OSC requests my comments on the OMI's Inspection Report.

March 24, 2014, I requested help from Congressman Dingell to help to shut down sterile instrument processing at the AAVAHS.

March 31, 2014 my response to OMI's report.

May 14, 2014 OMI's Supplemental Report to my response to their inspection report. **(OMI's response was just a restatement of their original response).**

May 27, 2014, Office of General Council sent OMI's Supplemental report to OSC.

June 12, 2014, OSC Sent the OMI's Supplemental Report to me for review and comments.

As construction has started I had the opportunity on March 25, 2014 from 7:30 a.m. – 7:45 a.m. to stand in the hallway in front of SPS/MSD and observe several events/modifications that could compromise sterility of our surgical instruments and harm our patients and employees.

1. The Chief of MSD, Michael Ruggiero, came out of Sterile Supply and handed supplies to a customer and then reentered Sterile Supply. He was dressed in civilian clothes with only a cover gown (which was not properly tied) and a beard cover cap. Policy Memorandum (PM) 90-13, November 15, 2013 Dress and Attire states basic attire is clean scrubs, blue warm-up jacket and shoe covers.

2. came out of the Decontamination locker room in scrubs with no cover gown and walked down the hallway. He then entered SPS/MSD, retrieved a blue warm-up jacket, came out of the SPS/MSD entrance and went back into the Decontamination locker room. PM 90-13 requires a cover gown outside Sterile Supply and a blue warm-up jacket inside Sterile Supply. The blue warm-up jacket should never be worn outside Sterile Supply.

3. The construction has started 10 feet to the south of SPS/MSD, and as I stood there watching, the construction worker cut and hammered the cinder block with dust going everywhere as two other workers were trying to re-duct tape plastic sheeting to the cinder block wall as a dust barrier.

   a. I believe this project is being rushed and proper safety measures are not in place to protect patients and employees.
   b. I believe from my 15-minute observation that a lax environment still exists in SPS and MSD.
   c. **I believe all sterile processing should stop until the SPS/MSD construction has been completed.**
   d. **I believe our Patients have not been protected properly for many years.**
   e. **I believe during construction there will be greater chance for contamination as you have read above.**

4. I observed a doorway in the Decontamination anteroom has been sealed closed. This door is required to be open for clean-to-dirty flow of staff. It also appears management has Decontamination staff entering and exiting Decontamination through the same door. Clean and dirty PPE cannot be in the same room. The dirty PPE contaminates the clean PPE. See Attachments 1, 3 and 4.

5. Separate locker rooms for clean and dirty staff are still not available as required by SPD Design Guide, dated February 2010, IAHCSMM), VA Manual 7176 and attachments 1&3. SPD Design Guide 2.7& 2.8

6. SPS/MSD, do not have anterooms for clean to dirty flow of staff. See attachments 1&3

7. Proper organizational alignment of responsibility between SPS and MSD has still not been accomplished. As required by IAHCSMM and Dr. Robert Petzel, Under Secretary for Health in the Department of Veterans Affairs (i.e. SPS is responsible for all reprocessed supplies to include Operating Room Case Carts and MSD is responsible for all expendable medical supplies). See attachment 5 Notes

    a. Here at the AAVAHS leadership and management have organized SPD/MSD differently than any other VA hospital, and for that matter, any civilian hospital I have contacted. They have assigned Operating Room (OR) case cart assembly to Medical Supply Distribution (MSD). OR case carts and surgical instrument trays are reusable medical supplies and the majority of case carts. There are expendable medical supplies in OR case carts, but they require special aseptic storage near the surgical instrument trays and away from expendable medical supplies used to stock secondary supply areas in the wards, Intensive Care Unit's (ICUs) and clinics. When the newly reconstructed SPS and MSD areas are completed the SPS area will house the surgical trays, case carts and expendable medical supplies used specifically for surgery. MSD will house a separate storage area for expendable medical supplies used to stock SPS, wards, ICUs and clinics where aseptic storage is not required. (See SPD design Guide February 2010 and the AAVAHS SPD design plan dated 10/24/12), the guidance from the International Association of Healthcare Central Service Material Management (IAHCSMM) and VA Manual 7176 are the same. It is SPS's primary responsibility to provide OR case carts to the OR and MSD's primary responsibility is to order and stock expendable medical supplies throughout the AAVAHS. (See attachment 5, The Processing Cycle and notes on bottom third of page).

    b. The staff in MSD is not IAHCSMM or VA level one trained or certified and they do not have the proper hands-on instrument experience required by IAHCSMM to work in this area. No other VA or civilian hospital I've contacted allows MSD staff to pull OR case carts. A video was sent out on November 18, 2010 with Dr. Robert Petzel, Under Secretary for Health in the Department of Veterans Affairs giving an overview of the VA's reorganization plan. In that presentation he made the point very clear that we are the largest health care system in the United States and we have to act as a system. He said we will no longer operate one way at one hospital and another way at another hospital. In sterilization the process is the same no matter if you are in Michigan or Texas. You must have

consistent work rules, training, SOPs, policies, and supervision. Having two Chiefs giving different instructions and training in an area as critical as SPS has and will continue to endanger patients.

c. This was no more evident when the OMI team noticed that MSD had different attire than SPS staff working in the same area with the same dress requirement no matter who is working in this area.

The bottom line is MSD should be responsible for expendable medical supplies and SPS should be responsible for all reusable medical supplies to include OR case carts.

I would like to turn your attention to attachment 1&2 which is the most visually telling of SPS/MDS shortcomings. I have attached the original floor plan that I signed annually to verify I understood the flow of traffic through sterile processing and storage. See Attachment 1 and compare it side-by-side to Attachment 2 from the Medical Inspector's Report (also named Attachment B in OMI's report).

1. Compare Attachment 1 Room DB39 Equipment Room with altered Attachment 2 Breakout Room.

   a. They have altered rooms' usage and put the breakout room on one side of SPS/MSD and the Bulk Storage room on the other side of SPS/MSD. This has caused high volumes of traffic to pass through sterile storage to stock and retrieve items from bulk storage DB33.

   b. Large quantities of stock are kept in the breakout room.

The following two paragraphs are taken from SPD Design Guide.

Receiving and Breakout Room: This room allows for the arrival of clean supplies and the breaking out of those supplies from shipping cartons and boxes. Packing debris should be removed without entering the Clean/Sterile Holding Room. Space for inventory management is provided in this space.

Location of Bulk Storage: Bulk storage is where supplies are received in case lots from the warehouse, prime vendors and other sources. The Bulk Storage area should be located near the SPD Clean/Sterile Storage area and connected to the SPD Breakout. No supplies are to be in this area; low unit of measure. (Note: Hospital sterilized items, including instrument sets, will not enter this area.)

Now let's look at DB39 the clean side of SPS/MSD. Compare the men's locker room and male toilet on Attachment 1 to break room and male toilet on see Attachment 2.

1. Attachment 1 (original floor plan) In the 5 years I've worked in SPS/MSD this has never been a men's locker room(clean side)--it has always been a break room. About 3 years ago the male toilet was removed and the break room was expanded.

2. Attachment 2 (Medical Inspectors floor plan): It is referred to as break room male toilet. There is no male toilet.

The following two paragraphs are taken from SPD Design Guide.

Facility design is crucial to the efficiency and effectiveness with which these needed environmental conditions are met. Design features deserving particular attention include:

- Separation of soiled areas from clean areas
  Restricted areas

Anteroom: This space serves to maintain proper air pressure relationships when personnel move between adjacent spaces.

Staff Lockers/Showers: One-way flow-through staff lockers are provided to ensure that Decontamination staff arrive, dress and work within the Decontamination area without cross-contaminating other spaces or public corridors. Separate lockers are to be provided for staff working in the Prep, Assembly, and Clean/Sterile Storage Rooms.

Staff Lockers: Dedicated lockers and a toilet are provided for staff working within the Prep, Assembly, and Sterilization Room and the Clean/Sterile Supply Storage Area. This dedicated one-way flow through locker room is designed to promote the maintenance of the clean environment in both major rooms.

Now let's look at DB48 SPD Decontamination Lounge, DB48b Decontamination Male Toilet and DB48c Decontamination Male Locker Room. The SPD lounge is really the decontamination anteroom as identified by AAVAHS Joe Jurasek Industrial Hygienist. The decontamination locker room and toilet are shared by both clean and dirty staff. I believe this was changed during the original construction of the clinical addition to the AAVAHS. In fact, I believe as much as half of SPD was changed from the original approved construction plan and made into Out-Patient Psychology; which would explain the missing parts of SPS/MSD (i.e. clean anteroom, sterile/non-sterile storage nursing units, sterile/non-sterile storage surgery unit and breakout/bulk storage.) I believe this facility should not have been certified to process sterile surgical instruments from its inception. The individuals who could give insight into that are

Elizabeth Smith of the National Center for Patient Safety (previous Chief SPD AAVAMC) and Karla Sandell VISN 11 Logistics Officer.

Now let's look at the HAC Janitor's Closet DB35 which has been converted into a water treatment room and housekeeping has used DB47 to clean both clean and dirty sections of SPS/MSD.

The flow of traffic arrows have been removed from the Medical Inspector's floor plan. I believe this was done intentionally to deceive the readers of the report.

In summary: This SPS/MSD operation is like trying to drive a car with no steering wheel (absent leadership and asleep at the wheel), bald tires (inefficient, could blow up at any time), low on gas (no one trained on refueling). I hope for the sake of our veterans someone will stop operations until the construction has ended and staff can be properly trained.

To have the OMI say they could not find any evidence patient safety was compromised is just disingenuous. Infections should be an anomaly; if everyone is doing their job correctly there will be no infections. OMI said they could not link any infections back to SPS. That's because SPS does not have a Quality Assurance Program. They have no hard to clean item list; there are no records of periodic QA testing of reprocessed Genesis trays to ensure a quality end product. Ask SPS management for the last five years results of random period testing of trays pulled from the storage area. Ask SPS for the last five years results of QA testing of the hard to clean items.

OMI reports SPS uses two sterility indicators in every load. Sterility indicators only measure that the conditions in the sterilizers meet the condition to kill bacteria and spores. If an instrument is not cleaned properly or has been re-contaminated with some type of protein after being cleaned it cannot be sterilized because protein cannot be sterilized. Indicators do not guarantee sterility; a quality consistent process can only give us a reasonable assurance of sterility.

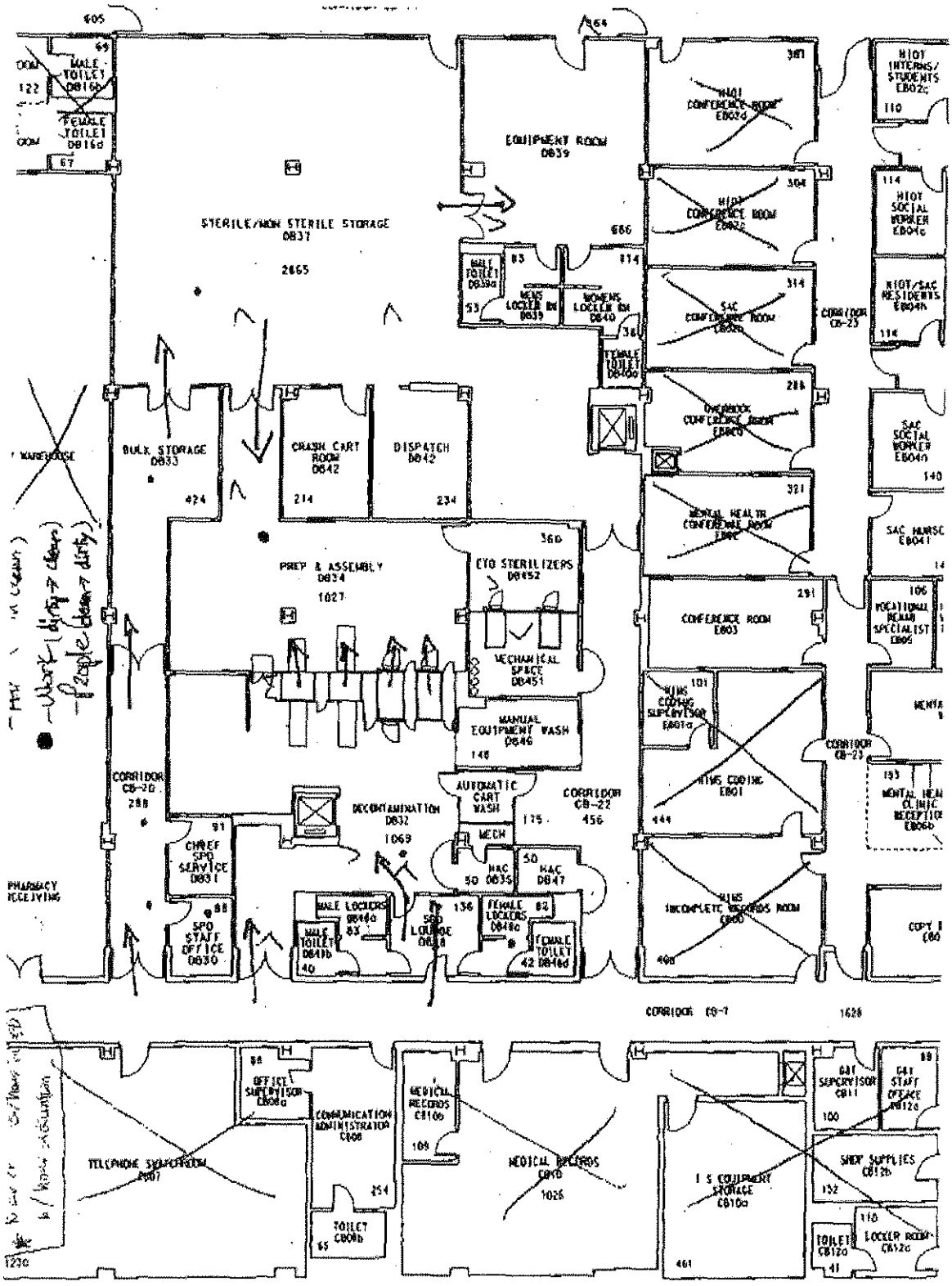
The OMI inspectors misstated that the blue gown worn by staff when outside clean/sterile is acceptable to be worn inside the SPS/MSD department. The long cover gown is not kept in a controlled area and is contaminated with dust and debris and should only be used outside the department. The appropriate attire for SPS/MSD (clean side) is scrubs, hair cover, blue warm-up jacket and shoe covers if dedicated shoes are not worn. Visitors must wear the same as staff and an additional option is a jump suit, shoe covers and hair covers. See Attachment 4, IAHCSMM Central Service Technical Manual, Traffic Control.

Management directed personnel working in the decontamination area in contaminated attire to remove clean Genesis trays from the cart washer on the clean side of SPS/MSD causing

recontamination of the trays and then sending the Genesis trays into sterile processing. This was allowed by OMI and later investigated by a union safety representative and the practice was stopped due to cross-contamination.

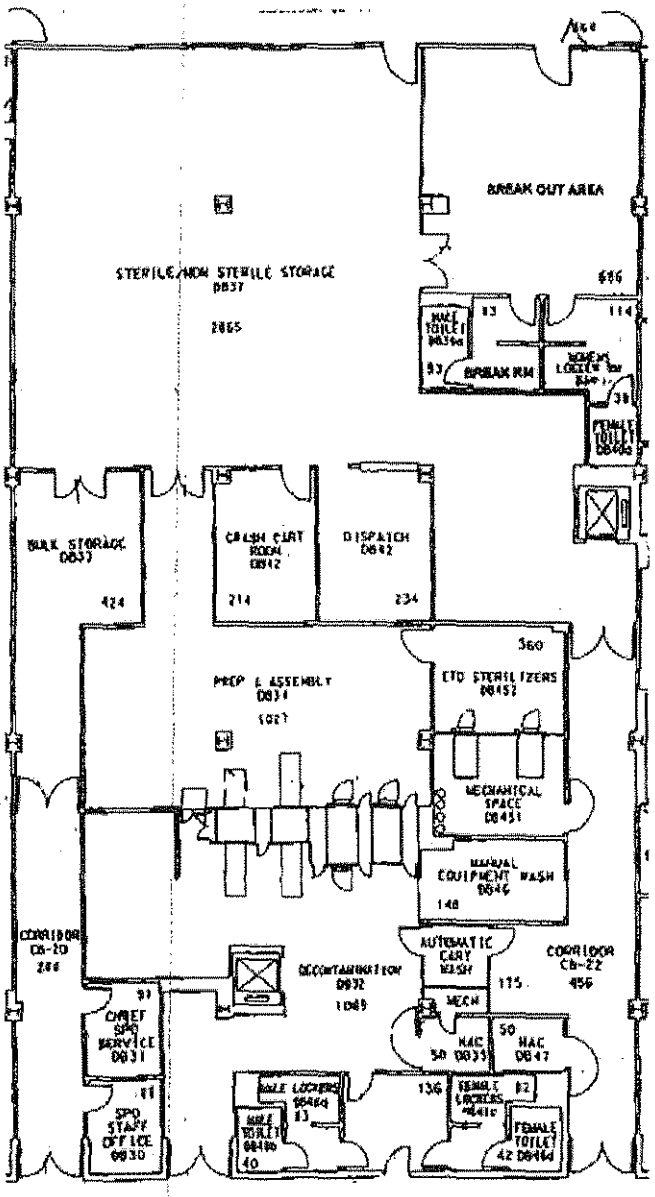
OMI states I did not respond appropriately on one occasion when I discovered contaminated items in SPS/MSD sterile storage. The whole event is much more troublesome than OMI is stating. The sterile storage area had not been cleaned appropriately in over a year and the many staff complaints to management fell on deaf ears. Dirt was very thick to the point the white floors were black under the shelving holding sterile supplies, restrooms filthy, decontamination had not had its floor bleached in months. I called Congressman Mike Rogers' office and talked to Stuart Pigler and after meeting with him he agreed to schedule a short notice (two-day notice) site visit of SPS/MSD. He contacted the Director's office and they were able to delay his visit until the following week, Tuesday January 22, 2012. The weekend before Stuart Pigler's visit on Tuesday management had several EMS staff using large motorized scrubbers come in and clean the entire department. When I arrived at work on Monday, January 21, 2012 the shelving had splash marks up at least 15 inches and hand prints up to five feet. I called the union office first because I had already been given a letter of reprimand for unprofessional conduct when I reported contamination once before and management proposed a three-day suspension for unprofessional conduct for explaining that the training material they were using was outdated. They were unable to pursue the suspension as two staff that witnessed my actions made written statements refuting management's allegations of unprofessional conduct. I contacted Union President, and he told me there was nothing I could do and that I had to let them do it. The following morning I called the union office again and spoke to the union's Chief Steward and told him we have to do something because the entire sterile storage department has been compromised. He had me come in and fill out a Report of Contact stating what I believe happened and he went with me to Amy Lyons, Chief of Infectious Diseases, to give her the Report of Contact. I explained what had happened and Ms. Lyons would not take the Report of Contact and I left. OMI states in their report that the Assistant Chief of SPS was contacted and she verified the splash marks and the packages were removed. As I stated earlier the entire department had been compromised -- not just a few packages. Ms. Lyons was told in our conversation that the entire department needed to be re-sterilized and all shelving cleaned.

Larry Ludtke 6/30/14

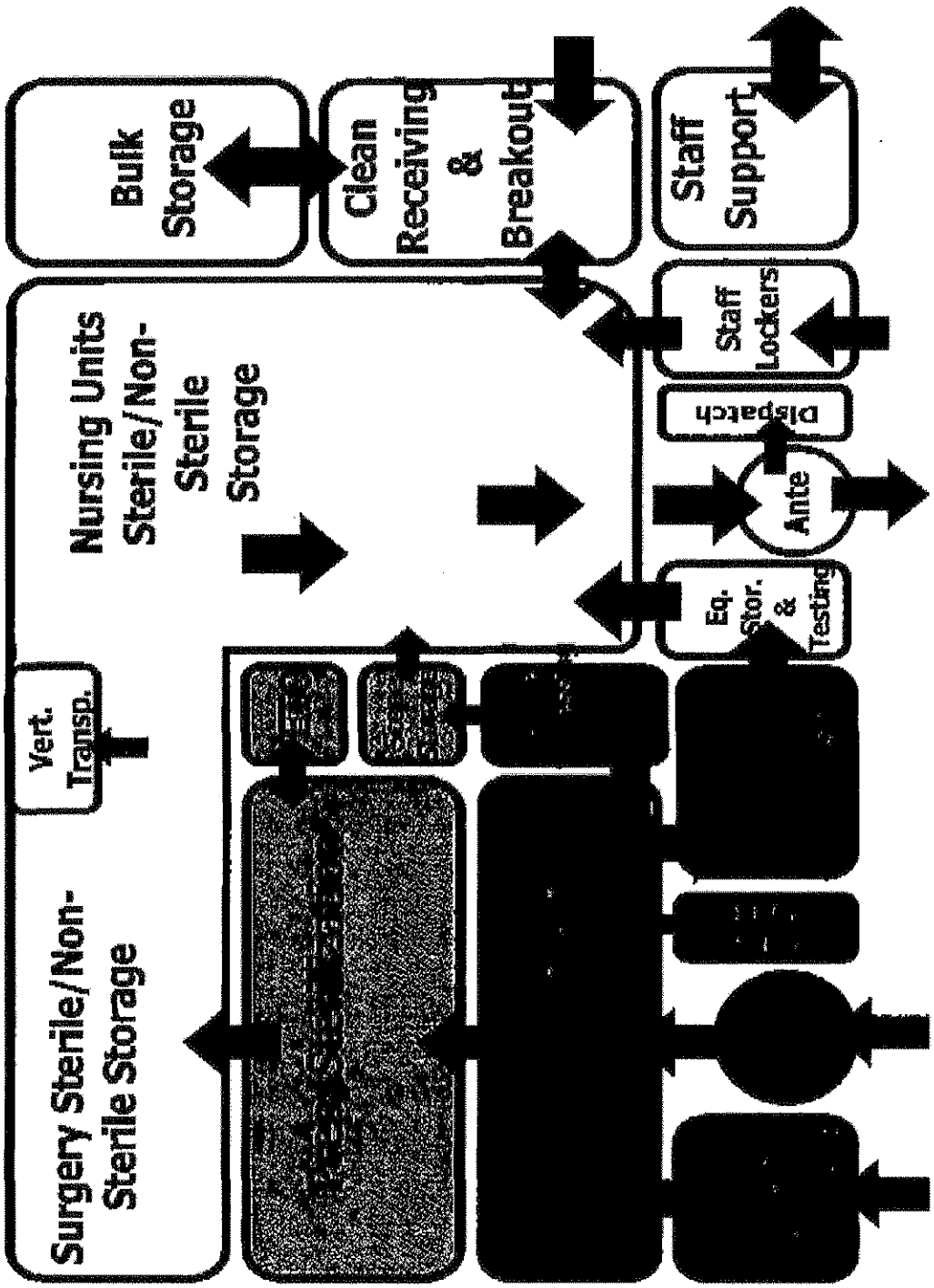


ATTACHMENT 1

Attachment B



ATTACHMENT 2 (also known as attachment B)



Functional Relationship Diagram

ATTACHMENT 3

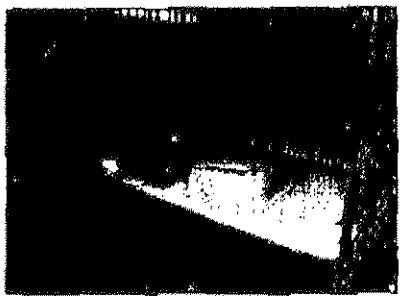


Figure 6.10

Other Requirements

Central Service departments are equipped with hand washing sinks conveniently located for easy access. Central Service Technicians should wash their hands only in dedicated hand washing sinks (not in those used for decontamination purposes).

The fixtures and furniture in Central Service departments must be constructed of materials that can be washed, and they must be cleaned on a regularly scheduled basis.

The area designated for sterile storage may consist of either open (rack) or closed (cabinet) storage units. The decision about the type of storage used is based on the types of items to be stored, and the amount of traffic in the area. For example, closed cabinets may be used in high traffic areas, and open shelving (racks) may be used in more controlled, low traffic areas.

Open rack systems should have a solid bottom so that items stored on the lower shelves are protected from contamination during housekeeping tasks. (See Figure 6.10)

Note: more detailed standards for design requirements for Central Service work areas can be found in ANSI/AAMI ST79:2006.

MAINTAINING CENTRAL SERVICE ENVIRONMENTS

Learning Objective 6. Review environmental aspects of Central Service work procedures that impact infection control:

- Traffic control
- Work area cleanliness
- Workflow

Engineering and design activities cannot prevent and control infection by themselves. The effective management of microorganisms relies on those who work within the Central Service department. Central Service Technicians must understand the infection control protocols within their facility, and they must adhere to them at all times. Failure to do so puts patients and employees at risk. Each infection control protocol is designed to protect patients and employees, and to maintain the integrity of the Central Service environment.

Traffic Control

The first step in maintaining environmental integrity is to control the traffic that enters and passes through the Central Service department. The dress codes discussed earlier in this chapter apply to all persons entering the Central Service department. Department dress standards for visitors (examples: sales representatives, maintenance personnel and clinical engineering staff) vary between facilities. In some facilities, they must change into surgical scrubs; in others coveralls (worn over their street clothes) are required. Central Service Technicians must protect the integrity of the environment by enforcing traffic control guidelines. This may sometimes mean educating visitors about dress code and traffic control protocols.

Dress code requirements may change as Central Service Technicians move from one area to another. For example, surgical scrubs and hair coverings may be appropriate for the clean assembly area, but OSHA-required PPE is necessary for the decontamination area. Dress codes are an important part of traffic control. Therefore, Central Service Technicians must understand what attire is appropriate in different areas. (See Figure 6.11)

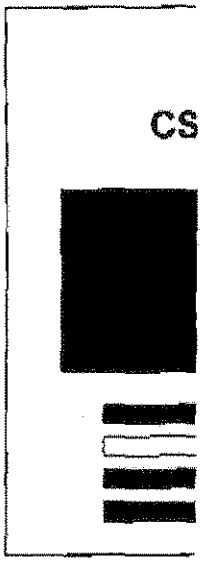


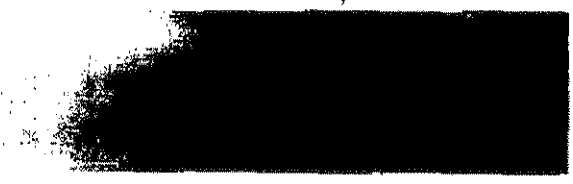
Figure 6.11

Figure 6.12

Areas that Central Ser
travel through may ha
control/dress code requir

- Biohazard – These a
from used equipment,
OSHA-required PPE

- Unrestricted – These
traffic areas such as ho
offices, locker rooms, a



ATTACHMENT 4

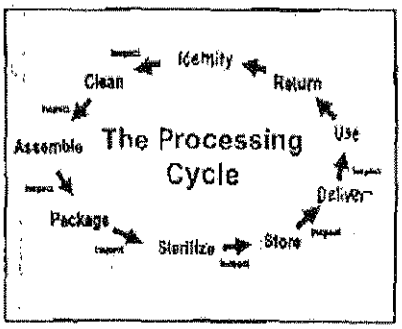


Figure 1.11 The Processing Cycle: Inspection plays an essential part of the process to ensure that a safe, quality product is provided for our patients.

The Processing Cycle

Work performed in Central Service usually follows the cycle just discussed. (See Figure 1.11) After use, items that can be reprocessed are returned to the decontamination area to start the process all over again. It is important to note that, at each step in the process, items are inspected to ensure that they are clean, in good repair, assembled and processed correctly, and/or that packaging materials have not been damaged to compromise sterility. Figures 1.12 through 1.15 illustrate steps in the use cycle from the user unit (in this case Surgery) to decontamination.

ATTACHMENT 5

compensated relative to organizational peers. As previously mentioned, there are a growing number of health care facilities that compensate Central Service staff members with pay increments based on experience, high performance, additional education and training, and upon certification.

IN CONCLUSION

The Central Service environment is dynamic and fast-paced. The work is challenging, highly technical, and complex. The performance of this vital department has a major impact on the smooth operation of the many departments to which it provides products and services.

Inefficiencies in productivity, errors that create the need for re-work, and poor quality performance, are costly to hospitals. With the ever-increasing costs of health care, Central Service professionals must strive to conserve resources and minimize expenses. More importantly, however, is the safety and welfare of the patients who have entrusted us with their care. [redacted]

Conscientious Central Service professionals will find great satisfaction in knowing that their efforts, service, special skills, and caring are a part of every surgical procedure, each patient recovery, every birth, each patient discharge, and each happy family reunion.

Central Service is an evolving occupational discipline. Over the years, there have been dramatic changes ranging from the increased use of technology and support services provided to the job skills, training, and educational requirements needed to fulfill these job responsibilities. Changes continue at a fast pace!

REFERENCES

Calbert, Bruce J. Workplace Readiness for Health Occupations. Second Edition. Thomson Delmar Learning. 2006.

Booth, Kathryn A. Health Care Science Technology: Career Foundations. McGraw-Hill Companies, Inc., 2004.

For National Health Care Skill Standards visit the National Consortium on Health Science & Technology Education (NCHSTE) website: www.nchste.org.

CENTRAL SERVICE TERMS

Integrated delivery network (IDN)

Service

Decontamination

Case cart system

Doctor preference card

Case cart pull sheet

Materiel Management department

Negative air pressure

Positive air pressure

Standard precautions

Nosocomial

Job description

Certification

Career ladder

ATTACHMENT 6

SPD DESIGN GUIDE OUTTAKES

General Considerations

General Planning Concepts

Flow with Sequence: Supply, Processing, and Distribution (SPD) are organizationally aligned under the Nurse Executive/Chief Nurse. The mission of SPD is to provide a steady flow of patient care supplies and equipment to points of need, and to return contaminated items to a central decontamination area for cleaning.

SPD is the first line of defense against harmful microorganisms. Contamination prevention is achieved by closely monitoring the following elements:

> **Air Flow:** To minimize microorganism movement from dirty to clean areas. In clean areas there is a positive air flow.
>
> **Staff Flow:** Personnel work either on the clean side or the dirty side of the SPD unit to avoid cross contamination.
>
> **Work Flow:** Refers to the movement of clean (sterile) supplies and the return of contaminated items for decontamination and sterilization.

Adjacencies: SPD must be closely affiliated with surgical procedure suites. SPD may be directly connected to the sterile support core for the Surgical Suite, or may be located with convenient and direct access via cart lifts and/or staff circulation.

Processing and Distribution Methods

SPD is divided into three main units/areas. The first unit is Decontamination, where all reusable medical and surgical items are sent for cleaning. It is essential that contaminated materials do not use the same path as the clean materials. The second unit is Preparation. In this unit, items are inspected and packaged for sterilization. Most sterilization is accomplished by using steam; or, in the case of materials that cannot withstand intense temperatures, ethylene oxide (ETO) gas (or another suitable gas) is used. Materials undergoing ETO sterilization must be adequately aerated to ensure that no hazardous traces are left on devices. The final unit in SPD involves the Distribution Process, including distributing surgical case carts. This unit is further subdivided into Primary Stock and Secondary Stock. Primary Stock refers to the supplies that are stored within the confines of the SPD department. Secondary Stock materials are those in user areas such as clinics, nursing care units, and intensive care units.

Current Trends

A current trend impacting SPD is the increasing complexity of many surgical procedures such as laparoscopy, endoscopy, laser, micro-vascular, and more complex surgeries. These complicated surgeries require more complicated instrumentation. This complex instrumentation has led to the trend for SPD technicians to be certified, thus requiring the staff to have a certain level of competency and to keep up with periodic/annual continuing education.

Another current trend in SPD is instrument tracking. This can eliminate hours of searching for lost instruments, location of key assets, tracking loaner equipment, and ensuring patient safety and the quest for zero "never events" through the validation of sterilization processes.

Future SPD Trends

An anticipated future SPD trend, sustainable decontamination and sterilization equipment has been embraced by many manufacturers who are reviewing the environmental impact of the product lines, and developing machines that are safer for the staff and kinder to the environment. Examples include equipment features that yield significant water savings, the use of fewer toxic or less-toxic chemicals, etc.

Other future trends include stricter protection of healthcare workers, since pathogenic organisms (Hepatitis B or C, and Human Immunodeficiency Virus (HIV)) have become known.

Special Considerations

ETO: The provision of ethylene oxide (ETO) gas (or another suitable gas) may be required to sterilize selected instrumentation that is unable to sustain the high heat of steam-based sterilization processing. Because of the high toxicity of the sterilizing agent used in this process, ETO sterilization must be sustained in a fully contained room that is part of the Prep, Assembly, and Sterilization space.

Location of Bulk Storage: Bulk storage is where supplies are received in case lots from the warehouse, prime vendor and other sources. The Bulk Storage should be located near the SPD Clean/Sterile Storage area and connected to the SPD Breakout. No supplies are to be in this area; low unit of measure. (Note: Hospital sterilized items, including instrument sets, will not enter this area.)

Endoscope Processing: Endoscopes may be rigid or flexible. Rigid Endoscopes are typically sterilized with the same vigor and care as the surgical instrumentation. Flexible Endoscopes typically require minimum high-level disinfection and occur in close proximity to where the procedure is performed (i.e., GI Suite). However, some SPD suites may need to accommodate the reprocessing of Flexible Endoscopes. This will require dedicated Endoscope Preprocessors'.

Architectural Considerations

Location of SPD

Several factors influence the location of the SPD. These include:

Access to the OR: In some circumstances, the sterile delivery side of the SPD can be directly linked with a sterile core of the OR, allowing a direct transfer of materials and instrumentation and minimizing transport time.

As an alternative, the SPD can be located on another level. The SPD may be linked via clean and soiled cart lifts. Dedicated clean and soiled cart lifts need to arrive and leave at appropriate locations within the SPD, and cannot be used for any other function, nor can a single lift be used for both clean and soiled transport. Clean and soiled dumbwaiters may be an alternative, but are not an ideal solution in new construction as they require the transfer of items onto the dumbwaiter, then off at the point of destination, while the cart lift allows for the transport of a fully loaded cart.

Access to Loading Dock: The SPD receives fresh supplies to store, inventory, and distribute to augment instrumentation that is then used to stock supply or case carts. Access to the loading dock needs to be straightforward and simple to allow the repeated and consistent delivery of material. If the loading dock is on a different level of the facility, care must be taken to plan the entire route from the dock to the SPD, confirming corridor width, elevator size, etc.

Environmental Requirements

Environmental considerations most critical to SPD are: temperature, humidity, ventilation, light, and protection from contaminants.

Facility design is crucial to the efficiency and effectiveness with which these needed environmental conditions are met. Design features deserving particular attention include:

- Separation of soiled areas from clean areas
- Restricted areas
- Containment area for ETO gas
- Heating, ventilation, and air conditioning (HVAC Systems)
- Room relationships (regarding function and staff utilization)
- Modularity of design/flexibility
- Interior surfaces and finishes

Space Planning Criteria

Space planning criteria for SPD includes the following considerations:

Quantity of Space: The quantity of space will be driven by the total through-put needs of the SPD, which is, in turn, driven by the surgical volumes and surgical procedure mix. Key factors in determining total size will be the total number of sterilizers needed and the total daily throughput of instrumentation carts. The relationship between surgical volumes and SPD through-put is direct; if the ORs are planned to expand, the SPD needs to have correlative capacity.

Location of Space: The relationship between SPD and the OR Suites is critical, as previously noted. In addition, a clear path from loading docks to the SPD is essential.

Quality of Space: The space itself must be able to provide an appropriately clean environment for the handling of soiled instrumentation and sterile instrumentation and supplies. Mechanical, electrical, and plumbing requirements are defined under "Engineering Considerations". In addition, finishes must respond to the need to be able to clean the environment appropriately.

Room Relationships & Adjacencies

One of the primary purposes of the SPD is to deliver clean/sterile supplies and instrumentation to the OR. It does so by receiving and cleaning soiled instrumentation and by staging and assembling sterile instrumentation and clean/sterile supplies for delivery to surgical sites and other areas that require sterile implementation within the hospital. In doing so, it must promote efficient delivery of material while maintaining the clean and sterile status of instrumentation and supplies. The four key spaces are sequentially linked, and include:

Decontamination: Soiled instrumentation arrives here as the first stage in the SPD process. Soiled instrumentation is received via closed case carts that may return via elevators, dedicated cart lifts, or dumbwaiters directly to the Soiled Receiving and Decontamination Room.

Preparation, Assembly, and Sterilization Area: This room is directly connected to Decontamination. Equipment passes through a washer decontaminator that allows the transfer of instrumentation through the washer/disinfector or sterilizer to the Preparation, Assembly, and Sterilization Area. Access for sterilizer maintenance must be provided, and there may be a pass-through window for small items.

Clean and Sterile Storage: This room is directly connected to the Prep, Assembly, and Sterilization Room and is used to store and pick sterilized instrumentation and sterile supplies for delivery to the point of use.

Staff Support: These spaces serve to provide administrative and break support for SPD staff.

It is critical to the functional efficiency and safety of the SPD that these spaces are sequentially linked for one-way flow-through of instrumentation and carts. This promotes the maintaining of the sterile state of instrumentation as it is cleaned for re-use.

Functions of Areas within SPD

Clean Receiving and Breakout Area: This space serves as an area to receive and break out disposable supplies received from the warehouse, prime vendor, or manufacturers. This area is also where specialty carts such as crash/code carts and isolation carts are returned after use for the supplies to be removed before the empty cart is taken to the Decontamination Area for cleaning. This area is also used to receive loaner instruments and equipment and for them to be picked up. Consignment supplies and implants are to be received here, as well.

Anteroom: This space serves to maintain proper air pressure relationships when personnel move between adjacent spaces.

Decontamination Area: This includes staging space and circulation space designed to allow for the gross decontamination of instrumentation, followed by the placement of the instrumentation on a washer decontaminator that will deliver clean instrumentation to the Prep, Assembly, and Sterilization Room. In addition, there is a pass-through window for selected items that are either too delicate or will not fit will be directed to the ETO Sterilizer in the Prep, Assembly, and Sterilization room.

Automatic Cart Washer: This room houses the equipment that receives soiled carts, washes them, and delivers them to the Clean and Sterile Storage Room.

Decontamination HAC: In order to maintain clarity of cleanliness, the Decontamination Area has a dedicated Housekeeping Aide's Closet, accessed only from the Decontamination Area and used only for cleaning in that space

Staff Lockers/Showers: One-way flow-through staff lockers are provided to ensure that Decontamination staff arrive, dress and work within the Decontamination area without cross-contaminating other spaces or public corridors. Separate lockers are to be provided for staff working in the Prep, Assembly, and Clean/Sterile Storage Rooms.

Clean Cart Lift: If a lift is used for the movement of clean carts, the clean cart lift must deliver the clean cart directly to the Surgery suite sterile storage space. Clean carts must be restricted to the clean cart lift.

Prep, Assembly, and Sterilization: This room preps, assembles, and sterilizes equipment and instrumentation. Instrumentation arrives through-wall washer/sterilizers or sterilizers; other selected items may arrive via a window pass-through. The room decants prepped and packed sterilized instruments into the Clean/Sterile Storage Room. As part of its function, the Prep, Assembly, and Sterilization Room have an ETO Sterilizer, used for devices that cannot withstand steam sterilization due to temperature or moisture.

Clean/Sterile Storage: This room contains a number of functions that support the staging and storage of clean and sterile supplies for distribution to point of service. Those functional zones include:

Case Cart Holding: This area is positioned immediately adjacent to the delivery door from Prep, Assembly, and Sterilization to facilitate the assembly of case carts with specific sterile packs for case carts.

Equipment Storage and Testing: This area, positioned to receive cleaned carts and cleaned medical equipment, accommodates the testing and storage of equipment and the temporary queuing of carts.

Case Cart Area: This area stores and stocks clean supply dedicated for OR use. These supplies have been broken out to accommodate final stocking on case carts or other dedicated cart delivery systems.

Dispatch/Control: These workstations accommodate staff that directs the flow of case carts and cleaned/tested equipment to point of use.

In addition, there are several rooms that have a direct relationship to Clean/Sterile Holding with all of its work zones. These include:

Receiving and Breakout Room: This room allows for the arrival of clean supplies and the breaking out of those supplies from shipping cartons and boxes. Packing debris should be removed without entering the Clean/Sterile Holding Room. Space for inventory management is provided in this space.

Bulk Storage: This room allows for the queuing of the storage Receiving and Breakout Room prior to unpacking and stocking shelving in the Clean/Sterile Storage Room.

Staff Lockers: Dedicated lockers and a toilet are provided for staff working within the Prep, Assembly, and Sterilization Room and the Clean/Sterile Supply Storage Area. This dedicated one-way flow through locker room is designed to promote the maintenance of the clean environment in both major rooms.

Support Spaces: There are several functions that support the core mission of the SPD. These include:

Staff Break Room/Conference Room: The Staff Break Room/Conference Room is designed to serve staff working with the SPD. Staff using this Break Room/Conference Room must return to their respective worksites with attention to cleaning and gowning protocols suitable for each key space.

Concerns Specific to Supply, Processing & Distribution

Equipment: Equipment may be purchased by either the VA (Owner) or the contractor and installed by the contractor (CC), or purchased by the VA (Owner) and installed by the VA or the Vendor (VV). If purchased by the contractor, specifications must be clearly written.

The Chief of SPD operations at each VA medical center is knowledgeable about equipment styles and types that best meet the needs of the facility, and should guide the selection of equipment. If purchasing equipment not listed in GSA catalogs, specifications must be sufficiently detailed to assure quality acquisition.

The selection of equipment should be fully coordinated with the facility's design in order that utility and space requirements are considered during design development. It is imperative that all power and water resources be fully accommodated, and that the mechanical and ventilation systems are designed to be responsive to heat loads created by specific equipment. Thus, the specific choice of equipment must be established early on to promote a consistent and coordinated plan. Careful attention must be given to the location and capacity of electric outlets, water and steam supply, drains, vacuum, exhaust ducts and other utilities, to insure capacity and compatibility with the equipment to be installed. Utilities and their locations are shown on the Guide Plates and are not project specific. It is the responsibility of the person selecting the equipment and the project designers to determine the adequacy of utilities in each space.

Sanitation Equipment: Frequent and thorough cleaning of shelves and room surfaces is essential to prevent build up of dust and unwanted particles which may contaminate medical and surgical supplies.

Room walls are manually scrubbed with either a detergent and/or disinfectant. Thus, to facilitate cleaning, walls are typically specified with a washable surface. Floors in the Soiled Receiving and Decontamination room may be damp mopped or cleaned with an electric floor scrubber. In the Sterile/Non-Sterile Storage Room; however, cleaning with a damp mop will suffice. Generally, storage shelves in the Sterile/Non-Sterile Storage Room are kept 200 to 250 mm (8 to 10 inches) above the floor to facilitate cleaning.

Washer/Disinfectors: Following the ultrasonic cleaning process, instruments are placed into washer/disinfectors. Instruments and trays are loaded into the unit on the Decontamination side of SPD, and removed upon completion of the cycle on the Prep/Pack side of SPD. Washer/Disinfectors are heated by either electric or steam. Automation systems for loading and unloading washer/disinfectors are highly recommended for departments that process large