

STERILE PROCESSING SERVICES (SPS)

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive provides procedures for the decontamination, high-level disinfection (HLD), and/or sterilization of critical and semi-critical reusable medical instruments and equipment and storage of items reprocessed in the Department of Veterans Affairs (VA) medical facilities.

2. SUMMARY OF CONTENT: This is a new VHA Directive that combines the policy and responsibilities of the SPS program previously contained in multiple VHA Directives. Specifically this VHA Directive:

a. Provides specific requirements for the organizational structure charged with oversight responsibilities for reprocessing specified reusable medical equipment (RME) at the Veterans Integrated Service Network (VISN) and medical facility levels.

b. Includes specific guidance for the standardization of equipment types and for ensuring that reprocessing requirements are met.

c. Defines standards that are to be applied anywhere sterile processing or HLD occurs in VA facilities.

d. Provides specific requirements for environmental controls for Sterile Processing Services.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The National Program Office for Sterile Processing (10NC6) is responsible for the content of this Directive. Questions may be addressed to VHASPSHSS@VA.GOV.

5. RESCISSIONS: VHA Directive 2007-001, dated January 4, 2007; VHA Directive 2009-004, dated February 9, 2009; VHA Directive 2009-031, dated June 26, 2009, and VHA Directive 2009-062, dated November 23, 2009 are rescinded.

6. RECERTIFICATION: This VHA Directive is scheduled for recertification on or before the last working day of March 2021.

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STERILE PROCESSING SERVICES (SPS)

1. PURPOSE

This Veterans Health Administration (VHA) Directive identifies Sterile Processing Services (SPS) as an organizational element within VHA and establishes the authority for the operation of SPS within VA medical facilities. This VHA Directive establishes SPS oversight responsibilities to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment (RME) in VA medical facilities, and establishes national policy to identify procedures related to proper reprocessing, maintenance, and storage of critical and semi-critical RME in VA medical facilities. It also provides specific requirements for the organizational structure charged with oversight responsibilities for reprocessing specified reusable medical equipment (RME) at the Veterans Integrated Service Network (VISN) and medical facility levels, and includes specific requirements for the standardization of equipment types and for ensuring that reprocessing requirements are met. This Directive applies anywhere sterile processing or HLD occurs in VA facilities. **AUTHORITY:** 38 U.S.C. 7301.

2. BACKGROUND

a. Multiple professional disciplines use different types of RME across a spectrum of clinical services within VA medical facilities. For this reason, clear lines of responsibility and accountability must be established to ensure a standardized process for proper reprocessing and maintenance of RME within VA medical facilities.

b. The VHA National Program Office for Sterile Processing is a distinct program office under the VHA Deputy Under Secretary of Health for Operations and Management and is responsible for establishing policy regarding reprocessing of critical and semi-critical RME. Proper reprocessing of RME within VA medical facilities necessitates written and accessible facility policy and procedure that mandates, but is not limited to the following: reprocessing RME according to current manufacturers' instructions; reprocessing RME in accordance with additional standards as cited in this Directive; training of personnel involved in RME reprocessing and validation of such training; and a quality assurance program for RME reprocessing.

3. DEFINITIONS

a. **Aseptic Technique.** Aseptic technique is an activity or procedure that prevents infection or breaks the chain of infection.

b. **Automated Endoscope Reprocessor.** The automated endoscope reprocessor (AER) is an automated machine designed to clean, disinfect, and rinse flexible endoscopes.

c. **Bioburden.** Bioburden is the number of microorganisms on a contaminated object; also called bioload or microbial load.

d. **Biohazard.** Biohazard relates to infectious agents that present a risk or potential risk to human health either directly through infections or indirectly through the environment.

e. **Biological Indicator.** A biological indicator (BI) is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

f. **Bowie-Dick Test.** A Bowie-Dick test is a test run daily to validate the vacuum function of a steam sterilizer. The test should be run daily in an empty load at the same time each day.

g. **Case Cart.** Case cart is an inventory control system for products and equipment typically used in the Operating Room (OR). An enclosed cart is generally for one surgical case and is not used for general supply replenishment; also called case cart system.

h. **Chemical Indicator.** Chemical indicators are systems that reveal a change in one or more predefined process parameters based on a chemical or physical change resulting from exposure to a process.

i. **Type 5 Integrating Indicators.** Type 5 chemical integrators react to the three critical variables of a steam sterilization cycle (time, temperature and the presence of steam). In addition, their performance is required to correlate to a biological indicator (BI). As a result, type 5 integrators are similar to those of a BI and can detect failures where the selected temperature is not reached. This failure condition is likely to occur when there is incorrect packaging and loading, air/steam mixtures, and/or incorrect cycle for load contents.

j. **Type 6 Emulating Indicators.** Type 6 emulating indicators are designed to react to the three critical variables of a specified steam sterilization cycle (time, temperature and the presence of steam). It is important to note that if a facility runs multiple exposure times and temperatures, one must use a specific type 6 chemical indicator to monitor each different cycle time and temperature.

k. **Critical Items (Spaulding Classification System).** Critical items (Spaulding Classification System) are instruments or objects introduced directly into the bloodstream or other normally sterile body areas.

l. **Decontamination Area.** A decontamination area is the location within a medical facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

m. **Endoscope.** An endoscope is a rigid or flexible device consisting of a tube with a light and a lens on the end that is inserted into a body opening or incision, typically used to examine hollow organs inside the body such as the esophagus, stomach, duodenum, colon or rectum, and is also used to take tissue from the body for testing.

Endoscopes can attach a camera to take color images of the inside of the body or for viewing on a video screen.

n. **External Chemical Indicators.** External chemical indicators are devices that monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or that are used in specific tests of sterilization equipment.

o. **External Chemical Indicators (Tape).** Placement of chemical indicator tape is essential to ensure package integrity. Tape should be placed in such a manner that no clear opening of package would result in pluming causing contaminants to enter the package. Two pieces of tape may be applied in the following manner: Two vertical, two horizontal or one vertical and one horizontal. More may be used for medium to large packages depending upon the type of fold used.

p. **Gross Soil.** Gross soil is tissue, body fat, blood, and other body substances.

q. **Floor Grade Instruments.** Floor grade instruments are instruments that are designed to be used in clinic settings. They usually have a shiny finish and will rust quickly after reprocessing. They are not designed for repeated use in the surgical environment.

r. **High-Level Disinfection.** High-level disinfection (HLD) is a process that uses a sterilant for a shorter contact time than that used for sterilization and that kills all microbial organisms but not necessarily large numbers of bacterial spores.

s. **Internal Chemical Indicator.** Internal chemical indicators are devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or that are used in specific tests of sterilization equipment.

t. **Lumen.** A lumen is the interior path through a needle, tube, or surgical instrument.

u. **Non-critical Items (Spaulding Classification System).** Non-critical items (Spaulding Classification System) are items that contact intact skin.

v. **Preparation/Assembly Area.** A preparation/assembly area is a designated place for the assembling, wrapping, and packaging of articles, trays, and basins prior to sterilization.

w. **Process Challenge Device.** A process challenge device (PCD) is an item designed to constitute a defined resistance to a sterilization process used to assess performance of the process.

x. **Reprocessing.** Reprocessing is all of the steps performed to make a contaminated item reusable or single-patient use device patient-ready; steps may include cleaning, functional testing, repackaging, relabeling, disinfection, or sterilization.

y. **Reusable Medical Equipment (Device or Item)**. Reusable medical equipment (RME) is equipment intended for repeated use on different patients with appropriate decontamination and other processing between uses.

z. **Satellite Storage**. Satellite storage is a dedicated storage room for clean or sterile supplies. Satellite storage areas often include storage of critical and semi-critical RME. Areas such as exam room cabinets, crash carts, patient room supply cabinets (including point-of-use cabinets not located in a dedicated storage area), and nurse servers are not considered satellite storage unless in these areas items are stored for greater than 72 hours.

aa. **Semi-Critical Items (Spaulding Classification System)**. Semi-critical items (Spaulding Classification System) are those that come in contact with non-intact skin or mucous membranes.

bb. **Single Use Device**. A single use device is a disposable item that is intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected, or sterilized) and used on another patient.

cc. **Sterile**. Sterile is completely devoid of all living microorganisms.

dd. **Sterile Storage Area**. The sterile storage area is the area of a medical facility designed to store clean and sterile supplies/instruments and to protect them from contamination.

ee. **Surgical Grade Instruments**. Surgical grade instruments are instruments used during surgical procedures which are made of German stainless steel with a matte or satin finish. If properly cared for, surgical grade instruments should last for many years.

ff. **Ultrasonic Cleaner**. An ultrasonic cleaner is a device that uses ultrasound waves in water to clean instruments by means of cavitation.

4. POLICY

It is VHA policy that all standards outlined in this Directive must be adhered to regarding reprocessing and maintaining of critical and semi-critical RME in the VA medical facilities. ANSI/AAMI standards will be applied to critical and semi-critical RME management. AORN, IAHCSSM and APIC guidelines will support and enhance all recommended standards which relate to instrument processing and infection control practices

5. SCOPE AND ROLE OF STERILE PROCESSING SERVICES

a. Sterile Processing Services (SPS) has the primary responsibility in facilities to decontaminate, high-level disinfect, and/or sterilize critical and semi-critical reusable medical equipment and instruments. SPS supports the medical facility by ensuring a continuous flow of processed critical and semi-critical instruments to all points of use.

Similarly, return of reusable soiled items to SPS is handled in a manner conducive to patient and staff safety as well as efficient reprocessing for future use.

b. The cleaning and storage of non-critical RME including specialty carts (crash or code carts, latex-free carts, isolation carts, etc.) is not a function of SPS.

c. This Directive applies to RME requiring HLD or sterilization in preparation for reuse on another patient and applies to both SPS and areas outside of SPS where SPS functions occur. This Directive defines the role of SPS in providing centralized support to the medical facility's access to care through patient care programs, which involve the use of RME while assuring appropriate aseptic conditions, economies of operation, and consistency in the decontamination, packaging, HLD, and/or sterilization of RME.

d. In addition to the standards in this Directive, VHA adopts the following standards that are to be applied anywhere sterile processing or HLD occurs in VA facilities:

(1) **American National Standards Institute/Association for the Advancement of Medical Instrumentation ST 58, ST79, and ST91.** American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) ST79, Comprehensive Guide to Chemical, Steam Sterilization and High Level Disinfection.

(2) **Association of Perioperative Registered Nurses Standards.** Association of Perioperative Registered Nurses (AORN) publishes standards and recommended practices to ensure safe patient care and a safe work environment in all settings where surgical and other invasive procedures are performed.

(3) **International Association of Healthcare Central Service Materiel Management Standards.** International Association of Healthcare Central Service Materiel Management (IAHCSMM) offers education, training and professional development opportunities to ensure the safe handling, reprocessing, and use of medical equipment.

(4) **Association for Professionals in Infection Control and Epidemiology.** The Association for Professionals in Infection Control and Epidemiology (APIC) publishes standards and recommended practices for infection and disease prevention.

6. RESPONSIBILITIES

a. **Deputy Under Secretary for Health for Operations and Management.** The Office of the Deputy Under Secretary for Health for Operations and Management, in cooperation with the Director, National Program Office for Sterile Processing, is responsible for ensuring this VHA Directive is effectively implemented by the VISNs and VA medical facilities.

b. **Director, National Program Office for Sterile Processing.** The Director, National Program Office for Sterile Processing (NPOSP), is responsible for:

(1) Development and oversight of national policy pertaining to the standardization and reprocessing of critical and semi-critical RME.

(2) Development of metrics, in collaboration with other specialty program offices (e.g., Dental, Gastroenterology and Surgical Services), to ensure expected actions and outcomes are met.

(3) Development, in collaboration with the VA Office of Construction and Facilities Management, appropriate temperature and humidity policies, design guides and manuals to ensure compliance with this Directive for the storage of critical and semi-critical RME and workplace controls for personnel engaged in the reprocessing of critical and semi-critical RME.

c. **Veterans Integrated Service Network Director.** Each VISN Director is responsible for:

(1) Appointing and maintaining a VISN SPS Management Board, charged with the oversight of SPS and all reprocessing of critical and semi-critical RME at VISN facilities. Members of the VISN SPS Management Board must have specialized knowledge of reprocessing RME.

(2) VISN SPS Management Board membership must include the Chief Medical Officer and at a minimum the following representatives:

(a) Associate Director for Patient Care Services (ADPCS).

(b) Associate Director.

(c) Patient Safety Manager.

(d) Infection Prevention and Control Professional.

(e) Chief of Staff.

(f) Chief, SPS.

(g) Chief, Environmental Management Service (EMS).

(3) Ensuring that VA medical facility Directors comply with the procedures and responsibilities outlined in this Directive.

(4) SPS must have a training/competency program in place at each facility within the VISN.

(5) Ensuring a quality assurance program must be in place at each facility within the VISN.

(6) Ensuring that each facility in the VISN that performs procedures utilizing RME must have standard operating procedures (SOPs) based on manufacturer's guidelines

that establishes a documented and systematic approach to critical and semi-critical RME processes.

(7) Ensuring that VISN and facility-led inspections are conducted as directed by the Assistant Deputy Under Secretary for Health for Operations and Management, Clinical Operations.

NOTE: *Other representatives for consideration for membership, as determined by the VISN, include: Biomedical Engineering, Logistics Service, and Quality and Risk Management.*

d. **VISN SPS Management Board.** The VISN SPS Management Board is responsible for:

(1) The VISN SPS Management Board has the authority and accountability for ensuring reprocessing (and other SPS functions) occurs to exacting standards, i.e., current manufacturers' instructions for use (IFU), across the VISN facilities as described in this Directive, by:

(2) Ensuring that medical facility Directors comply with the actions detailed in this Directive.

(3) Ensuring that an SPS training program is in place at each medical facility within the VISN.

(4) Ensuring an SPS quality assurance program is in place at each medical facility within the VISN.

(5) Ensuring that each medical facility organized under the VISN that performs procedures utilizing RME has standard operating procedures (SOPs) to establish and document systematic critical and semi-critical RME processes in accordance with this Directive.

(6) Ensuring that VISN and medical facility-led inspections are conducted at a frequency determined by the Assistant Deputy Under Secretary for Health for Operations and Management, Clinical Operations.

(7) Identifying any VISN projects that are required for compliance with the environmental controls section of this Directive. Existing facilities have until October 1, 2018, to comply with the requirements in this Directive.

(8) Ensuring that all plans for renovation of existing space or new construction of facilities within the jurisdiction of the VISN comply with the environmental control requirements in this Directive.

(9) Ensuring that the VISN Sterile Processing Services Management Boards' inspections of facilities within the jurisdiction of the VISN include a review of the

documentation of climate control in areas where the reprocessing or storage of critical or semi-critical RME occurs.

e. **VA Medical Facility Director.** VA medical facility Directors are responsible for ensuring facility compliance (and compliance of affiliated sites, e.g., Community Based Outpatient Clinics) with critical and semi-critical RME processes, specifically:

(1) Ensuring the Chief, SPS is delegated responsibility for reprocessing of critical and semi-critical RME wherever reprocessing occurs throughout the medical facility and affiliated sites (e.g., Community Based Outpatient Clinics).

(2) Verifying that the transportation of critical and semi-critical RME, which has been cleaned, disinfected or sterilized to areas outside of SPS, is assigned to an appropriate service .

(3) Establishing processes for determining which medical instruments and equipment are utilized, involving all the stakeholders and including the needs and training of the operator, Infection Prevention and Control, Logistics, SPS, and Biomedical Engineering.

(4) Establishing processes requiring the Chief, SPS to verify that the medical facility can reprocess a new piece of critical or semi-critical RME in accordance with the current manufacturers' IFU prior to purchase or lease.

(5) Ensuring that medical facility construction projects involving areas where critical or semi-critical RME is reprocessed or where reprocessed items are to be stored are in conformance with established design configuration requirements and are approved by the Chief, SPS, the National Program Office for Sterile Processing, and the VA Office of Construction and Facilities Management.

(6) Ensuring that independent repair maintenance contracts or in-house service agreements are executed in compliance with manufacturers' maintenance and repair guidelines. Biomedical Engineering must review and approve all requests for independent repair maintenance contracts or in-house service agreements.

(7) Ensuring there is a systematic standardization and quality assurance plan for reprocessing RME, according to current manufacturers' IFU, and to systematically retire and replace older equipment.

(8) Ensuring that device-specific standards and systematic RME processes are established and documented based on manufacturers' current IFU and include at least the following elements:

(a) Defined process and accountability for performing and documenting initial competency for staff, including required training to be accomplished prior to initial use and initiation of reprocessing.

(b) Process and accountability for validating continued staff competency.

(c) Process and accountability for reprocessing and maintenance of equipment and supplies utilized in critical and semi-critical RME procedures.

(9) Ensuring that a quality assurance program follows an interdisciplinary approach to monitoring compliance with established process(es), and documenting outcomes related to the defined process(es). This interdisciplinary approach requires participation by the Chief, SPS; a representative from Quality and Risk Management; a Nursing Service representative; an Infection Prevention and Control Professional; a Patient Safety Manager; and a representative from Biomedical Engineering. Ensuring that facility-led inspections are conducted each year as directed by the Assistant Deputy Under Secretary for Health for Operations and Management, Clinical Operations.

(10) Ensuring the acceptable operating range for humidity is 30 to 55 percent based on the geographical location. All sterile items are inspected for condensation or moisture collection in the event of any sudden fluctuations in humidity above 55 percent. Any items suspected of being damp or having the integrity of packaging compromised must be reprocessed (if reusable) or discarded if the item is single use.

(11) Storage locations where humidity exceeds the acceptable range of 55 percent, items must be relocated to a temperature and humidity controlled environment until humidity control can be re-established. Items should be considered for removal if communication from Facility Management Service (FMS) corrective actions for the humidity cannot be immediately addressed.

(12) Ensuring that all applicable areas within the medical facility are compliant with the environmental control requirements of this Directive.

(13) Developing interim measures, in collaboration with Engineering (Facilities) Service and SPS, for environmental control until full compliance is achieved. Interim measures could be, but are not limited to relocating critical and semi-critical RME to an area that meets the requirements of this Directive.

f. **Facility Chief of Staff.** Facility Chiefs of Staff are responsible for partnering with the Associate Facility Director, Patient Care Services (ADPCS) to ensure the proper critical and semi-critical RME processes are in place in all clinical areas.

g. **Associate Director, Patient Care Services.** Each medical facility ADPCS is responsible for:

(1) Ensuring the medical facility Chief, SPS or equivalent implements all provisions of this Directive.

(2) Providing oversight, organizational responsibility, and leadership of the local SPS operations. The day-to-day operational oversight for SPS may be assigned to a designee; however, SPS will directly report to the ADPCS.

(3) Overseeing of the development, deployment and management of SPS training programs and RME competencies.

(4) Providing support for training and encouragement of certification for SPS employees.

(5) Ensuring that SPS is involved in any decision that may impact SPS-related functions, support or operations. This includes any medical facility design changes or construction contracts that may impact where RME is reprocessed or stored or procurement of SPS-related equipment.

(6) Establishing a medical facility policy for the monitoring of temperature and humidity in areas where the reprocessing and storage of critical and semi-critical RME occurs that at a minimum complies with the requirements in this Directive.

h. **Chief, Engineering Service.** The Chief, Engineering Service, or designee, is responsible for:

(1) Inspecting and maintaining the ventilation system in compliance with established standards.

(2) Performing air flow checks annually at minimum and providing a written report of the results of these checks to the Chief, SPS. Air flow must also be checked after repair of the heating, ventilation and air-conditioning (HVAC) system, extended shut-down or equipment replacement. In the event that air flow is outside established parameters, corrective action must be taken immediately and the Chief SPS notified of test results.

i. **Chief, SPS.** The Chief, SPS is a title that refers to anyone who has supervisory responsibility over SPS staff members who perform the functions of decontamination, HLD, and sterilization of all critical and semi-critical RME. The Chief, SPS, is responsible for:

(1) Completing Level 1 training and Level 2 certification through the VA national SPS training program or certification through a professional Central Service certification program such as IAHCSSM or the Certification Board for Sterile Processing and Distribution (CBSPD).

(a) Level 1 must be completed as soon as possible, but not to exceed 90 days from time of appointment in SPS.

(b) Level 2 certification must be completed within 6 months from time of appointment.

(c) SPS certification is a condition of employment and must be maintained while in this position. Failure to maintain certification may be grounds for removal from this position.

(2) Ensuring that the medical facility's reprocessing of critical and semi-critical RME is performed with high reliability according to current manufacturers' IFU. This responsibility can be met by:

(a) Ensuring that all individuals charged with reprocessing duties are appropriately trained and competency is documented prior to the performance of the assigned tasks. Staff members should participate in ongoing education and training to maintain proficiency.

(b) Ensuring that when significant changes are made to manufacturers' IFU, all designated staff are retrained and are able to validate proficiency.

(c) Ensuring that appropriate training is completed and documented whenever new or different equipment is used.

(d) Ensuring that temporary or contract personnel are not permitted to reprocess RME until training and competency assessments have been completed, and proficiency has been verified. Contract personnel should have specific tasks assigned for allowing safe, efficient process and resource utilization.

(e) Ensuring that specific processes and procedures are in place for reprocessing all critical and semi-critical RME. A process should be in place for reprocessing of RME (including endoscopes) after hours. Some instruments and equipment can be damaged by prolonged or delayed reprocessing.

(f) Developing SOPs and competency assessments for the reprocessing of all critical and semi-critical RME and for the operation and maintenance of equipment used in the reprocessing of critical and semi-critical RME according to manufacturer's guidelines.

(g) Ensuring that all SOPs are kept up-to-date, reviewed at least every 3 years and updated when there is a change in process or a change in manufacturers' IFU. Methods must be in place to replace outdated versions and to disseminate revised IFU, as well as to ensure compliance and competence in the execution of any revised procedures. SOPs must be written in plain language and must be accessible to all staff at all times. **NOTE:** *oneSOURCE Tech Ready documents may be used as SOPs if appropriate.*

(h) Ensuring that a process is in place to track items that have been high-level disinfected.

(i) Ensuring that a quality management program is in place to ensure appropriate and safe reprocessing of all critical and semi-critical RME.

(j) Ensuring that testing for adequacy of ventilation systems is being performed by Engineering Service. An inspection schedule must be developed by the Chief, SPS in collaboration with Engineering Service. This schedule must be available for review at all times. SPS must notify Engineering Service if interval changes are necessary.

(k) Understanding the principles of infection prevention and control as they relate to the reprocessing of critical and semi-critical RME including the proper use of personal

protective equipment (PPE), which is specialized clothing or equipment worn by an employee for protection against a hazard.

(l) Providing technical oversight for the reprocessing of all critical and semi-critical RME wherever these processes are being performed.

(m) Developing and implementing a continuing education and staff development program to include an initial orientation program for new SPS employees, Level 1 training, and recurring on-the-job training for all SPS employees. **NOTE:** *Level 2 training or certification (IAHCSMM or CBSPD) for all employees should be the goal of the employee development program.*

(n) Providing training in proper handling techniques to any staff member handling soiled containers or who are involved in the collection and/or transport of potentially soiled items. These techniques are defined by Infection Prevention and Control guidelines and are in keeping with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard, title 29 Code of Federal Regulations (CFR) 1910.1030.

(o) Maintaining selection authority for all positions within SPS and coordinating service-level recruitment actions with Human Resources staff. This includes maintaining and updating position descriptions/functional statements, performance standards, and competency assessments for SPS personnel as needed.

(p) Ensuring that the National Program Office for Sterile Processing and the VA Office of Construction and Facilities Management have been consulted in the initial design process, as well as at 35 percent, 65 percent, 95 percent, and 100 percent of any plans for construction or renovation of an SPS area. See VA SPS/Logistics Service Design Guide dated October 1, 2015.

(q) Providing input into any decisions that impact or require SPS-related functions or support, specifically including the purchase or lease of any critical or semi-critical RME, which requires reprocessing.

(r) Ensuring there is a plan in place to systematically retire and replace older medical instruments and equipment, in order to support standardization in the equipment used for any given procedure.

(s) Coordinating with clinical area personnel to support the management of instrument sets, and the identification and repair of instruments.

(t) Developing a local policy to address hazard communication within SPS, and ensuring employees who are reprocessing RME are provided with the necessary information about chemical and industrial hazards to which they may be exposed. **NOTE:** *Hazard communication is discussed in paragraph 8.*

(u) Coordinating with Logistics Service on the maintenance of operating supplies and back-up instrumentation within SPS. These supplies and back-up instrumentation

must be maintained with appropriate par levels and replenished in a timely manner to avoid disruption of patient centered access to care.

(v) Development of a memorandum of understanding (MOU) with a neighboring medical facility to provide SPS assistance in the event of an emergency situation or a disaster that would otherwise prevent proper sterilization of equipment.

(w) Participating on a variety of medical facility committees (e.g., Infection Prevention and Control, RME Committee, etc.).

(x) Ensuring SPS employees are provided with PPE and training on the appropriate use of PPE.

(y) Cooperating with EMS or equivalent service or department to develop, implement and enforce a written daily cleaning schedule for all SPS areas as outlined within the Environmental Services Sanitation Procedure Guide.

(z) Ensuring that sterilization monitoring is being performed and for reviewing sterilization records for items sterilized both inside and outside of SPS. The Chief, SPS, or designee must review all sterilizer records daily.

(aa) Providing employees who are reprocessing RME with the necessary information about chemical and industrial hazards to which they may be exposed.

(3) Verifying that the correct decontamination and sterilization procedures are being followed in all areas where processes are taking place for critical and semi-critical RME. Ensuring manufacturers' IFU and all supplemental SOPs related to the handling, reading and recording of all biological indicators are readily available in the work area.

(4) Ensuring that all sterilization records are reviewed on a daily basis to include: high temperature sterilization (steam); Ethylene Oxide; and Gas Plasma.

(5) Ensuring that all equipment used in the SPS is inspected daily.

(6) Performing an annual risk analysis to identify potential problems or process failures that could occur, and reporting the results to the VISN SPS Management Board.

j. **RME Committee.** The RME Committee is responsible for:

(1) Submitting to the facility Director and monitoring an action plan for ensuring compliance with the environmental control requirements of this Directive by all areas of the facility.

(2) Reporting facility progress on the action plan to the NPOSP on a quarterly basis until all areas are in compliance.

k. **Infection Control Committee.** The Infection Control Committee is responsible for developing, in cooperation with the RME Committee, the facility policy for cleaning and disinfecting non-critical RME.

7. TRAINING AND CERTIFICATION

a. **Level 1 Training.** During initial orientation, all new SPS employees must complete the SPS Level 1 training program within 90 days of hire. This training is conducted through the VHA online learning management system or VHA printed SPS Level 1 training program packet when an online learning management system is not readily accessible. A certificate is received upon successful completion of all of the modules.

b. **Level 2 Certification.** The Chief of SPS is to encourage all SPS employees to obtain Level 2 of the national SPS certification program training. Prior to beginning Level 2 certification an orientation program and all Level 1 requirements must be met. Level 2 of the National SPS certification program requires the employee to successfully complete a standardized test with a minimum score of 75 percent.

c. **Nationally-Recognized Organizations.** Membership or certification by other nationally recognized organizations such as IAHCMM or CBSPD is encouraged.

d. **Continuing Education.** All SPS employees must participate in the continuing education program.

(1) Computer-based training (such as a webinar) is acceptable as a method of continuing education. The primary focus of the training is always on the technical aspects of SPS and any current reprocessing issues, although other program areas may be covered in these sessions.

(2) In-service education sessions focusing on the technical aspects of SPS are to be held at least once per month; this includes:

(a) An annual training plan, which must be developed to include these in-service education opportunities.

(b) Documenting this in-service education including an attendance roster, clear objectives of the training and a brief description of the content to be covered. Additionally, any handouts are to be maintained for the record.

e. **Continuing Education for Certification.** Continuing education units (CEU) are credits received for completing training and attending seminars directly related to a profession. One CEU is generally given for each hour of training or seminar attendance. SPS employees who are certified by a national organization must obtain annual CEU as set forth by their certifying body. All other SPS employees must obtain a minimum of 12 educational hours annually.

f. **Training Folders.** A training folder must be maintained and kept in SPS for each employee documenting orientation courses, training instruction and dates of attendance. Individual employee files must include copies of certificates of completion, copies of certifications or completion of Level 1 and Level 2 certification, competency assessments, and records of educational hours, CEUs or credits.

g. **Performance Reviews.** Career development goals are to be reviewed during the formal annual and mid-term performance reviews for SPS staff.

8. COMPETENCY

a. Competency assessment is an ongoing process, and competencies must be assessed when an employee begins working in SPS, during the orientation period, and throughout employment in SPS.

b. Initial competencies focus on the knowledge, skills, and abilities required until the employee is deemed proficient to work independently. While each section of SPS may share some initial competencies (those that apply to the entire service); there may be additional initial competencies that are specific to each section within SPS. Reprocessing equipment can be included in initial competency assessments or as required based upon individual learning needs. Initial competencies are to be based on core job functions and those job functions that are repeatedly used or considered high risk. Frequently used equipment and high-risk instrumentation must be included in initial competencies. Initial competencies will be re-assessed based upon the RME annual risk analysis. On-going competencies are to be developed based on new items or procedures, changes in existing processes (instructions for use), new technologies, policies, practices, etc. These must also include any high risk and problem-prone areas identified by the annual risk analysis. Examples of problematic RME/instruments include, but are not limited to endoscopes, robotics, orthopedic systems, implant trays, etc.

c. A risk analysis must be performed annually to identify potential problems or process failures that could occur. The SPS risk analysis must be part of the SPS/RME Committee reporting to the VISN SPS Management Board. All other competency assessments not identified by the risk analysis must be performed and documented every 3 years or more frequently as determined by the SPS/RME Committee. Areas identified by the risk analysis must have competency assessments conducted and documented annually. Other competency assessment examples include, but are not limited to general stainless steel instrumentation, low complexity, high-use, non-problem prone instrumentation, and reprocessing equipment.

d. Risk analysis equals risk assessment plus risk management plus risk communication.

(1) Risk assessment involves identifying the potential source of a process failure, estimating the likelihood that such a failure will occur, assessing the consequences if that failure does occur, and assessing how prepared the facility is to manage the failure.

(2) Risk management entails determining which of the potential process failures identified in the risk assessment process require management and selecting and implementing the plans or actions that are needed to ensure that those process failures are controlled.

(3) Risk communication involves an interactive dialogue between sterile processing personnel, clinical personnel, and infection prevention and control professionals (infection preventionists).

e. Competency: A utilization of a two verification method is required to validate and measure the proficiency of an individual for a specific task. Competency verification methods can include return demonstrations, observation, verbalization, etc. Those assessing competence must be familiar with the process. These assessments can be performed by the SPS Chief, Assistant Chief, SPS supervisors, educators, or other designated staff members. If a suitable individual is not available to assess staff competency, the facility can utilize an outside individual for this task.

f. If an employee has not demonstrated competence, an action plan is to be developed, which includes actions to be taken by the employee, any additional training that must be accomplished, and a deadline for the actions to be reviewed.

9. HAZARD COMMUNICATION

All SPS employees are required to review the medical facility's disaster plan, fire plan, and other policies and procedures for hazard communication upon initial employment and annually thereafter. A local policy to address hazard communication within SPS must be developed by the Chief, SPS to include specific procedures for SPS employees. The local policy must include actions to be taken during a fire or a fire drill, and must involve all personnel in the area of the fire or drill.

a. The Chief, SPS, is responsible for providing employees who are reprocessing RME with the necessary information about chemical and industrial hazards to which they may be exposed. All SPS employees must be trained in the occupational hazards associated with hazardous materials, the practices and precautions required to work with materials safely, and how to use a safety data sheet (SDS) for information if exposure takes place.

(1) The SDS is a document providing information on the physical and health characteristics of a hazardous material, as well as other information such as the chemical name, common name, trade name, manufacturer, and list of components.

(2) The supervisor shall ensure that all employees review the SDS for all new chemicals added to the department prior to working with those chemicals. A notation must be placed in employees' training records certifying that they have reviewed the SDS.

(3) A readable copy of SDS must be available in the work areas during each work shift. Hard copy format, indexed and cross-indexed for easy access by employees is recommended.

(4) Supervisors will be responsible for inventory and review of the contents of the SDS file in SPS at least annually to ensure that all chemicals used have a corresponding current SDS. When new chemicals are received, the supervisor will add the SDS to the existing file in SPS. Chemicals will not be used until the SDS is obtained and available in the work area.

(5) Supervisors will ensure that all hazardous chemicals are properly labeled. Labels must list at least the chemical identity, appropriate hazard warnings, what to do if exposed, the name and address of the manufacturer, importer, or other responsible party and expiration date. Supervisors will ensure that all employees handling hazardous chemicals know how to interpret information on the label of chemical containers as well as information found in the SDS.

(6) Employees must not wear headphones or use other personal listening devices while working in SPS, i.e. iPods, iPads, and personal cellular phones. These items can distract from and hamper the safety of the work environment.

10. INFECTION PREVENTION AND CONTROL

a. **Hygiene Practices.** The following practices must be strictly adhered to, to prevent cross-contamination and to protect the employee. Monitoring of hygiene practices is a fundamental element of the SPS quality assurance program.

(1) Hand hygiene must be done before entering and leaving the work area, and whenever hands become soiled or contaminated. Hands must be washed immediately and thoroughly if they become soiled with blood, body fluids, secretions, or excretions. Effective hand washing consists of using water to wet the hands, lathering with soap, and vigorously rubbing hands together (including between fingers and around nails) for 15-20 seconds. Rinse well with water and thoroughly dry hands. If a hand hygiene sink is not readily available and hands are not visibly soiled, an alcohol-based hand rub may be used.

(2) Employees working in all sections of SPS must keep fingernails short and clean. They must be less than one-fourth inch in length. Fingernail polish and artificial fingernails (including bonding, tips, wraps, tapes, acrylics, etc.) can harbor harmful microorganisms and are not permitted in SPS.

(3) False eyelashes may not be worn in any area of SPS. Artificial hair extensions that are not contained within the cap may not be worn in any area where sterilization or high level disinfection processes take place. Both false eyelashes and non-contained artificial hair extensions can trap dirt and bacteria, creating irritation and infection. This increases Veterans' risk to infection due to the additional risk of exposure to pathogens.

(4) Any jewelry including, but not limited to, facial or body piercings, earrings, necklaces, watches, bracelets, etc., which cannot be contained or confined within the SPS attire or covered must not be worn. Rings worn under gloves may compromise their barrier effectiveness by puncturing or weakening the glove where it comes into contact with the ring.

(5) The use of tobacco products, eating, drinking, or the storage of food items (including beverages) are not permitted in SPS where the processes of decontamination, sterilization or clean/sterile storage are performed.

(6) A medical facility shower must be available. A shower is recommended at the end of the shift or when clothing becomes wet or soiled.

b. **Attire.** Each area within SPS has a dress code that must be strictly adhered to. The purpose of the dress code is to prevent cross-contamination and to protect the employee. Monitoring of proper work attire is a fundamental element of the SPS quality assurance program.

(1) The attire for the Preparation and Sterile Storage Areas consists of:

(a) Scrub suits. When working in the Preparation Area, a jacket with cuffs down to the wrists must be worn if short-sleeved scrub suits are provided. The jacket can be reusable (same material as scrub suits) or disposable and must be kept closed. Fleece or other lint shedding jackets may not be worn.

(b) When leaving the SPS area lab coats are optional.

(c) Scrub suits and jackets are not to be worn outside of the medical facility, nor can they be laundered at home. Clean attire must be worn daily. The attire must be laundered at the medical facility or off-site laundry service supporting the medical facility.

(d) Approved head and hair covering must be worn. A disposable bouffant cap must be worn to cover both ears completely. Disposable surgical hoods that cover side hair, ears, and the nape of the neck can also be worn. Head/hair covering must be removed upon exiting the area. Skull caps (surgical caps that cover only the top of the head) are not to be worn. Reusable head coverings are not to be worn.

(e) Facial hair must be covered at all times when in the Preparation Area.

(f) Shoes worn in the SPS environment must be clean. If shoe covers are used, they should be removed prior to exiting SPS. Shoes that are worn only in this area may help to reduce contamination of the SPS environment. Shoes must have closed toes and backs as well as non-skid soles.

(g) Authorized visitors entering either area must wear a jumpsuit or cover garment. This garment must be one that is designated for use in the Preparation and/or Sterile Storage Areas only. The cover garment must be completely buttoned or

fastened to cover the clothing and must be at least knee length. Visitors must also wear head and hair covering, facial hair covering, and shoe covers as appropriate.

(2) The attire for the Decontamination Area consists of:

(a) Scrub suits (these are not considered PPE as they are not impervious to fluids).

(b) Proper PPE.

(3) Attire is always to be changed when wet, soiled, or visibly contaminated with blood or body fluids.

(4) Attire must also be changed if an employee is leaving the Decontamination Area to work in another area of SPS (Preparation Area or Sterile Storage Area).

11. SAFETY

a. **Personal Protective Equipment.** It is the responsibility of the Chief, SPS to ensure SPS employees are provided with PPE and training on the appropriate use of PPE. It is the technician's responsibility to follow the policies and procedures implemented by the Chief, SPS regarding PPE in the employee's work area or job assignment.

(1) Entry into any Decontamination Area without the designated PPE is prohibited at all times, regardless of the level of activity being performed at the time of entry. PPE must be put on before entering the Decontamination Area and maintained during the entire time staff is inside this area.

(2) Types of PPE required for the Decontamination Area personnel include:

(a) Approved head and hair covering. Disposable bouffant caps are to be worn and must cover both ears completely. Disposable surgical hoods that cover side hair, ears, and the nape of the neck can also be worn. Skull caps are not to be worn. Reusable head covering is not to be worn in the Decontamination Area.

(b) Full-length face shields (cover entire face from ear lobe to ear lobe and below the chin) or a combination of fluid-resistant mask and eye goggles must be worn.

(c) Heavy duty, impervious decontamination gloves must be worn (not regular patient exam or surgical gloves). Gloves must be a minimum of 12 mils in thickness. Gloves must have a long cuff that extends beyond the wrist (at least 12 inches in length) and must be appropriately sized to facilitate dexterity.

(d) Long-sleeved gown (disposable or reusable), made of impervious material from elbows to cuffs and from neck to bottom of gown, must be worn. The gown must be long enough to prevent a gap between the lower hem of the gown and the top of the shoe cover.

(e) Impervious knee-length shoe covers must be worn. A skid-resistant sole is preferred.

(3) If reusable cloth gowns are used, they must be laundered at the medical facility or off-site laundry service supporting the medical facility. Reusable gowns have a limited use, the number is provided by the manufacturer's instructions for use IFU and must be tracked by EMS or laundry. A light table is required prior to each use to illuminate tears, holes, and or stains; which must be appropriately patched according to the IFU or discarded.

(4) At all times, authorized visitors entering the Decontamination Area must be provided with the appropriate PPE. These individuals must wear an impervious gown or coveralls, knee-length shoe covers, gloves, a bouffant cap, and face shield.

(5) Adequate PPE should be stored inside the Decontamination Area so that it is easily available. It must be stored in a closed cabinet or container. If automated endoscope reprocessors (AERs) are located in the Decontamination Area, clean examination gloves, and gowns or full-cover aprons must be available for the employee to don before removing processed items to prevent recontamination. Bulk storage of PPE is to be outside the Decontamination Area.

(6) PPE worn while working in the Decontamination Area is not to be worn in any other area of SPS or the medical facility. All PPE must be removed prior to leaving the Decontamination Area. At the completion of the decontamination tour-of-duty, or in the event an unanticipated contamination of clothing occurs, employees must have a place to shower and change into clean work attire.

(7) An Infection Prevention risk assessment for PPE requirements can be made for areas outside of SPS where the decontamination process is taking place (i.e., endoscopy suite or clinic area). Professional society guidelines for PPE requirements may also be taken into consideration in conjunction with a risk assessment for those areas outside of the SPS Decontamination Area. Decisions related to a change in PPE requirements for areas outside of SPS must be reviewed and approved by the local Infection Prevention and Control Committee.

(8) In order to avoid employee contamination, the proper sequence for removal of PPE is as follows:

(a) For facilities utilizing gowns that remove from the back (reusable linen):

1. Remove shoe covers.
2. Remove gloves.
3. Untie the gown from the back of the neck and remove. The back of the gown is not considered contaminated, but the gloves are.

4. Remove the face shield by pulling the elastic at the back of the head being careful to avoid touching the front of the face shield.

5. Remove bouffant cap by pulling off from the back of the head.

6. Employee must wash hands for 15-20 seconds using soap, friction, and running water, and thoroughly dry prior to leaving the Decontamination Area.

(b) For facilities utilizing gowns that are removed by pulling from the front (disposable):

1. Remove shoe covers.

2. Remove gown. As sleeves are being removed, gloves should be simultaneously removed. Gown and gloves should be rolled away from the body and discarded to avoid contamination.

3. Remove the face shield by pulling the elastic at the back of the head being careful to avoid touching the front of the face shield.

4. Remove bouffant cap by pulling off from the back of the head.

5. Employee must wash hands for 15-20 seconds using soap, friction, and running water, and thoroughly dry prior to leaving the Decontamination Area.

b. **Environmental Cultures.** Environmental cultures of sterile items are not to be done, unless requested to do so by the Chief, Infectious Diseases or the Infection Prevention and Control Committee for the evaluation of specific problems.

c. **Home Health Equipment.** Home health equipment (or other health equipment used outside the medical facility) is not to be returned to SPS. The medical facility or VISN must establish a policy for the return, inspection, cleaning and reissue of home health equipment. Telehealth equipment used in the Community-based Outpatient Clinics (CBOC) must be handled in accordance with manufacturers' IFU and policies developed by the Office of Telehealth and the National Program Office for Sterile Processing.

d. **Emergency Eye Wash Stations and Showers.** OSHA requires that a suitable eye wash station/shower be available with unobstructed access for immediate emergency use in areas where the potential for exposure to hazardous chemicals or material exist. Technicians must be knowledgeable in how and when to use this equipment (see OSHA standards, VHA Directive 2009-026, Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment, or subsequent policy issue, and ANSI/ISEA Z358.1 on location, selection, installation, maintenance, and testing of emergency eyewash and shower equipment).

12. ENVIRONMENTAL CONTROLS (SEE APPENDIX A)

a. People flow (traffic flow) must be controlled to minimize contamination of the environment due to microorganisms present on human bodies and clothing. Maintaining environmental integrity is accomplished through traffic control in SPS. Traffic needs to be restricted to authorized personnel only. Other personnel with official business, and when accompanied by an appropriate supervisor, or designee, will be authorized entrance to SPS. Individuals seeking entrance must wear appropriate dress attire to include PPE (if required) including personnel performing equipment repair, building maintenance, and housekeeping activities in areas of SPS. All protective clothing must be removed and properly stored or disposed of, as appropriate, prior to leaving the area.

b. Air flow is carefully controlled in SPS to minimize the movement of microorganisms from dirty areas to clean areas. Commercial airflow directional devices must be utilized to enable SPS staff to verify the airflow direction. These devices are to be installed in the following areas: Preparation, Decontamination, and Sterile Storage. Actual measurements of air exchanges must be taken and recorded at least once a year by the medical facility's Engineering Service. Airflow must be checked by Engineering Service any time there are indications the pressure has changed or any modifications of equipment replacements have occurred in HVAC systems.

c. Work flow is the order in which RME is received into SPS, processed, and dispensed for patient use without cross-contamination occurring. Material flow is generally considered to be either incoming contaminated RME or clean or sterile supplies coming into the service. Shipping cartons may harbor microorganisms and are considered contaminated. Clean or sterile packaged items must be removed from shipping cartons and corrugated boxes before being brought into SPS or other Clean or Sterile Storage Areas.

(1) Contaminated reusable items must be transported to the Decontamination Area in such a manner as to protect people and the environment from contamination.

(2) After the decontamination process, items go to the Preparation Area where they are inspected, packaged, and sterilized as necessary. They are then transferred to the appropriate storage area and maintained until issued.

(3) Items that do not need to be sterilized for patient care use must be moved from the Decontamination Area to the Clean or Sterile Storage or Distribution Area for distribution to the appropriate clinical area.

d. Doors are to be made of a material with a durable finish that can be cleaned frequently and can withstand the potential damage incurred from carts. Exposed pipes, ducts or cables are to be kept to a minimum. Where existing, these items must be cleaned on a weekly basis, or more often if necessary. The determination of who has the responsibility of cleaning these items is provided by the medical facility Director or designee.

e. Windows are discouraged in SPS. Ultraviolet (UV) rays can compromise package integrity. If windows are unavoidable, they should be covered with a UV protective film or other material to prevent sunlight from entering. Items are not to be stored on windowsills. Windows must remain closed at all times.

f. Portable personal or area fans are not permitted in SPS or any area where SPS functions occur. Fans create a turbulent air flow which recirculates dust and microorganisms from the floor and work areas.

g. The ADPCS and the Chief, SPS must consult with the National Program Offices for Sterile Processing and VA Office of Construction and Facilities Management prior to the installation of portable air conditioning (A/C), humidifier or de-humidifier equipment in any area of SPS. In all cases where a portable A/C unit or dehumidifier is used, SPS leadership must provide an action plan to the National Program Offices demonstrating how the medical facility ventilation will be corrected to provide appropriate heating and cooling to SPS.

h. Reprocessing and storage areas for critical and semi-critical RME require temperature 66-75°F, humidity 30-55% with positive filtration and four air exchange parameters in order to protect RME integrity.. A monitoring system capable of documenting continuous humidity and temperatures is required in all SPS areas. This Directive does not preclude the medical facility from setting room temperatures lower than the prescribed range in order to maintain the correct humidity range in specified rooms based on geographical location. If needed, supply air temperature should be lowered at the air handling unit to meet the dehumidification requirements (see Appendix B). If high-level disinfectants are being used, room temperatures cannot be set lower than the requirement for storage and use of the disinfectant.

i. Each VA medical facility, by December 31, 2017, must have monitored, climate-controlled areas for the reprocessing of critical and semi-critical RME including the storage of those reprocessed items. The minimum climate control parameters apply to all areas where reprocessing of critical or semi-critical RME occurs or where reprocessed critical or semi-critical RME is stored (see Appendix B).

13. ENVIRONMENTAL CLEANING

Environmental cleaning is a vital component in the overall infection prevention and control process within SPS. Environmental cleaning procedures in areas of SPS should be handled in accordance with the Environmental Services Sanitation Procedure Guide found on the EPS Web site, <http://vaww.vhaco.va.gov/eps/>. **NOTE:** *This is an internal VA Web site and is not available to the public.* Application of these procedures should result in a clean environment and minimize the exposure risk of health care personnel to potentially infectious microorganisms.

a. In cooperation with EPS or equivalent service or department, the Chief, SPS must develop, implement and enforce a written daily cleaning schedule for all SPS areas as outlined within the Environmental Services Sanitation Procedure Guide. EPS

or equivalent staff responsible for cleaning SPS must be given proper training on work flow, people flow, and other information pertinent to SPS. Dedicated cleaning equipment must be provided and maintained in the SPS Decontamination Area. Separate dedicated cleaning equipment must be provided and maintained in the Preparation Area which may also be used in the Sterile Storage Area. This equipment is not to be used in other areas of SPS or the medical facility. Personnel will never go from the Decontamination Area to the Preparation Area while cleaning. A Memorandum of Understanding (MOU) must be developed, agreed upon and signed by EPS and SPS leadership to outline these duties and responsibilities. An MOU template is available within the Environmental Services Sanitation Procedure Guide.

b. Cleaning encompasses wet mopping of floors with a hospital-approved disinfectant (germicide) at least once a day and more often if necessary.

c. Microfiber mops are approved and can be used in SPS. The positively-charged microfibers attract dust (which has a negative charge) and are more absorbent than a conventional, cotton-loop mop. Manufacturers' IFU must be followed regarding the frequency of changing the microfiber mop.

d. Floors and horizontal work surfaces must be thoroughly cleaned at least once daily or more often as needed to control microbial contamination. Other surfaces such as walls, and air intake and return ducts, should be cleaned monthly or more often if needed. Lighting fixtures or covers should be cleaned at least once every 6 months.

e. Sweeping, dry dusting, or dry vacuuming is prohibited in all areas of SPS (except administrative areas).

f. In addition to the environmental cleaning performed by EMS personnel, it is the responsibility of SPS personnel to clean all horizontal work surfaces and utility sinks in SPS, at a minimum daily using a hospital-approved disinfectant (germicide).

g. Sterilizers (including the internal chamber) and other processing equipment are to be cleaned regularly according to the manufacturers' IFU by SPS personnel. Sterilizer door gaskets, chamber drain screens, and external surfaces are cleaned daily using a lint free cloth and clean water. Sterilization carriages and carts are to be cleaned on a daily basis to remove dust and dirt. Annual de-scaling of the steam sterilizer chambers should be considered if any signs of discoloration or build-up are noted; this should be accomplished by outside professional sources.

h. All SPS shelves, bins and baskets, and equipment storage areas are to be cleaned weekly, or more often as necessary by SPS personnel. Bottom shelves must be solid or have an impervious shelf liner to prevent contamination of stored items. It is important to remember that events can contaminate the integrity of reprocessed items when cleaning shelving and storage areas where these items are stored. Reprocessed items must be checked for package integrity when cleaning the storage shelves.

i. The SPS areas must be kept free of insects, rodents, and other vermin. Reports of pest infestations will be investigated, and appropriate action must be taken as

directed by the pest management protocols of Environmental Programs Service (EPS) (see the EPS Web site for further information regarding pest management at <http://vaww.vhaco.va.gov/eps/>). **NOTE:** *This is an internal VA Web site and is not available to the public.*

14. TRANSPORT OF SOILED ITEMS

a. Contaminated items should be contained before transport through the medical facility to minimize airborne or contact spread of microorganisms, and to reduce the risk of cross-contamination and infection. Reusable collection containers must be solid, lightweight, durable, and made of material that can be properly cleaned and decontaminated. If a rigid container is used, it must have a lid that fits snugly over its opening. Disposable, impervious plastic bags may be used to transport single items or small instrument sets. Pouches used for sterilization must not be used to transport contaminated items.

b. All nursing units and clinic areas are to have a designated soiled utility room. Designated soiled utility rooms can be shared space between units, if necessary. Enclosed containers must be provided in these rooms. All clinical procedure trays and other critical and semi-critical RME must be placed in these containers.

c. Containers with biohazard labels used in the soiled utility room must be transported to SPS in a closed or impervious covered cart. Containers are to be exchanged at each pick-up location, and the containers must be cleaned between each use.

d. Soiled biohazard labeled containers are to be dedicated for soiled transport and storage. Soiled biohazard labeled containers are never used to transport clean equipment.

e. Gross soil must be removed from RME at the point-of-use by the user prior to transport. This practice is considered pre-treatment and must contain the following steps: 1) The reusable devices are placed in a properly-sized, biohazard-labeled, closed container. 2) It is the user's responsibility to dispose of sharps appropriately before returning RME to SPS. 3) Pretreat by spraying enzymatic gels or foam prior to transport to prevent drying. 4) All RME must be transported within four hours to the Decontamination Area of SPS for reprocessing. This includes clinics using RME outside the main facility (CBOCs).

f. A biohazard label is to be placed on containers used for contaminated equipment or RME.

g. Carts used for soiled collection and transport must be enclosed. Carts must be easy to maneuver and be made of durable material that can withstand frequent cleaning. Carts used for soiled collection must be cleaned daily or more often if needed. Soiled case carts must be cleaned after each use. **NOTE:** *Automatic cart washers are recommended for the cleaning of soiled carts.*

h. Dedicated lifts and dumbwaiters reduce handling and provide a direct link between the user area and SPS. They must be cleaned on a weekly basis, or more often as needed. Cart lifts and dumbwaiters must be dedicated as either clean or dirty and must not be interchangeable. Care must be taken so that cross-contamination does not occur.

i. Case carts used in the storage and transport of soiled surgical instruments are to be transported to the Decontamination Area for manual cleaning or cleaning in an automatic cart washer. Clean case carts are then returned to the department or service responsible for restocking.

Pneumatic tube systems are not to be used to transport clean or sterile instruments or contaminated instruments. The pneumatic tube system can be contaminated by soiled items being placed in the system.

j. When transporting outside the medical facility:

(1) The closed, soiled container to be transported to the host medical facility must be exchanged for a clean container at each scheduled pick up. The closed, soiled container must be placed in a larger container or closed cart for transport. The cart or container must be properly labeled for biohazard transport according to local, state, and federal Department of Transportation regulations. Soiled items must be contained in such a way as not to contaminate the person or persons in the transport vehicle or the vehicle itself.

(2) Clean containers are to be dedicated for clean transport and storage. Clean containers must be clearly designated as such and are never to be used to transport soiled equipment. Reprocessed items (high-level disinfected or sterilized) must be transported in an enclosed vehicle. The design and materials used in the construction of transport vehicles needs to allow for appropriate decontamination processes, especially if the vehicles are to be used alternately for the transport of clean or sterile items. Transport vehicles are to be checked periodically to ensure that they do not leak.

15. DECONTAMINATION AREA

a. Decontamination of semi-critical RME may be performed in the SPS Decontamination Area or in areas outside of the main SPS (e.g., endoscopy suite) if determined more feasible by medical facility leadership. The Chief, SPS is responsible for reviewing these areas and verifying that the correct decontamination procedures are being followed.

b. The Decontamination Area must be physically separated from all other areas of SPS. Semi-critical and critical instruments and equipment must be transported to the Decontamination Area in impervious bags, covered/closed containers, designated carts, cart lifts, dumbwaiters, or automated transport systems.

c. The following must be adhered to for the Decontamination Area:

(1) Cabinet doors in this area must be kept closed. All cabinets, shelves, and work surfaces are to be made of material with a durable finish that can be cleaned frequently, preferably stainless steel.

(2) The area must have adequate lighting to allow for inspection of articles during reprocessing. A magnifying light is to be available in this area to aid in the inspection of certain difficult-to-clean instruments.

(3) Work flow must originate from outside the Decontamination Area and travel inside through a dedicated entry way or dumbwaiter or lift system. Work flow patterns need to be designed to ensure that contaminants are contained and employee exposure to bloodborne and other disease producing (pathogenic) microorganisms is minimized.

(4) If AERs are located in the main SPS Decontamination Area, air and work flow evaluations are to be performed to ensure there is proper separation of clean and soiled work areas. The proper technique must be used when removing items from the AER to avoid recontamination.

(5) Model-specific manufacturers' IFU for cleaning and disinfection must be available in this area.

d. Both the washer disinfector and the ultrasonic cleaner in the Decontamination Area must be checked weekly with a commercially prepared monitoring device to verify the function of the equipment for quality assurance purposes. Results of this verification must be documented. A course of action is indicated if verification demonstrates failure.

e. When applicable and following manufacturers' IFU, instruments must be disassembled for complete cleaning and reprocessing. **NOTE:** *Every effort should be made to replace items that cannot be disassembled.*

f. Eye instruments must be processed separately from general surgical instruments and equipment. These instruments must be thoroughly rinsed to remove all residue left on the instruments after being cleaned and disinfected in accordance with manufacturers' IFU. A designated cleaning area and ultrasonic equipment dedicated to the cleaning of eye instruments is to be identified.

g. All devices with lumens must be brushed with a brush long enough to extend through the lumen or channel and must make contact with interior lumen walls.

h. Disposable cleaning brushes are recommended. Brushes that are labeled disposable must be discarded after use.

i. If reusable cleaning brushes are used for instrument cleaning, they must be cleaned and disinfected or sterilized at the end of each shift or more often if heavily soiled.

j. Disposable cleaning brushes for endoscopes are required.

- k. Reusable cleaning brushes that are worn must be discarded.
- l. All brushes are to be inspected for defects prior to use so as not to damage instruments or endoscopes.
- m. Abrasive brushes should never be used because they can scratch the surface of the instrument and accelerate corrosion.

16. PREPARATION AREA

a. The Preparation Area must be physically separated from the Decontamination Area. This area is a designated place for the inspection, assembling, and packaging of instrument sets prior to sterilization.

b. Devices found to have residual soil must be immediately returned to the Decontamination Area for additional cleaning. Items in the Preparation Area have been decontaminated and are considered safe to handle (use of gloves is not required). The use of gloves is acceptable if the SPS technician requests them. Wearing gloves is not to be used as a replacement for frequent hand hygiene.

c. A minimal amount of operational supplies can be stored in the Preparation Area. Bulk storage of operational supplies is to be outside the Preparation Area. Back-up instruments must be stored in closed cabinets or drawers.

d. New instruments in vendor packaging must be cleaned and disinfected in the Decontamination Area prior to storage.

e. All cabinets and storage devices must be made of material that can withstand frequent cleaning.

f. The Preparation Area is not to be used as a distribution or case cart area. Items that do not require packaging and sterilization are not to be taken into, or stored in this area (with the exception of back-up instrumentation).

g. Magnifying lights are required in this area and must be used to aid in the inspection of instruments during set assembly.

h. Single use devices are not to be reprocessed for use on multiple patients. In the event of a tear or accidental opening, the device must be discarded. The device is not to be repackaged or re-sterilized. Reusable devices must be purchased if the intent is to re-sterilize for reuse on multiple patients.

i. Identification and control of the use of floor grade instruments is required. Most floor grade instruments are manufactured to be disposable. **NOTE:** *They may not be a low cost alternative to purchasing surgical grade instruments.*

j. Written manufacturers' IFU and any supplemental SOPs must always be followed when reprocessing reusable items. A readable copy of all manufacturers' IFU for sterilization must be maintained on file in SPS and must be reviewed, at a minimum, every 3 years. If there are no specific instructions in the packaging, the manufacturer needs to provide written instructions for reprocessing.

k. If a hand-washing sink is not available in the Preparation Area, alcohol foam or gel dispensers must be installed to afford employees the opportunity for proper hand hygiene in their work area. The wearing of gloves does not replace the requirement for hand hygiene.

17. STERILE STORAGE AREA

- a. Storage environments should be clean, dry, and easily accessible by authorized personnel.
- b. Clean or sterile packages are not to be stored near or under sinks or exposed water pipes.
- c. Packages are to be kept at least 8 inches above the floor to prevent contamination.
- d. There is to be at least 18 inches between the highest package and the ceiling to allow for proper air circulation and proper distance from sprinkler heads.
- e. It is important to keep packages at least 2 inches away from exterior walls, windows or window seals where condensation can form on interior surfaces of exterior walls.

18. STERILIZATION

- a. **Manufacturers' IFU.** All items requiring sterilization must be sterilized according to manufacturers' IFU. The Chief, SPS must maintain a file (electronic or paper copy) for all reusable devices. This file must contain the manufacturers' IFU for the proper method of sterilization for each item. The One Source documents (see Web site at: <http://OneSourcedocs.com>) can be utilized for these instructions. A contingency plan must be in place in the event of computer downtime if electronic files are utilized for manufacturers' IFU.
- b. **Malfunctioning Sterilizers.** A malfunctioning sterilizer must be brought to the immediate attention of the supervisor and the Chief, SPS. The sterilizer must be taken out of service and the responsible Engineering Service notified. Three consecutive, acceptable biological indicators and Bowie-Dick tests for pre-vac sterilizers must be completed for new sterilizers or after a major repair (identified as a repair outside the scope of maintenance) to ensure the sterilizers are functioning properly prior to use. These tests must be run in an empty sterilizer chamber.
- c. **Sterilizer Training.** The individual conducting the training must ensure documentation is completed. This training must include:
 - (1) Sterilizer operation and maintenance.
 - (2) Work practices and precautions for safe use.
 - (3) Safe handling and storage of sterilizing agents.
 - (4) Accidental spill or leak plan.
 - (5) SDS for sterilizing agents.

d. **Extended Cycle Times.** The manufacturers' recommendations for cycle times must be followed to ensure sterility. Sterilization packaging may be affected by extended exposure times. The Chief, SPS or designee must consult with the packaging product manufacturer for validation of extended exposure times. Biological indicators may also be affected by extended cycle times. The Chief, SPS or designee must also consult with the manufacturer of the biological indicator for extended cycle times.

e. **Table Top Sterilizers.** The use of table top sterilizers is not authorized.

f. **Unapproved Methods.** The following sterilization methods are not approved for use in VA facilities:

(1) Dry heat sterilization.

(2) Liquid chemical (cold) sterilization.

(3) Ozone sterilization.

g. **Immediate-use Steam Sterilization.** Immediate-use steam sterilization (IUSS), previously referred to as flash sterilization, has traditionally been used to describe steam sterilization cycles in which unwrapped medical instruments are subjected to an abbreviated steam exposure time and then used promptly after cycle completion without being stored. This is in contrast to traditional "terminal sterilization" cycles in which instruments are sterilized within containers, wrappers, or primary packaging designed to maintain the instruments' sterility and allow the devices to be stored for later use.

(1) IUSS must be used only in an emergency when there is insufficient time to process by the preferred wrapped or container method. Items sterilized in this manner are to be used immediately and not stored for later use.

(2) IUSS must not be used as a substitute for insufficient instrument inventory. This method of sterilization is not to be used for convenience, as an alternative to purchasing additional instrument sets or to save time.

(3) This sterilization cycle may be used for an unanticipated event during the course of a surgical procedure (e.g., dropped instrument or unplanned emergency). Large trays of instruments such as facility owned or loaner trays must NOT be sterilized in this manner. IUSS may only be performed by SPS staff or Operating Room staff at point of use.

(4) Non-biological implantable devices are not to be sterilized by IUSS.

(5) Instrument(s) to be sterilized must be placed in a rigid container designed and intended for IUSS. It is not recommended that items with lumens or power equipment be sterilized in this manner due to their complexity.

(6) All sterilizers used for IUSS events must have a Type 5 chemical integrator run with each cycle. A biological indicator must also be run each day. If the sterilizer being

utilized for IUSS is a vacuum-assisted type, a Bowie-Dick test must also be performed daily.

(7) Loaner (borrowed) instrument trays must be received in the SPS Decontamination Area a minimum of 48 hours prior to use in order to provide adequate time for reprocessing. IUSS is not allowed for trays arriving late to the medical facility. Vendors must provide manufacturer's IFU and inventory count sheets for loaner instrument trays. Every effort must be made by SPS staff to provide timely reprocessing for those loaner instrument trays brought in for emergency procedures such as orthopedic fracture cases.

(8) The total number of IUSS cycles including the types of instruments processed and the reason the cycles took place must be reported monthly by SPS to the Infection Prevention and Control Committee. This Committee reviews the sterilization report to determine what action must be taken to prevent reoccurrence of the IUSS event.

h. **Ethylene Oxide Sterilization.** The use of ethylene oxide (EtO) to sterilize RME is permissible in VHA and must be available when needed; however, the use of EtO needs to be minimized when possible. OSHA currently regulates the use of and exposure to EtO under title 29 CFR 1910.1047. Federal and state Environmental Protection Agencies (EPA) regulate EtO waste emissions and typically require construction, installation, replacement, and operating permits.

(1) EtO is used in SPS to sterilize items that cannot be exposed to the temperature and moisture of steam sterilization. SPS must be in compliance with the requirements outlined in VHA Directive 2011-015, Safe Use of Ethylene Oxide, or subsequent policy issue.

(2) An annual review must be completed and documentation maintained of all items sterilized by EtO. This documentation must include the exact name of the item and must be reported to the medical facility RME Committee or equivalent. SPS must evaluate the sterilization requirements for new items prior to purchase in order to minimize the use of EtO. **NOTE:** *Whenever possible, consideration is to be given to purchasing items that can be sterilized by means other than EtO.*

(3) Chief, SPS or designee should consult the EtO unit-dose container manufacturer to determine how many unit dose cartridges may be stored in the sterilizer area. In general, however, if each dose contains 50 or more grams of EtO, then only 1 day's supply of cartridges, up to a maximum of twelve cartridges, should be stored in the immediate area of the sterilizer. If more than 48 cartridges are to be stored in one place, the area is to be made suitable for flammable liquid storage and therefore, conform to National Fire Protection Association (NFPA) 30.

19. MONITORING PROCEDURES

a. The following procedures must be followed for sterilizer monitoring:

(1) All instrument sets and packs must have an internal chemical indicator. A Type 5 or Type 6 (formerly known as Class 5 and Class 6) integrating indicator is required. Using integrators does not negate the requirement for the use of a biological indicator.

(a) The person examining the indicator from the sterile package must be adequately trained in the interpretation of the specific indicator used. Instructions for appropriate use, placement, and interpretation of results must be communicated to the product users.

(b) In the event that an instrument set is opened and the internal chemical indicator is missing, the clinical staff is to contact SPS to obtain another set.

(2) Sterilizers located in other areas outside SPS which process critical and semi-critical RME must be monitored following the same requirements as the sterilizers inside SPS proper.

(3) Sterilizers located in the Research and Laboratory areas are not subject to SPS oversight.

(4) All sterilizers must have an automatic recording (printout or graph) device. The sterilizer operator must check the printout or graph after each sterilizing cycle for:

(a) Sterilization date.

(b) Time the cycle was started.

(c) Time sterilization phase began.

(d) Sterilization temperature.

(e) Pressure achieved during steam sterilization phase.

(f) Actual length of sterilizing cycle at desired temperature (i.e., exposure period).

(5) After each cycle, the printout must be examined for verification of correct parameters and signed with full, legible signature by the sterilizer operator before any items are removed.

(6) The load control number and a register of contents must be maintained. The register must be as detailed as possible in the event a recall is necessary. The register must be maintained in SPS, along with other sterilization records, for a period of 3 years for all sterilizer loads.

(7) Sterilizer malfunctions as indicated by the recording device will be reported immediately to the supervisor. The Chief, SPS must:

(a) Review and make the final determination on the use of the sterilizer,

(b) Initiate an appropriate request for service, and

(c) Implement reprocessing of the items contained in the sterilizer load.

(8) Biological indicators for all sterilizers must be used and must be read in accordance with manufacturers' IFU. Rapid read biological indicators are required for use in steam and EtO sterilizer loads.

(9) It is recommended that a biological indicator be run with every sterilizer load. However, each sterilizer (including IUSS sterilizers in the OR) must be biologically monitored a minimum of the following:

(a) At least once each day that the sterilizer is used,

(b) With each load containing an implant,

(c) With each EtO or Gas Plasma load,

(d) With the first load after a repair (and after the three consecutive biological indicators have been run in an empty chamber).

(10) The biological test will be performed within a normal load. Commercially-prepared self-contained biological monitors must be used, when available, and must always be placed in an appropriate process challenge device.

(11) In the event a biological indicator has not reached the time requirement for being read before the close of business, it is permissible to read it on the next business day.

(12) Implants must be quarantined until the biological indicator is read as negative after processing. Sets must also have sufficient time to cool down before being released.

(13) An early implant release waiver must be requested and approved by the Chief of Staff in the event that a sterilized implant must be released prior to obtaining the negative rapid reading of the biological indicator. The early implant release waiver is to be initiated by the OR Nurse Manager, signed by the Chief of Staff or Acting Chief of Staff, and received in SPS prior to the release. SPS must record the reading of the biological indicator on the early implant release waiver when the reading is obtained. **NOTE:** *An example of an early implant release waiver can be found in ANSI/AAMI ST79.*

b. **Written Report for Load Failure.** A positive biological indicator demonstrates a failure for the entire load and should be immediately reported to the supervisor and/or Chief, SPS, the ADPCS and to Infection Prevention and Control. A written report should also be sent to include the following:

(1) Time and date of the sterilizer cycle in question.

(2) Description of the sterilizer and load (including load control number).

- (3) Results of any other monitoring (external chemical indicators) if available.
- (4) List of items processed in the load that could not be recalled.

c. **Load Release.** It is important to determine whether a load was properly processed. The following steps ensure a load was properly processed:

- (1) Sterilizer printout reviewed to verify that the correct cycle was used, exposure time, temperature, and pressure parameters were met.
- (2) Biological indicator for that load is read as negative.
- (3) Biological control for the lot number used is read as positive.
- (4) Contents of the load have been recorded on the load control sheet.
- (5) Verification that the load control label is attached to each sterilized package.
- (6) Load is then ready for release and storage.

20. HIGH-LEVEL DISINFECTION

a. SPS must develop and communicate medical facility specific SOPs for HLD to staff involved in this process.

b. Items removed from high-level disinfectant or AER must be handled in such a manner to avoid recontamination or cross contamination of the items.

c. Items that have been high-level disinfected must be stored in a plastic bag or clean, closed cabinet, closed drawer or closed storage container. The exception to this rule is laryngoscope blades. High-level disinfected laryngoscope blades must be individually packaged in a plastic or paper bag (not a peel pouch).

d. Items that have been high-level disinfected are to be marked with the date of disinfection. These items should be stored in a clean environment. A clean environment is an area free of dust, dirt, or surface contamination.

e. A vented cabinet (mechanical or gravity) is required for the storage of high-level disinfected endoscopes with lumens.

f. Under no circumstance is packaging used for sterilization to be used to store devices that have been high-level disinfected.

g. Liquid disinfectant solutions must be tested to ensure the minimum effective concentration (MEC) of the active ingredients is accurate. For manual HLD, this testing must take place before each use. For VA medical facilities using automated HLD equipment, the manufacturers' IFU must be followed to correctly test the MEC.

h. All high-level disinfectant solutions must be discarded at the end of their prescribed use life, regardless of effective concentration. High-level disinfectant solution must be dated and discarded when expiration date is reached. The solution must be discarded if the test strip indicates the solution is below the MEC, even if it is still within its use life. Manufacturers' IFU must be followed for quality testing when opening a new bottle of test strips.

i. HLD records must be kept for 3 years. Records can be kept as a checklist, electronically or by other means. These records are to include, but are not limited to:

(1) A list of what is being processed including serial number or other unique identifier. This documentation is critical to enable a complete look back investigation if one is required.

(2) The name of the individual reprocessing items.

(3) The date and time of disinfection process.

(4) The type of disinfectant and lot number.

(5) The test results before each process including the proper MEC and expiration date of test strips.

(6) The temperature of disinfectant.

(7) The submersion time. Timers are required in order to ensure correct length of submersion is accomplished.

(8) The documentation of rinsing cycles.

21. REPROCESSING OF FLEXIBLE ENDOSCOPES AND ACCESSORIES

Flexible endoscopes can be difficult to clean and disinfect. They are also easily damaged because of their intricate design and delicate materials. Meticulous cleaning must precede any sterilization or HLD of these instruments. Failure to perform this cleaning can result in sterilization or disinfection failure, and can compromise patient care.

a. Current manufacturers' IFU must be available in each area where reprocessing occurs for each type of endoscopic equipment used. It is imperative that the manufacturers' IFU are followed at all times when cleaning and reprocessing endoscopes. Personnel assigned to reprocess endoscopes must be trained according to device-specific IFU in order to ensure proper cleaning, HLD, and/or sterilization.

NOTE: *Failure to follow the manufacturers' IFU could result in a potential risk for the patient and possible damage to the scope.*

b. Training to establish documented competency must be completed for all models of endoscopes and any reprocessing equipment associated with flexible endoscopes

that are being used in the medical facility. The required competency assessment must be documented by the individual assessing competence to ensure compliance with current standards and manufacturers' IFU. All clinical and technical personnel involved in endoscope reprocessing are to be trained by someone who is knowledgeable in infection prevention and control protocol.

c. The following steps are required for cleaning and reprocessing flexible endoscopes and accessories:

(1) **Pre-Treatment.** Pre-treatment of flexible endoscopes and accessories must occur at the point of use by clinical staff.

(2) **Transportation.** After pre-treatment, contaminated flexible endoscopes and accessories are to be transported to the reprocessing area before any remaining organic material is allowed to dry on the surface or in the channels of the endoscope. During transport, soiled flexible endoscopes must be contained in a manner that prevents exposure to staff, patients, or the environment to potentially infectious microorganisms.

(3) **Leak Testing.** Leak testing of fully submersible endoscopes is done in the reprocessing area and before cleaning. It is necessary to consult the manufacturers' IFU for the proper testing procedures.

(4) **Manual Cleaning.** Manual cleaning is the most important step in reprocessing flexible endoscopes. Endoscopes must be completely disassembled according to manufacturers' IFU so that all surfaces may be reached for thorough cleaning.

(5) **Brushing.** All endoscopes with lumens must be brushed with a brush long enough to extend completely through the lumen or channel and must make contact with the interior lumen walls. Disposable brushes are required.

(6) **AER Use.** The procedures which need to be followed are:

(a) It is highly recommended that a commercially-available product be used for verification of the cleaning process. Verification must be done following the manufacturers' IFU for the testing process.

(b) All required manual cleaning or disinfecting steps must be performed according to IFU prior to placement in the AER.

(c) The AER being used must be approved for reprocessing the endoscope to be disinfected.

(d) Establishment of correct connectors between the AER and the device is critical to ensure complete flow of disinfectants and rinse water.

(e) Clean examination gloves and gowns or full-cover aprons must be donned before removing high-level disinfected endoscopes from the AER to prevent recontamination.

(7) **Drying.** Regardless of whether the endoscope is processed manually or with an AER, a final drying step is needed before storage in accordance with the manufacturers' IFU. This can include an alcohol flush if in accordance with manufacturers' IFU.

(8) **Storage.** A closed, vented cabinet that allows air circulation around the endoscopes is required when storing an endoscope with lumens.

(a) Endoscopes that have been high-level disinfected are to be hung vertically with the distal tip hanging freely in a clean, well-ventilated, dust-free area. They are to be hung so that no part of the scope touches the bottom of the cabinet and in sufficient space for storage of multiple endoscopes without touching.

(b) Endoscope storage cabinets must be cleaned and disinfected on a weekly schedule with a hospital-approved disinfectant.

(c) If absorbent material is placed in the bottom of the scope cabinet, it must be changed daily (or more often if needed) on the days scopes are reprocessed.

(9) Flexible endoscopes that have been reprocessed in accordance with the manufacturers' IFU, properly dried, and stored by hanging in a clean, closed, and vented cabinet can be used for up to 12 days after reprocessing and storage. Flexible endoscopes that are seldom used and are not reprocessed after 12 days can be segregated in a separate storage cabinet. The cabinet should be labeled to indicate reprocessing is required prior to use of the segregated endoscopes. Any flexible endoscope not used within 12 days must undergo full reprocessing before the next patient use.

(10) Each VA medical facility must have a procedure in place that delineates how each flexible endoscope will be tracked through the decontamination, cleaning, and storage phase and then to each patient use.

(11) The manufacturers' carrying case must not be used to store or to transport the clean and/or reprocessed RME (i.e., endoscopes, probes or dilators) within the medical facility, and must not be used to transport any contaminated RME. If a clean endoscope is transported to another clinical area, it must be carried in a clean, closed container which can be cleaned after use.

(12) SPS must have a quality management program to ensure appropriate and safe reprocessing is being performed. This program must include testing each model of endoscope to ensure bioburden has been removed after reprocessing. Frequency of this testing should be determined by SPS leadership, but must be at least a minimum of 10 percent of endoscopes reprocessed.

22. USE OF ENDOSHEATHS

a. The Food and Drug Administration (FDA) has cleared the use of sheath systems for flexible endoscopes and other medical devices. These devices are marketed under the FDA's 510(k) cleared process. Sheaths provide a sterile, protective cover for their

intended medical device and can reduce the frequency of sterilization or HLD. Only those sheaths which are cleared by the FDA and are specific to the device or equipment must be used.

b. The proper application and integrity of the protective sheath must be verified according to the manufacturers' IFU prior to the start of each procedure.

c. Inspection of the medical device and the sheath must take place after the sheath is removed. Manufacturers' IFU for the sheath must be followed to disinfect the flexible endoscope between each patient use.

d. Sheath compromise is indicated if there is evidence of moisture on the medical device or the sheath is not intact. If this occurs, the medical device must be fully reprocessed by HLD and/or sterilization according to the device manufacturers' IFU prior to next use.

23. APPROVED PACKAGING AND PROCEDURES

a. **Event-Related Sterility.** The shelf life of a packaged, sterile item is event-related and depends on the quality of the packaging material, the storage conditions, the amount of handling, and the conditions during transport. Sterilized packages are to be considered sterile unless the integrity of the packaging is compromised (damaged) or suspected of being compromised. Packages or containers must be visibly inspected for package integrity prior to distribution and prior to use.

(1) An event-related sterility system must be used in all VA facilities. Event-related sterility is based on the concept that sterility is not altered over time, but may be compromised by certain events or environmental conditions. SPS employees and end users must be able to recognize signs of sterility compromise (tears, abrasions, "worn" areas, punctures, compromised seals, dirt or evidence of moisture).

(2) Some events that may affect sterility of a package include, but are not limited to:

(a) Multiple handling which can lead to breaks in the seal or a loss of package integrity.

(b) Compression during storage.

(c) Moisture penetration.

(d) Exposure to airborne and other environmental contaminants.

(e) Storage conditions (e.g., type of shelving, cleanliness, temperature, humidity, traffic control).

(f) Use of sterility maintenance covers and sealing methods.

(3) Expiration dates on commercial products must be adhered to as they reflect product usability or stability rather than sterility of the contents.

b. **Packaging.** All packages to be sterilized must be labeled with a description of the package contents and initials of the individual assembling the package before sterilization. Sterilized materials are to be packaged, labeled, and stored in a manner to ensure package integrity.

(1) No sterilized item will be released from SPS without a load control number.

(2) Packaging material such as peel packages, non-woven materials, etc. are not to be used inside instrument sets to hold instruments together, as these materials can prevent proper contact of the sterilization agent to the device being sterilized. However, products designed for use inside an instrument tray are permissible.

c. **Instrument Count Sheets.** All instrument sets including loaner sets must have a detailed instrument count sheet.

(1) The count sheet must list each item that is placed in the set including the name, size, quantity and type of instruments. If the instrument has more than one part and is placed separately in the set, each part must be listed. All items placed in the set must be included on the count sheet.

(2) The count sheet must also have a place for two checks by SPS technicians in the Preparation Area. The second check should ideally be performed by a team lead, supervisor, manager, employee in charge or an employee assigned the responsibility of instrument set validation for that tour of duty or day. This employee will be responsible to assure the completeness of the instrument set and assure no bioburden has been overlooked in previous inspections. The count sheet can also include a place for two checks by the end user if the medical facility utilizes them for OR or procedure room count recording.

(3) A pen with indelible ink must be used to prevent running or bleeding, which can occur if a ballpoint pen is used.

(4) Instrument count sheets can be placed inside the set; however, they should be inside an approved sterilization envelope. If a sterilization envelope is used, a chemical indicator is to be placed inside the envelope. The count sheets are never to be placed in a peel package inside a rigid container or instrument set.

d. **Instrument Tray Liners.** Surgical x-ray detectable towels used as instrument tray liners must be left in their original configuration. If using disposable towels, they must be x-ray detectable. If other material is used for liners, only material manufactured for this purpose can be used. Manufacturers' IFU must be followed. Do not use linen liners in containerized sets unless approved by the container's manufacturer. Linen surgical towels can impede drying in some container systems.

e. **Wrapping Materials.** Both sequential and simultaneous wraps are approved for use in VA facilities. Sequential wrap describes the package being wrapped twice or “a package within a package.” Simultaneous wrap describes the package being wrapped once using a special, double-layer non-woven material bound on two or four sides. If simultaneous wraps are used, SPS leadership must develop a plan and communicate it to the end users.

f. **Textile Packaging.** Textile packaging requires more labor for inspection to ensure there are no tears or punctures from previous use, the requirement of a light table and the process of de-linting. It is the policy of the National Program Office for Sterile Processing that textile packaging may only be used if the procedures described in the current edition of the IAHCSMM manual are strictly followed. Quality assurance measures must be in place if textile packaging is used.

g. **Peel Pouches.** Care must be taken when selecting peel pouches as some material may not be compatible with all types of sterilizing agents.

(1) Paper or plastic peel pouches are not to be placed in rigid containers or wrapped instrument sets.

(2) Double packaging in paper or plastic peel pouches is not to be performed without documentation from the manufacturer that the paper or plastic pouch has been validated for this use.

(3) Care must be taken to ensure the seal is properly closed when using a heat seal, as well as self-adhesive peel pouches and/or sterility maintenance covers. Care must be taken to avoid gaps, wrinkles, or creases which compromise the seal integrity for both heat seal and self-seal closure systems. If heat sealing is used for paper or plastic pouches, the manufacturers' IFU must be followed for the proper time and temperature settings. Inspecting packages for seal integrity should be included as part of the SPS quality assurance program to ensure seals are being properly applied.

h. **Sterility Maintenance Covers.** Sterility maintenance covers may be used to further protect the integrity of properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling before use. They may be heat-sealed or self-sealed. The sterility maintenance covers must be applied before the package leaves the Preparation Area and only after the package has thoroughly cooled. Identification of package contents and load control number must be clearly visible through the sterility maintenance cover. If a sterility maintenance cover is found to be torn or not intact, reprocessing is to occur due to the event that caused the tear.

i. **Verification of Set Assembly.** Instrument sets must be double-checked by SPS. The first check must be performed by the person who assembled the set and checked the instruments for cleanliness, functionality, and size. The second check for completeness must be performed by another employee unless the Preparation Area has only one employee. Both employees must initial the count sheet. If the Preparation

Area has only one employee, periodic random quality checks need to be performed by the Chief, SPS, or designee, to verify completeness.

(1) If instruments are missing when the set is obtained in the Preparation Area, the missing instrument(s) must be reported to the supervisor and the end-user immediately.

(2) Errors in instrument sets (missing or malfunctioning instruments) are to be identified on the count sheet by the user. The count sheet must be returned to, and reviewed by, the Chief, SPS or designee. Every effort must be made not to contaminate the count sheet during the procedure. Errors reported are addressed with appropriate action by the Chief, SPS or designee.

j. **Surgical Instrument Identification.** The use of instrument tape, bands, or heat-fused nylon (dipping) for surgical instrument identification is authorized. Application of instrument tape to any surgical instrument must be done in accordance with manufacturers' IFU. Instrument bands must be moved to allow for proper cleaning. A quality assurance process must be in place for inspection and replacement of the tape, bands or heat-fused nylon when cracks, chips or peeling is identified.

k. **Load Control Number.**

(1) A load control number must be assigned for each sterilizing cycle to identify the following:

- (a) The numerical designation of the sterilizer being used.
- (b) The sterilizer cycle number per 24-hour period.
- (c) The date of sterilization (mm/dd/yyyy).

(2) Load control labels must be applied to all packages. SPS technicians must ensure the load control label is in place prior to storage.

(a) An expiration date is not required on the load control label.

(b) Labeling with an expiration statement such as "sterile unless opened or damaged" should occur for sterilized items prior to leaving the Preparation Area. This label must be placed on the outside of the package.

l. **Sterilization Cycles.** All sterilization cycles must be accounted for and documented including cycles for:

- (1) Bowie-Dick test cycles for all pre-vacuum sterilizers.
- (2) Diagnostic test cycles.
- (3) Any cycle run for maintenance or repair.

m. **Verification of Package Integrity.** Reprocessed items must be handled carefully to avoid damage or contamination.

(1) All items must be examined for package integrity by all who handle the package.

(2) Verification of the sterilization process by examination of the external chemical indicator tape must be performed prior to storage.

n. **Transport of Reprocessed Items.** Reprocessed items being used and stored in satellite storage areas must be transported in a closed or impervious covered cart to protect the items from environmental contamination. Small quantities of items may be hand-carried in impervious bags or containers.

(1) The type and quantity of items must be verified before transporting them to the point-of-use.

(2) Carts must have a solid bottom shelf or shelf liner that is made of material such as metal, hard plastic or plexi-glass.

(3) Reprocessed and soiled items must never be transported together on carts or in the same containers.

(4) Technicians must never leave carts unattended. Leaving carts unattended could cause patient or employee injury, loss or theft, and possible contamination.

24. QUALITY ASSURANCE PROGRAM

a. A quality assurance program must be in place to ensure appropriate and safe reprocessing is being performed.

(1) Achieve efficient and sustainable processes.

(2) Identify meaningful measurements and tracking mechanisms of those measurements.

(3) Create and maintain document and record control processes.

(4) Achieve a systematic process for continuous improvement and internal auditing.

(5) Allow incorporation of all levels of the organization.

b. **Documentation of Quality Assurance.** Quality assurance measures must be documented. All sterilizer recording charts, digital printouts, lists, biological and Bowie-Dick test results, reports, and other associated quality assurance documentation must be maintained for 3 years or longer depending upon state and local regulations.

c. **Required Monitoring.** Required areas for quality assurance monitoring include:

(1) Biological indicator monitoring.

(2) Physical (mechanical) monitoring (time, temperature and pressure recorders, displays, digital print outs, and displays).

(3) Chemical indicator monitoring.

(4) MEC for high-level disinfectant solutions.

(5) Monitoring of equipment function (ultrasonic cleaner, washer disinfectant, reverse osmosis filtration units, deionized water systems, sterilizers, heat sealers, etc.).

(6) Expiration dates (chemicals, external chemical indicator tape, biological indicators, etc.).

(7) Testing of each model of endoscope to ensure bioburden has been removed after manual cleaning of flexible endoscopes.

(8) Verification of complete instruments and sets.

(9) Verification that instruments are in proper working order.

(10) Immediate-use steam sterilization rates.

(11) Case cart accuracy.

(12) Compliance with PPE requirements.

(13) Compliance with dress attire requirements.

(14) Exposure monitoring in accordance with OSHA requirements.

(15) Package integrity monitoring to include correct size of wrapping material, correct taping and correct labeling.

d. SPS is responsible for the daily inspection of equipment used in the service. SOPs and instructions for all equipment used in SPS for reprocessing functions (e.g., sterilizers, washers, heat sealers, etc.) must be maintained in SPS and readily available (electronic or paper copy). The SPS equipment operator must monitor charts, printouts, and gauges ensuring that they are functioning within normal limits. Additionally, parts such as soap pumps, automatic doors, and audio or visual alarms are observed for working readiness according to manufacturers' IFU.

25. BIOLOGICAL AND NON-BIOLOGICAL IMPLANTABLE DEVICES

a. SPS does not order, store or maintain biological implants of any kind.

b. The following information only applies to Non-biological Implantable Devices (NBID):

(1) Non-sterile NBID must be delivered to SPS for proper reprocessing and sterilization in accordance with the manufacturers' IFU.

(2) SPS does not have the responsibility for receipt, verification of sterility, or the delivery of NBID packaged sterile by the manufacturer. Verification of package integrity and sterility must be assigned to a department deemed appropriate by medical facility leadership.

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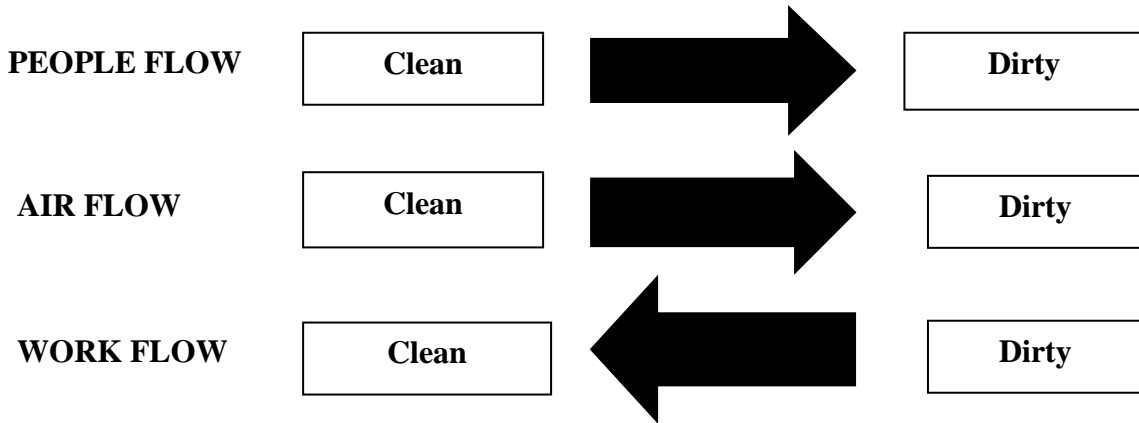
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THE DIRECTION OF FLOW IN STERILE PROCESSING SERVICES (SPS)



CLIMATE CONTROL PARAMETERS FOR STERILE PROCESSING SERVICES

AREA	AIR FLOW	MINIMUM AIR CHANGES (ACH)	TEMPERATURE	HUMIDITY
Soiled or Decontamination Area	Negative	10	66°F to 72°F (set point 69°F)	30% to 55%
Dedicated Endoscope Cleaning Area	Negative	10	66°F to 72°F (set point 69°F)	30% to 55%
Sterilizer Equipment Access Room	Negative	10	Not to exceed 85°F	No requirement
Restrooms and Housekeeping	Negative	10	Not to exceed 75°F	No requirement
Preparation, Assembly, Sterilization Area	Positive	10	66°F to 75°F (set point 70°F)	30% to 55%
Clean or Sterile Storage, Satellite Storage Area	Positive	4	66°F to 75°F (set point 70°F)	30% to 55%

NOTES:

(a) *Satellite Storage a dedicated storage room for clean or sterile supplies. Satellite storage areas often include storage of critical and semi-critical reusable medical equipment (RME). Areas such as exam room cabinets, crash carts, patient room supply cabinets (including point-of-use cabinets not located in a dedicated storage area), and nurse servers are not satellite storage and are therefore exempt from temperature and humidity monitoring, unless in these areas items are stored for greater than 72 hours.*

(b) *Higher than minimum air change rates per hour. Air conditioning/heating (ACH) may be required to maintain temperatures and humidity within acceptable ranges based on room loading.*

(c) *For conservation of energy, the minimum stated ACH are allowed to be reduced down to four ACH provided that all the following conditions are fully met:*

(1) *Heating, Ventilation and Air Conditioning HVAC system controls are adequate to provide continual space monitoring for both temperature and humidity with an override to any ACH reduction when necessary to maintain temperature and humidity within acceptable ranges.*

(2) *ACH reductions can only be effected no earlier than 60 minutes after all work and equipment processes have ended and the rooms unoccupied.*

(3) Final filtering of supplied room air shall be Minimum efficiency reporting value (MERV) 14 at a minimum.

(4) Pressure relationships to adjacent spaces are to be maintained at all ACH to a minimum of 0.01 inches wc (2.5Pa).

(d) Room make-up air transferred from adjoining occupied space(s).

(e) Relative humidity can vary higher or lower (non-uniform) within a space. The upper limit on relative humidity of 55 percent is established to account for these fluctuations and to provide a nominal operational buffer for facility actions to minimize occurrences of condensation.