

VA**U.S. Department
of Veterans Affairs**Office of Construction &
Facilities Management*Office of Facilities Planning
Facilities Standards Service*

STANDARDS ALERT

**OCTOBER 31, 2022
003C2B-SA-019**

VA's SPS and Logistics Service Design Guide, Digestive Diseases and Endoscopy Svc. Design Guide, HVAC Design Manual, and Master Specifications Section 08 56 19

REQUIREMENT: The information contained herein provides updated standards in the PG-18-12 Design Guide: 284-Logistics Service and 285 Sterile Processing Service (hereinafter referred to as "SPS Design Guide"), and also is applicable to the 287 Digestive Diseases and Endoscopy Design Guide.

DISCUSSION: VA Planning, Design and Construction Standards (PDC) are required to be used as a basis of design for all new, renovation and retrofit projects. The following Requirements are changes to basic Standards for planning and design of the physical environment of care supporting SPS functions including GI-Endoscopy procedures as well as scopes used in other procedures. Illustrations have been updated showing the basic principles and modifications to selected Design Guide diagrams and room templates.

BACKGROUND: VHA Program Offices, VAMC's, project teams and designers are obligated to our Nation's Veterans to implement infection control practices that mitigate the risk of infections resulting from the contamination of equipment and supplies used for direct patient care services. The national Office for Sterile Processing (OSP), the Office of Healthcare Engineering (HEFE), and the Office of Construction and Facilities Management (CFM) support the Department's mission through development and application of Standards as a basis for disciplined planning, design, construction, and retrofit of VA facilities. Planning, Design, and Construction Standards are published in the VA Technical Information Library (TIL) (www.cfm.va.gov/TIL). Pursuant to any forthcoming updates to the SPS Design Guide and the Digestive Diseases and Endoscopy Design Guide, it is necessary to make adjustments issued as a Standards Alert.

ISSUES:

- 1) Flow Diagrams:** The SPS Design Guide was updated and published on the TIL September 1, 2022. The updated design guide includes revisions to several process flow

diagrams and includes new process flow diagrams to reflect current VA sterile processing practice. The following diagrams have been revised or added:

- a) Diagram 1
- b) Diagram 3.1
- c) Diagram 3.2
- d) Diagram 8
- e) Diagram 9
- f) Diagram 10

- 2) Double Door Interlocking Pass-Through Window Unit:** The Design Guide calls for a **Pass-Through Window (0041)** to be provided as a means of passing items from the Decontamination Room to the Sterile Processing Room. Due to the need to ensure required pressure relationships between these two rooms is maintained to minimize the risk of cross-contaminated air flowing from the dirty side to the processing side, the pass-through window as depicted in the previous version of the SPS Design Guide did not specify the type of pass-through window needed to achieve this purpose. This Standards Alert provides a sample specification in **Attachment A** for the double door interlocking pass-through window unit until such time as the VA Master Specification Section 08 56 19 is updated.
- 3) Personal Protective Equipment (PPE) Alcove:** This Standards Alert updates the purpose of the PPE Alcove. The PPE Alcove is to be used for donning PPE. It is not to be used to doff PPE. The doffing of PPE occurs within the Decontamination Room prior to exiting into the PPE Anteroom. The Design Guide language will be revised to reflect these separate functions.
- 4) Incorporation of new Pass-Through Automated Endoscopy Reprocessing (AER) technology:** Diagram 3.2 has been added to the updated SPS Design Guide to reflect Pass-Through AERs in the sterile processing workflow. The use of Pass-Through AERs eliminates the need for a scope reprocessing room as shown in Diagram 3.1. The Pass-Through AER allows for the scopes to go through decontamination, be reprocessed in the Pass-Through AER and transferred directly into the Scope Staging room. This Standards Alert provides a sample image in **Attachment A** of a standard model. Manufacturer specifications and site requirements may differ depending on the model unit selected or needed.
- 5) Scope Storage Cabinets:** These type cabinets are not to be placed in areas where negative pressure exists and are not to be placed in open areas and corridors. These cabinets must be located within a room that maintains positive pressure to adjacent spaces. Two types of storage cabinets for HLD-processed endoscopes are currently available: drying cabinets and conventional cabinets. There is no clear consensus at this time among professional organizations as to which type of cabinet is best; however, drying cabinets have been shown in scientific studies to reduce the risk of retained moisture and microbial contamination (Perumpail, 2019 [254]; Saliou, 2015 [284]) (see Annex K). Endoscopes hung in HEPA-filtered storage cabinets that do not have drying capabilities need to be dried prior to storage. Both cabinets are designed to store endoscopes (with or without channels) in a controlled environment. Neither cabinet type is designed to clean and/or disinfect



endoscopes (BS EN 16442 [47]). Additional detailed information is provided in **Attachment A** of this Standards Alert.

6) Temperature, Humidity and Air Changes per Hour (ACH) updates: The following areas have been updated in the VA HVAC Design Manual. HVAC requirements are to follow the VA HVAC Design Manual in lieu of the SPS Design Guide.

- a) Pg. 6-47 Dental Clinic: DNSC3 Sterile Instrument Storage has been revised to reflect a temperature of 70°F (21°C) and humidity range 30%-60%.
- b) Pg. 6-155 SPS SR505 Sterile Durables Storage: The temperature has been revised to require 70°F (21°C).
- c) Pg. 6-155 SPS SR504 Sterile Storage: The temperature has been revised to require 70°F (21°C).

7) Pressure Relationships:

- a) An update to the VA HVAC Design Manual will be made to reflect a change to the Sterile Processing Service Air Flow Relationships diagram to indicate that LR002 Toilets/Lockers and CSCR1 Soiled Transition/Drop Off Ante Room as follows:
 - LR002 Toilets/Lockers are to be negative to the corridor and Decontamination is double negative (--) which is negative to LR002 Toilets/Lockers.
 - CSCR1 Soiled Transition/Drop Off Ante Room is to be negative (-) to the corridor.
- b) A clarification to Diagrams 3.1 and 3.2 in the SPS Design Guide regarding Soiled Scope Drop Off and the PPE alcove is as follows:
 - When both functions are combined into a single room, it is to be negative (-) to the corridor.
 - When both functions are physically separated by a wall, both are to be negative (-) to the corridor.
 - In either arrangement, Decontamination is to be double negative.

Refer to the VA HVAC Design Manual, Pg. 6-149: Sterile Processing Service Air Flow Diagram in Attachment B in this Standards Alert.

8) Three (3)-Bay Sink setup: In general, the VA National Program Office for Sterile Processing requires a three-bay sink arrangement for the cleaning of instruments. The sinks must be arranged in the following order:

- The first sink is for dirty rinse
- The second sink is for washing
- The third sink is for final rinse (with critical water)

Refer to ANSI/AAMI ST 91:2021, Section 4.3.2 and ANSI/AAMI ST 79:2017 rev. 2021. Facilities must verify the use of the current version of the ANSI/AAMI standards.



9) Water Quality for Sterile Processing Service: The VA Plumbing Design Manual has been updated to expand Section 10.6 pertaining to Sterile Processing Service and now refers to AAMI TIR 34 for requirements on water quality for utility water and critical water testing and monitoring. Section 10.6 also addresses general layout, distribution and storage, and requirements for instrumentation, meters, and/or gauges for monitoring and alarming of water treatment parameters.

10) Medical Vacuum: This Standards Alert corrects the Room Data Sheet on Pg. 73 for the Scope Processing Room plumbing section to indicate “No” instead of “Yes”. This change brings the design guide into compliance with NFPA 99, 5.1.14.1.4 (2018).

11) Connecting Corridor to Temporary SPS Trailer(s): The standard of practice for VHA facilities when using a temporary SPS trailer for conducting sterile processing is to ensure sterilized products are protected from potential exposure to exterior environmental conditions that can result in contamination of the sterilized products or have carts transport exterior contaminants into a hospital environment. It is also important to ensure staff are protected from exterior weather conditions that could interrupt or cause delay in SPS operations. When a temporary SPS trailer is planned for use, the SPS trailer must be located functionally adjacent to the permanent building, and it must be connected with an enclosed corridor designed to provide the following at a minimum.

- Protection from weather
- Environmental controls for heating and cooling
- Proper interior lighting
- Complies with NFPA code
- Have finishes that are cleanable (refer to your local Environmental Management department for acceptable finish material surfaces)

DEFINITIONS:

Double Door Interlocking Pass-Through Window Unit: An intermediate chamber with two airtight doors or openings to permit passage between two dissimilar spaces; the transfer of parts and equipment in and out of a cleanroom. A prefabricated box shaped unit with interlocking doors (one door opens only if the opposite door is closed) installed in a wall separating two rooms or spaces of differing air pressures to prevent loss of pressure of either room or space to minimize the risk of cross-contamination.

Pass-thru Automated Endoscope Reprocessor (AER): Automated equipment designed to clean, disinfect, and rinse Reusable Medical Devices (RMD) such as flexible endoscopes and probes. This unit is physically located in the wall separating Decontamination from Scope Staging and Storage Area.

Automated Endoscope Reprocessor (AER): Automated equipment designed to clean, disinfect, and rinse Reusable Medical Devices (RMD) such as flexible endoscopes and probes. This unit is physically located in the Scope Reprocessing Area and is not a pass-through type unit.



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ATTACHMENTS: .

Attachment A — Equipment Examples

Attachment B — VA HVAC Design Manual Pg 6-149, Sterile Processing Service Air Flow
Diagram



Attachment A

EXAMPLE: Double Door Interlocking Pass-Through Window Unit

There are varying models and sizes of these type units available on the market. Facilities must review and evaluate which model is best suited for the intended purpose and the size of trays and/or RMD that will be passed through. The unit must be cleanable to VA SPS standards and must be able to withstand cleaning agents used without deterioration of the finish surfaces. The sample specification provided here is for guidance only until the VA Master Specification Section 08 56 19 is updated. This sample specification is for units without a built-in HEPA filter. Sample specification:

- Factory fabricated and assembled; fully welded stainless-steel box unit; unit size optional
- Type 304 Stainless Steel with #4 finish
- Two interlocking (door 1 cannot open until door 2 is closed and in locked position); Stainless Steel; mechanical interlock
- Type 315 Stainless Steel continuous flush-mount hinges
- Clear tempered safety glass viewing window
- Silicon bulb gasket
- Type 316 stainless steel lever compression door latches
- Seamless interior with radiused edges to prevent particulate from collecting in the corners and edges, designed specifically for aseptic applications



Example image of an interlocking unit

Note that these units have the option for electronic interlocking doors or mechanically operated interlocking doors. The facility must determine which is best suited for their purposes. If electronically operated interlocking doors is selected, it will require electrical connection and must be supported by the facility's emergency electrical system.



EXAMPLE: Pass-through Automated Endoscope Reprocessing Unit

There are various manufacturers of Pass-Through Automated Endoscope Reprocessing Units available on the market. Facilities must review and follow the manufacturer specifications and site requirements as they may differ depending on the manufacturer and model unit selected.



Example image of a Pass-Through Automated Endoscope Reprocessing Unit

SCOPE STORAGE CABINETS

Endoscopes processed with High Level Disinfection (HLD) or Liquid Chemical Sterilization (LCS) should be stored in a cabinet that is of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without any components touching the bottom of the cabinet, or the cabinet should be designed as intended by the manufacturer for horizontal storage of flexible endoscopes.

Cabinets used for storage of flexible endoscopes should be situated in a secure location, but not within the endoscopy procedure room. Locating the storage cabinet in the secured clean workroom or in a clean area outside of the procedure room helps prevent contamination of processed endoscopes. Storage cabinets should have doors and be located at least 3 ft (0.9 m) from any sink. Ensuring that storage cabinets have doors and are separated from sinks by at least 3 ft (0.9 m) provides protection and reduces the potential for processed flexible endoscopes to be contaminated by water droplets. Cabinets should remain closed to protect the integrity of the disinfected endoscope. Cabinets and endoscopes shall be visually inspected to ensure cleanliness when the endoscope is placed into the storage cabinet, and also when the endoscope is removed for patient use. An endoscope that is removed from a visibly dirty cabinet or is not dry shall be processed before use. Storage cabinets should be cleaned in accordance with the manufacturer's instructions for use (IFU) and in accordance with VHA Office of Sterile Processing requirements.



Refer to the following ANSI/AAMI ST 91:2021 standard for use of endoscope drying cabinets.

- 11.2.2.1 Endoscope drying cabinets

Facilities must verify the use of the current version of the ANSI/AAMI standards.



Attachment B

VA HVAC Design Manual, Pg. 6-149: Sterile Processing Service Air Flow Diagram

