

Sterile Processing in the Surgical Suite

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The 2014 *Guidelines for Design and Construction of Hospitals and Outpatient Facilities* requirements for sterile processing areas in a surgical suite have been updated to reflect current practices. The new edition provides guidance for designing these critical areas in a manner that will support and encourage clinical personnel to comply with current professional practice guidelines for cleaning, decontaminating, and sterilizing surgical instruments.^{1, 2}

Updating an Outdated Design Approach

A long-accepted practice has been to design surgical suites with a “substerile” room between every two operating rooms or a steam sterilizer(s) located in a “clean core.” This design was intended to support the practice of flash sterilization or emergent sterilization of surgical instruments. However, sterilization practices have changed significantly in recent years, and this design approach does not support today’s sterilization practices.

The term “flash sterilization” was historically used to describe steam sterilization of unwrapped items intended to be used immediately in the operating room. The sterilization cycles of flash or emergent sterilization traditionally comprised either 3 or 10 minutes of exposure, with minimal or no dry time and no cooldown period, which made the sterilization cycle shorter than the time needed to achieve wrapped or terminally sterilized items. In flash sterilization, the item to be sterilized was placed in the steam sterilizer chamber in an open basket. Once the chamber door was opened, the sterilized item(s) was exposed to the environment and could be contaminated by improper handling. As well, the open basket did not protect the sterile item from exposure to environmental contaminants during transport to the point of use. For these reasons, it was desirable to locate the sterilizer as close as possible to the operating room, leading to the expensive practice of placing multiple steam sterilizers throughout the surgical suite, often between every two operating rooms.

Use of emergent sterilization was originally intended for only one or two instruments, such as a surgeon’s special scissors or forceps. These simple instruments were easy to clean and sterilize quickly. Today’s surgical instruments are far more complex and require careful and thorough cleaning by skilled and well-trained personnel familiar with the intricacies of the sterilization

¹Association of periOperative Registered Nurses (AORN). “Recommended practices for sterilization.” In *Perioperative Standards and Recommended Practices*. Denver, Col.: AORN, Inc., 2014: 575-602.

²Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST79:2010/A3:2012: *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, Va.: AAMI, 2012.

process and the specific instruments. Often it is necessary to sterilize large sets of instruments that have multiple components and various configurations, increasing the difficulty of cleaning the items prior to sterilization per the manufacturer’s instructions. Some instruments require extended sterilization times or other variations on the “standard” flash sterilization cycle. The substerile rooms provided in the past often do not have the space or the cleaning chemicals and devices needed to perform the first critical step in the sterilization process, cleaning.

Sterilizing unwrapped items in an open basket is no longer a recommended practice. Substerile rooms are no longer needed, and steam sterilizers placed in a central core are no longer necessary

Facilities that Support Current Practices

Today, flash sterilization has been replaced by what is called “immediate-use steam sterilization,” or IUSS.³ In this method, sterile items emerge from the sterilization process in rigid, enclosed containers designed and intended for IUSS use that protect the items from exposure to contamination during transport from the sterilization chamber to the point of use. This change in practice has practical implications for the built environment.

A hospital or ambulatory surgery facility may have one, multiple, or no sterile processing rooms in its surgical suite, depending on how sterilization is performed.

As previously, sterilization of all surgical instruments may be performed in a central sterile processing department in the hospital, where they are properly cleaned, packaged, and terminally

Comparison of General Inpatient Surgery Sterile Processing Requirements

2010 FGI Guidelines	2014 FGI Guidelines
2.2-3.3.6.14 A substerile room. If the functional program requires emergent sterilization, a room(s) for this purpose shall be provided in the surgery suite. . . .	*2.2-3.3.6.13 Sterile processing room. When sterilization processes are conducted in the surgical suite, a sterile processing room shall be provided.
(1) This substerile room shall be either accessible from the operating room(s) it serves or shall be located inside the clean core if the clean core is directly accessible from the operating rooms(s). This room shall be able to be accessed without traveling through any operating rooms. (2) This room shall be equipped with the following: (a) A steam sterilizer as described in the functional program (b) A countertop (c) Built-in storage for supplies	(1) General (a) The sterile processing room shall consist of a decontamination area and a clean work area. *(b) Sharing of the sterile processing room between two or more operating rooms shall be permitted. (c) The sterile processing room shall be designed to provide a one-way traffic pattern of contaminated materials/instruments to clean materials/instruments to the sterilizer equipment. (i) Entrance to the contaminated side of the sterile processing room shall be from the semi-restricted area. (ii) Exit from the clean side of the sterile processing room to the semi-restricted area or to an operating room shall be permitted.

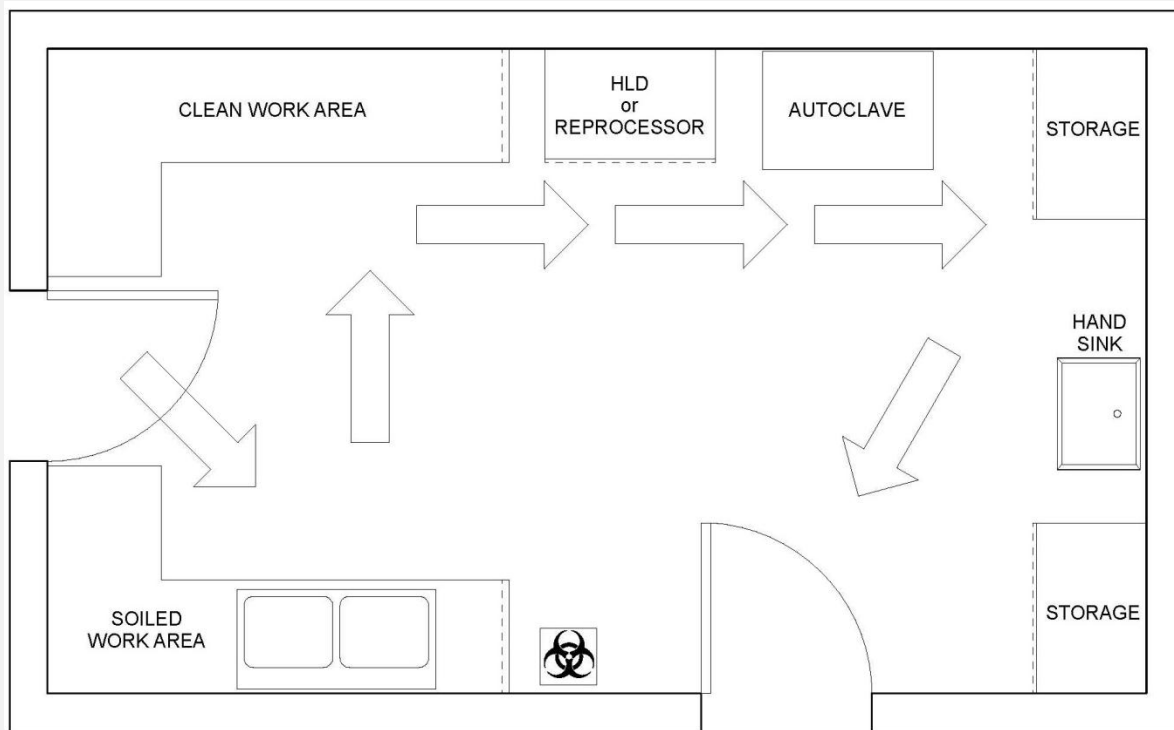
³AAMI, AORN, et al., “Immediate-Use Steam Sterilization,” available from www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf.

sterilized. But if instruments are sterilized in the surgical suite, the 2014 *Guidelines* requires provision of a functionally equivalent sterile processing room designed to facilitate a one-way dirty-to-clean traffic pattern.

Because the IUSS process uses rigid sterilization containers that protect the sterile item from contamination during transport from the sterilizer to the point of use (i.e., the sterile surgical field), it is no longer necessary to build multiple spaces in a surgical suite for sterile processing. In fact, use of a single sterile processing room to serve multiple operating rooms or even an entire surgical suite is acceptable. And, if sterile processing is not performed in the surgical suite, a sterile processing room in the suite is not required.

Buildings that have a central sterile processing department located near the surgical suite and a system that supports the operating rooms during hours of operation do not need to have dedicated floor space and duplicate equipment in the surgical suite for sterile processing.

One-Way Traffic in Sterile Processing



As described in appendix item A2.2-3.3.6.13 (1)(c) in the 2014 *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*, in the sterilization process practiced today, the circulating nurse carries contaminated materials or instruments in a tray into the decontamination area of the sterile processing room, cleans and then sterilizes the material or instrument, and returns it to the point of use through the clean work area of the sterile processing room. This practice creates a one-way traffic pattern, which helps decrease the potential for cross-contamination of sterile instruments. The new *Guidelines* requirements provide requirements for both the decontamination area and the clean work area in the sterile processing room. (Illustration adapted from ANSI/AAMI ST79-2010: Comprehensive guide to steam sterilization and sterility assurance in health care facilities)

However, in all locations where sterilization processes are performed, the building design should provide functionally equivalent space for decontamination and sterilization of surgical instruments. In other words, the sterile processing area in the surgical suite should be designed to be functionally equivalent to sterile processing areas in the central sterile processing department.

Cost Impact of the Changes in Sterile Processing Requirements

The potential cost savings from the change in surgical suite sterile processing requirements in the 2014 *Guidelines* are enormous. One health care design firm has estimated that the cost of providing a single substerile room that complies with the 2010 *Guidelines* requirements (see table and complete text in the 2010 edition) as follows:

- Equipment: \$40K - \$100K
- Mechanical and electrical systems: \$60K
- Floor space (50 square feet) @ \$1,200/sq. ft.: \$60K

This would result in a total minimum cost per room of \$160K times the number of substerile rooms provided in a surgical suite. Added to this cost would be long-term operational costs for:

- Maintenance
- Energy
- Sterilization efficacy monitoring supplies (e.g., chemical indicator strips, biological monitors, incubators, mechanical monitor strips, test packages)
- Personnel time to perform sterile processing and sterilization efficacy monitoring tasks (testing, documenting results, reporting process failures, etc.)

When a facility requires sterile processing in a surgical suite, only one sterile processing room would be required according to the 2014 *Guidelines*. The cost for this would be approximately \$80K more than for the substerile room described above as plumbing for a clinical sink is required and the room is larger to accommodate decontamination and clean areas in the same space. However, a facility that complies with the 2014 *Guidelines* might eliminate all these costs if no sterilization is performed in the surgical suite. In a large hospital, all sterile processing may be done in a central sterilization department. In an ambulatory surgery center or critical access or other small hospital, a sterile processing room in the surgical suite may be the only sterile processing area in the facility. Some surgery centers may choose to outsource all sterile processing to a third party and not perform any sterilization on-site, in which case no sterile processing facilities or equipment would be required.

Inclusion of substerile rooms in a surgical suite design is no longer recommended as these rooms perpetuate outdated sterilization practices and are costly and inefficient to build and maintain. It is time to make this design obsolete and build cost-effective, efficient surgical suites. Health care organizations must look for safe and practical means of decreasing costs. We cannot continue to waste money on outdated and unnecessary features. There is a better way to build! The 2014 edition of the *Guidelines* provides clear, up-to-date guidance for designing surgical suites that accommodate today's practices.

About the Author

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Health Guidelines Revision Committee (HGRC) and the 2010 and 2014 HGRC Steering Committee.

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