



CENTRAL STERILE MODERNIZATION: A Guide to On- vs. Off-Site Facilities

BY JOSHUA M. HEACOCK

Central Sterilization Services (CSS) is one of the least recognized yet highly critical departments of any healthcare system. Often referred to as the Sterile Processing Department (SPD), CSS is responsible for the decontamination, cleaning, sterilization, and preparation of instruments and consumables used in medical procedures – thus having a direct impact on patient care and safety.

At some point every healthcare facility will face the need to modernize its CSS and evaluate their options. While there are many solutions

for modernization, the most common approaches include:

1. Renovation of the existing CSS in place
2. Relocation to a new area within the existing facility or campus
3. Relocation to an off-site facility owned and operated by the healthcare organization
4. Relocation to an off-site facility owned and operated by a third-party vendor

While there is no “one-size-fits-all” approach, one recommendation for all modernization projects is a thorough analysis of facility needs

and characteristics, including an infrastructure assessment. This paper provides the framework for such analysis, beginning with a review of the most common driving forces for modernization and identification of elements associated with a comprehensive facility evaluation. A high-level overview of the types, functions, and processes associated with CSS departments is provided, as well as a review of on- and off-site solutions, and the conditions under which each may be justified. The author does not set forth to discuss every challenge or solution a healthcare organization may encounter, but rather to provide stakeholders with an understanding of common factors to address when modernization is being considered.

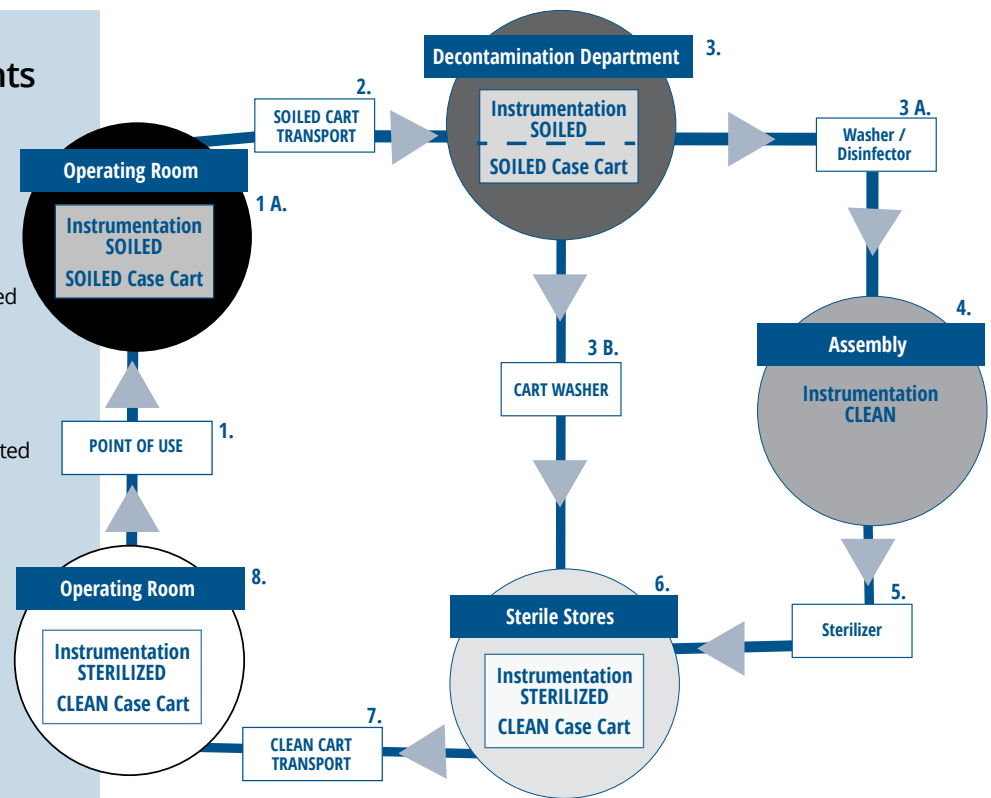
CSS & drivers for change

Up until the 1940s, equipment sterilization functions were mostly performed within the department in which the instruments were to be used. As medical procedures, equipment requirements, and code enforcement began to expand, healthcare facilities started establishing separate, specialized departments – the forerunners to today's modern CSS – to provide more efficient services and improved patient safety.

The functions of current-day CSS departments typically encompass decontamination, cleaning, sterilization, tray assembly, and storage of

Circle of Life for Instruments

1. Case cart and surgical instruments used during procedure
- 1 A. Resulting in soiled case cart ready for reprocessing
2. Soiled case cart and instruments returned to Decontamination department
3. Soiled case cart disassembled
- 3 A. Soiled instruments and trays through manual wash, ultrasonic and/or automated washer/disinfector
- 3 B. Soiled case carts through cart washer
4. Washed instruments reassembled and wrapped
5. Wrapped instruments and assembled instrument trays through sterilizer
6. Clean case cart build
7. Assembled clean case cart transported to surgery department and staged for use
8. Instruments ready for procedure



REPROCESSING FLOW CHART

This diagram represents a traditional CSS process workflow based on a 3-zone layout. Workflow may vary by facility or with the implementation of a 2-zone layout. (Related reading: ["Typical CSS Department Configurations."](#))

medical/surgical supplies and equipment for use by various departments in a healthcare facility. The combination of instruments and trays required for a procedure are assembled in CSS, packaged on case carts, and delivered to the point of use. Any errors occurring during this “Instrument Circle of Life” (see page 2) can have a significant impact on a healthcare system and its patients.

Advancements in patient care and the medical industry have forced many healthcare providers to face difficult decisions regarding their CSS and the need for modernization. These challenges are brought on by several common drivers for modernization, which include:

- Campus or healthcare system growth
- Inefficient workflow processes
- New/specialized instruments and technology requiring specific sterilization equipment and processes (e.g., robotic-assisted surgical systems)
- Inadequate and deteriorating infrastructure (mechanical, electrical, plumbing, technology) that does not allow for newer equipment and technologies
- Increased case volume resulting in increased tray volume
- Advances in surgical efficiencies (allowing for more procedures per day)
- Changes in codes and standards by industry organizations including the Association for the Advancement of Medical Instrumentation (AAMI), the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), and The Joint Commission

Upgrading to higher-capacity process equipment may be sufficient for modernization if an increase in tray volume is the main issue facing a facility. However, in most instances new equipment requires significant building infrastructure modifications and increased footprint. This becomes a challenge since CSS departments are generally “land-locked” within the lower level of a facility. Allocating potential revenue-generating space for an expanded or new CSS elsewhere on campus can be difficult to justify. Additionally, renovation and expansion often result in a phased approach that is disruptive to CSS operations, increases risk of patient infection, extends construction duration, and increases construction costs.





Evaluating an existing CSS

A basic understanding of CSS functions and the importance of modernization provide a foundation for healthcare administration to initiate an evaluation of their existing CSS. An evaluation is typically a collaborative effort between owner, design team (engineer and architect), CSS consultant and, in some instances, a logistics consultant. An effective evaluation starts with a comprehensive assessment of the existing CSS and includes infrastructure analysis of existing architectural and MEPT systems, observation of existing workflow processes, tracking of tray volumes, reviewing annual procedure volumes, and identifying operational inefficiencies. This section provides a brief description of these critical parts of an effective study.

INFRASTRUCTURE ANALYSIS: Evaluation of existing MEPT infrastructure and the ability

to re-use or the need for replacement is a critical component to a long-term plan. To fully understand capital improvement needs, a comprehensive infrastructure analysis should include a review of the capacities of the existing central plant (boiler, chiller, etc.), major equipment (air handling units, exhaust fans, etc.) and distribution systems (pipe capacity, normal power, emergency power, etc.).

EXISTING VOLUMES: A detailed review of existing case volumes is critical for understanding current and future needs. A comprehensive analysis evaluates a facility's historical information, compiling data on the number of annual cases, case complexity, and average number of trays per case. This information establishes a baseline for space, equipment, process, and infrastructure needs for a CSS modernization.



COMMON CSS INEFFICIENCIES

1. Outdated case cards
2. Obsolete trays
3. Under-performing equipment
4. Poor workflow

EXISTING OPERATION & DEFICIENCIES: When upgrading any CSS space, consideration should be given to improving operational workflow and inefficiencies. A CSS often evolves slowly and trails advancements in equipment, processes, and workflow. As a result, changes in procedure are usually reactive instead of proactive. Departmental staff are challenged when new equipment and technologies are introduced into their CSS, resulting in a need to implement changes incrementally, often creating a disjointed and inefficient workflow.

Healthcare systems often fail to evaluate their CSS workflow holistically. When given the opportunity to renovate, relocate, or build new, significant effort should be given to create new processes, workflows, and resolve inefficiencies. Common operational deficiencies include:

- Outdated case cards resulting in unused instrumentation and unnecessary reprocessing
- Instrument trays for surgeons who no longer work at the facility
- Excessive vendor tray storage
- Lack of tray standardization
- Inefficient instrument workflow and equipment that crosses paths
- Poor equipment layout

CONTAINERIZING VS. WRAPPING: Many approaches that can be utilized within CSS processes have a direct impact on space planning workflow considerations. For example, analysis by a design team can



compare instrument storage concepts – such as containerizing versus wrapping – and provide the advantages and disadvantages of each.

INSTRUMENT TRAYS: Instrument trays are generally classified as single-level or multi-level and are utilized based on application. Understanding when each type of tray should be used and how it impacts equipment cycle time is important for process planning. For example, implant trays are usually multi-level and count as multiple trays during decontamination processes but count as a single tray during sterilization.

The design team can assist a healthcare system in evaluating tray types used for each application. A detailed understanding of an organization's future service volumes can impact tray multipliers. For example, most neurology cases require multi-layer, ultrasonic-sterilized vendor trays. If a facility intended to expand neurology case volume – increasing from six to 12 operating rooms – a tray-to-case growth ratio of 2:1 would be applied. In contrast, a service such as laparoscopic may have a 1:1 relationship and result in no tray-to-case multiplier when determining future growth needs.

SPECIALTY INSTRUMENTATION: Specialty instrumentation – such as DaVinci robotic surgical devices – have varying reprocessing requirements that may include specialized sterilization/washing equipment. Instructions for Use (IFU) associated with specialty instrumentation are often stringent and cause reprocessing to take a significant amount of time. Therefore, specialty instrumentation sterilization/washing equipment should be considered during space planning and workflow process development.

VENDOR LOANER INSTRUMENTS: Instruments provided by manufacturers for a specific case and then returned to the manufacturer following the case are considered “vendor loaners.” Because vendor loaners are reprocessed twice per use – once before they can be used and again before they can be returned – it is critical to quantify the number of vendor loaners used by a healthcare system. Depending on case volume and services offered, vendor loaners can impact equipment sizing, cycle times, and process workflow.

CAPACITY PLANNING: In addition to documenting existing case volumes, case complexity, and services offered, the consulting team should engage the healthcare system to understand their vision. Anticipation of future case types, volumes, complexities, and services

offered are significant factors that affect design team approach. An understanding of existing campus master plans (e.g., surgery expansion, relocation of existing services off-site) and historical growth trends assist in establishing baseline growth values for future-proof design. For example, if an orthopedic department accounts for 10 percent of current case load and does not anticipate growth, the tray-per-case average is expected to remain consistent. However, if an orthopedic department intends to increase case volumes to 30 percent, the hospital will need to modify its tray-per-case average to reflect this future state.

EVALUATING THE CULTURE: Evaluating the healthcare system environment and understanding its culture is important for gauging how a modernization project – on-site or off-site – will be received. Positive and proactive support from administration, surgeons, CSS employees, etc., is important for a successful transition. Each step and each department included in the process plays a valuable role in the overall success of the project. It’s critical for each department to understand how their performance can impact upstream and downstream processes.



LOAD-LINE BALANCING: Think of CSS as a manufacturing facility with an assembly line; each component (and its duration to complete) critically affects its adjacent upstream and downstream process. An inefficiency in one step of the process causes the entire system to become inefficient. To mitigate this issue in a CSS, load-line balancing is a design aspect that should be addressed.

For example, if a facility workflow requires 16 soiled case carts to be delivered to CSS every 75 minutes, the CSS department must be able to completely reprocess all 16 case carts prior to the next delivery. If the time to reprocess a delivery exceeds the delivery schedule, a backlog of reprocessing creates a bottleneck of contaminated equipment – and may result in a delay in instrument availability and adversely affect surgical procedure schedules.

LOADING DOCK & LOGISTICAL EVALUATION: Understanding the flow of supplies (consumables) and materials from delivery to point-of-use may have a significant impact on CSS operations. When evaluating potential CSS locations on an existing campus, consideration must be made to proximity of the loading dock. Extended travel path of consumables and CSS supplies may require additional staff or specialty planning.

When evaluating an off-site solution, it is important to understand how increased activity at existing loading docks will impact other

TYPICAL CSS LAYOUTS

Learn how CSS departments are physically laid out in the accompanying article, [“CSS Configurations.”](#)



hospital operations and logistics. This requires an understanding of high-volume delivery times, types of deliveries, and how the addition of case cart delivery will affect each dock.

BUSINESS CASE: If a feasibility study determines that an existing CSS is not able to accommodate future growth, the need to make a full business case may be moot since change is required regardless of the business case outcome. However, a business case is often pursued if the feasibility study determines both on-site and off-site solutions are viable and remain in consideration. In this scenario, completing a business case will assist in identifying and comparing overall operating expenses for each option as well as determining the viability of contracting with a third-party vendor.

A comprehensive business case should address, at a minimum, the following:

- Cost of transport trucks, gas, maintenance, insurance (if building off-site)
- Real estate costs (if purchasing)
- Lease/building costs
- Utilities
- Full-time equivalent employees (FTEs)
- Equipment depreciation
- Service agreements (maintenance for equipment inside the building)
- Overall supply costs (changes to the processing method may result in additional cost)



On-site solution strategies


If a hospital can allocate space within its main facility or campus, keeping the CSS department on site is the recommended and most common option. (There are exceptions, of course. For example, an ambulatory facility with an on-site CSS would not necessarily make financial sense.) In addition to eliminating the need for transportation, an on-site solution typically realizes lower labor cost per tray, reduces reprocessing turn-time, and can utilize just-in-time case cart build strategies.

The level of utilities and infrastructure (e.g., steam, domestic water, pure water, electrical) needed to support a CSS department is significant and the ability to utilize existing campus central plant infrastructure (boilers, chillers, etc.) can provide great value to the project by taking advantage of built-in system capacities and redundancies.

While there are many advantages to remaining on site, there are several disadvantages that

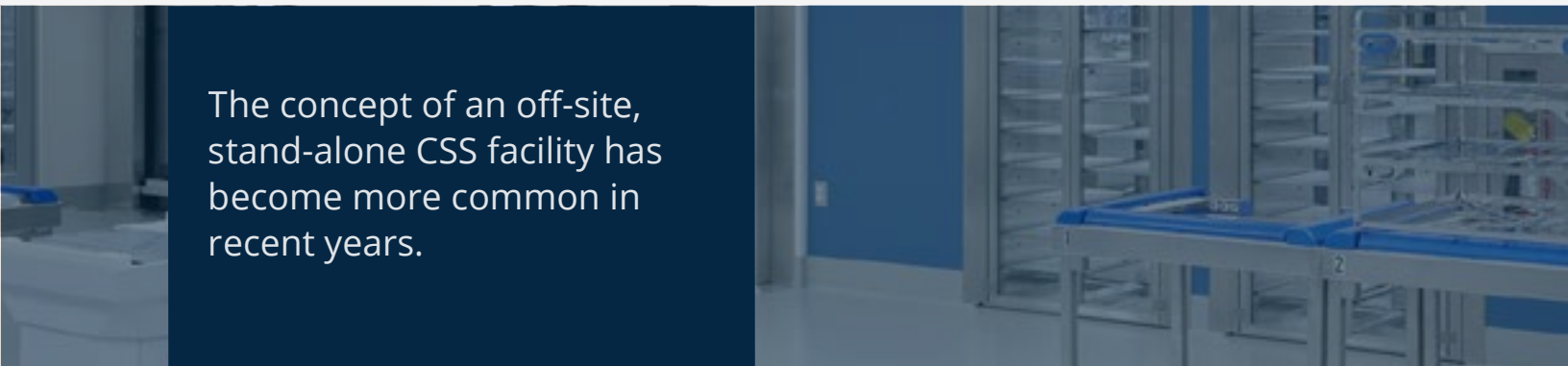
should be understood. Renovation projects are typically disruptive to adjacent spaces and provide challenges associated with patient safety and satisfaction. Many times, expansion and renovation projects also require longer construction schedules and implement a phased approach that can be disruptive to CSS workflow, increase risk of infection, and elevate construction costs. To alleviate inefficiencies associated with phased renovation, healthcare systems may opt to explore the use of temporary mobile CSS solutions – however, this approach has its own set of challenges and is extremely cost prohibitive.

Hospitals also often experience overall building pressurization issues that can negatively impact testing and balancing of a new CSS space. Identifying existing HVAC deficiencies (outside the CSS department) and beyond the project scope of work can be difficult, and as a result even a perfect CSS HVAC design does not always correlate to perfect operation or eliminate the possibility of space pressurization issues.



THINKING OUTSIDE THE BOX: One on-site option that may be considered is a CSS addition that extends beyond the physical footprint of the existing hospital but remains connected. This approach realizes the benefits of remaining on site, removes the need for excessive vehicle transportation, and allows construction of the department without negatively affecting ongoing hospital operations. Depending on

placement of the expansion and its location relative to the surgical suite, a CSS could be paired with other support services (materials management, loading docks, laundry, engineering services, etc.) to create synergy among functions. This approach could also take advantage of B-Occupancy construction, resulting in lower construction costs when compared to interior renovations.



The concept of an off-site, stand-alone CSS facility has become more common in recent years.

Off-site solution strategies

When a healthcare facility doesn't have available space to accommodate an expansion and/or modernization on site – or wants to consolidate multiple facilities' CSS departments – it should evaluate off-site solutions. One trend that has become more common in recent years is the concept of an off-site, stand-alone CSS facility. Moving a CSS department off campus does present challenges, but if done correctly can optimize efficiency and save resources for a healthcare system. For example, an off-site solution is beneficial when a healthcare system is expanding within their regional market and there is a strong desire that new facilities not incorporate individual CSS departments.

In this scenario a single, centralized, off-site CSS can make economic sense and allow increased square footage of programmable space at each care-providing location. Utilizing a centralized CSS also enables the healthcare system to consolidate and standardize the system's sterilization processes, instruments, and workflow, leading to increased operational efficiency. In addition, a better-controlled environment leads to improved quality assurance, with all appropriate and necessary equipment provided to a staff that is free of disruption and last-minute interruptions.

FEASIBILITY ANALYSIS: When investigating whether an off-site solution works best for a healthcare system, several questions need to be answered, including:

- What is the hospital's ability to retain and educate staff for CSS functions? If the facility is in an area where it's hard to find or keep sterile processing technicians, or the hospital doesn't want to be responsible for that part of the operation, contracting with a third-party may be the solution.
- What's the cost? Can the hospital build and run its own off-site facility at the same or lower cost compared to outsourcing to a third party and paying the markup?
- Does the hospital want to maintain liability for reprocessing?
- What happens if the relationship between the hospital and the vendor deteriorates?

Understanding logistics and physical limitations of a facility will assist in determining if transportation of materials to multiple sites is realistic and provides an understanding of what modifications are required at each location. Using this information, a healthcare system model can be created to determine logistics (truck patterns, etc.) and if an off-site solution can support the entire healthcare system or just

part of the healthcare system. Other logistical considerations requiring study include:

- Identification of required infrastructure work needed for loading docks, staging areas, vertical transportation, etc.
- Case cart travel routes to and from point-of-use
- Identification of a proposed greenfield site, its constraints (ingress/egress, utilities, etc.), and proximity to locations served
- Travel distance and vehicle transportation routes (including alternate routes in the event of accidents, road closures, railroad crossings, etc.)
- Traffic patterns, congestion, and delivery schedule
- Standardization and sharing of instruments across multiple locations
- Delivery model (i.e., reprocess and return vs. reprocess and case cart build)

Whereas an on-site solution is likely able to utilize existing central plant utilities, an off-site solution generally requires its own central plant source equipment (boilers, chillers, generators, domestic water system, etc.). In addition to initial capital costs of source equipment, it's also important to consider overall central plant capacity, the amount of redundancy, and maintenance staff and costs.

When evaluating an off-site CSS, the costs and footprint associated with an on-site turn-center should be considered.

ON-SITE TURN CENTER: Healthcare systems utilizing an off-site CSS often require a small, on-site turn center. This need is driven by several factors including the type of healthcare facility (e.g., a trauma center requiring quick turn-around), its distance from the off-site CSS, as well as its need for limited and specialized instrumentation or immediate reprocessing. At minimum, an on-site turn center should include a sink, ultrasonic washer, and two small immediate-use steam sterilization units (IUSS). IUSS units provide quick sterilization of instruments: for an emergency procedure; when a non-replaceable instrument has been contaminated and needs to be replaced to the sterile field immediately; and when an item has dropped to the floor and is needed to continue a surgical procedure.

For organizations considering an off-site CSS facility, three basic options exist: third-party-owned, joint venture, and hospital-owned. In any of these three options, the construction of an off-site solution allows a healthcare system to “soft-start” its off-site go-live by offering training and implementation of new workflows while continuing to operate the existing CSS to avoid compromising patient safety.

THIRD PARTY VENDORS: Utilizing a third-party vendor is similar to contracting with an off-site

laundry service; the vendor owns and operates the CSS building and employs its own staff. Third-party vendors generally charge their fees based on a per-instrument cost and have the ability and certification to serve multiple facilities and healthcare systems. Variations of the third-party model include:

- A joint venture between the reprocessing vendor and a healthcare system. In this approach, the healthcare system may own the building while the vendor provides staffing and services.
- A joint venture among competing hospitals. In this approach, the CSS is owned by one of the hospitals and provides services to multiple healthcare systems. Though the goal is to share costs, this is a more complicated solution that is rarely pursued due to competition and perceived conflict of interest.
- A healthcare system operating as a third-party vendor for other healthcare systems. Like a joint venture among competing hospitals, this is a complicated arrangement that requires the vendor healthcare system to prove the need for and the ability to provide this service – criteria that is easier for a traditional third-party vendor to achieve.



STAND-ALONE FACILITY: A healthcare organization owning and operating an off-site CSS is an emerging option that has been adopted by several healthcare organizations in recent years. While moving a CSS department off campus in conjunction with its modernization does present additional challenges, under the right conditions and if done correctly it can optimize efficiency, increase quality control, and save resources. For example, instrumentation can be standardized and shared across multiple locations, leading to a reduction in implement expenditures across the system.

The ability to save resources and money with an off-site CSS is entirely dependent on the organization and its current status, challenges, and efficiency. For a hospital that is already efficient in utilizing staff, an off-site model might end up increasing their overall costs. However, if the new building and processes will

OFF-SITE CASE STUDY:

Learn about the [University of Iowa Hospitals & Clinics' new off-site CSS](#) in an accompanying case study.

be substantially more efficient than current on-site operations, a hospital may be able to make the move to an off-site CSS – and add staff for the future department as needed – and still increase overall cost efficiency.



Getting started

This document does not cover all CSS situations or solutions, but does provide a high-level roadmap for healthcare executives faced with the need for modernization. To begin evaluation of your CSS department, start by contacting qualified engineering and central sterile consultants experienced in modernization projects.

Your design team should provide a comprehensive analysis specific to your facility and needs – as outlined in this article – and determine what various design-informed replacement models would look like. This will lead to identification of the best solution for your needs – on-site or off-site, and that supports your entire system, part of the system, etc. Throughout the process be sure to involve your medical staff, CSS technicians, and other stakeholders who will be affected by this decision. Their feedback and concerns regarding all options are critical.

Unless there is an obvious case for change (e.g., adding a patient/surgery tower) a business case is recommended to determine the financial viability of each option and fully understand the reality of your decision.

Finally, talk with other organizations that have recently modernized their CSS departments. Their lessons learned can be invaluable as you navigate your way to a solution that is right for your healthcare facility.



ABOUT THE AUTHOR

[Josh Heacock, PE](#), is an associate principal and healthcare client executive for IMEG Corp.

Stephanie Karr, a principal with Integrated Supply Solutions, LLC., contributed to this report.

ADDITIONAL READING

Article: [Typical CSS department configurations](#)

Case study: [University of Iowa Hospitals & Clinics Off-site CSS](#)

