MANUAL 5: Sterile Processing

Design & Construction

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Introduction STERILE PROCESSING

Sterile processing and support space play crucial roles in ensuring the safety and success of surgeries within hospitals. These areas are responsible for the cleaning, sterilization, and organization of surgical instruments and equipment, as well as providing support services for the surgical team. Here are some key aspects of sterile processing and support space requirements for surgery within hospitals:

Sterile Processing Department (SPD):

Layout and Design: The SPD should be strategically located within the hospital, preferably near the operating rooms. The layout should facilitate a unidirectional flow of instruments from dirty to clean areas to prevent cross-contamination.

Space Requirements: SPD requires adequate space for cleaning, decontamination, inspection, assembly, packaging, sterilization, and storage of surgical instruments and equipment.

Equipment: SPD should be equipped with autoclaves, ultrasonic cleaners, washer-disinfectors, sterilization packaging equipment, and storage units.

Ventilation: Proper ventilation and air quality control are crucial to maintain a clean and sterile environment.

MANUALS IN TOOL KIT:

- 1. How we begin Developing the Team
- 2. Design in Depth building codes, room types, terminology.
- 3. Construction Projects Steps
- 4. Reading construction Documents
- 5. Design Guide for SPD
- 6. Infection control and prevention

"If you need a new process and don't install it, you pay for it without getting it."

- Ken Stork

Phases of a Project

OCCUPANCY Grand Opening • Change Management • Transition Planning	 Supply/stage space Trial/practice runs Open Doors! Post Occupancy Evaluation Evaluate performance to the original design intent
CONSTRUCTION ADMINISTRATION Break Ground • City and State Reviews	 Shop drawing Reviews On-site observations Review and Process change orders
CONSTRUCTION DOCUMENTS Prepare Documents • Final coordination with each discipline	 Confirm constructability with Construction Manager (CM) Final documentation and coordination ("blueprints") Final review with regulatory agencies
DETAIL DESIGN Focus on Details • Room-specific requirements • Furniture, fixtures, and equipment (FF&E)	 Review mechanical, electrical, IT, security Coordinate code requirements Discuss site details and landscape Reconfirm scope and cost Finalize and sign off interior/exterior design & signage
CRITERIA DESIGN Key Adjacencies and Critical Flows • Department adjacencies and locations • Critical flows (review and improve)	 Site plan layout Building footprint/massing Capture future space needs Confirm scope and costs Opportunities for innovation
 VALIDATION Big Picture Define high-level space program Review future state process maps 	 Detail space planning Align needs/wants with schedule and budget

The icons on this page are distributed throughout the manuals and provide a quick reference to the phase of the project. Each icon will provide the reader with a quick reference and understanding of the current phase of the project and what decisions should be made or should have been made leading up to that moment.

The six phases of a construction project begin with Initiation and Concept, where initial planning and stakeholder discussions define the project's purpose and feasibility. This is followed by **Planning and Design**, involving the development of detailed plans and blueprints, and securing necessary permits. **Pre-Construction** includes site analysis and finalizing contracts, setting the stage for **Procurement**, where materials and labor are acquired. **Construction** is the phase where the building takes shape, with site preparation and the installation of systems and finishes. Finally, **Close-Out and Handover** ensures the project is completed to specifications, with a final inspection and transfer of the completed project to the client.

The Areas of SPD

STERILE STORAGE

- **Location:** Sterile storage areas should be located close to the operating rooms to minimize the transportation time of sterile instruments.
- **Temperature and Humidity Control:** Proper temperature and humidity control are essential to maintain the sterility of stored instruments and supplies.
- **Organization:** The storage area should be wellorganized with clear labeling and shelving to facilitate easy retrieval of sterile items.

PREOPERATIVE HOLDING AREA (Prep/Recovery):

- **Space for Patients:** A dedicated preoperative holding area is required for patients to prepare for surgery. This area should have privacy, comfortable beds, and space for family members.
- Access to Amenities: Proximity to bathrooms, changing areas, and other amenities is important for the convenience of patients and their families.

OPERATING ROOM (OR) SUPPORT SPACES:

- Equipment Storage: Adequate space is needed for storing surgical equipment, supplies, and disposables within the operating room.
- **Traffic Flow:** The layout should allow for efficient traffic flow, ensuring easy access to and from the operating room for the surgical team and equipment.
- **Communication Systems:** Integration with communication systems, such as audiovisual equipment and electronic medical records, is essential for effective coordination.

POST-ANESTHESIA CARE UNIT (PACU):

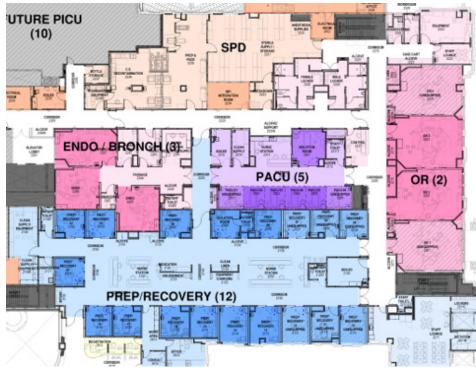
- **Space for Recovery:** The PACU requires space for patient recovery, monitoring, and postoperative care.
- Accessibility: Proximity to the operating rooms is crucial for quick transportation of patients from the OR to the PACU.

STAFF FACILITIES:

• **Break Rooms:** Providing break rooms and rest areas for surgical staff is important for their well-being and to ensure they are well-rested and focused during procedures.

Compliance with regulatory standards, such as those set by organizations like the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Medicare & Medicaid Services (CMS), is crucial in designing and maintaining these spaces within hospitals. Additionally, ongoing training and adherence to established protocols are vital for maintaining a sterile and efficient surgical environment.

https://www.aami.org/Sterilization-Persona/ sterilization-overview



Sterile Spaces

In the context of sterile processing, the sterile core space refers to a controlled and designated area where activities related to the decontamination, preparation, packaging, and sterilization of medical instruments and equipment take place. The sterile core is crucial in maintaining aseptic conditions to ensure the safety of patients and healthcare professionals. Here are some key aspects and requirements for the sterile core space:

PHYSICAL LAYOUT

- **Controlled Access:** The sterile core space should have restricted access to authorized personnel only. This helps in controlling the environment and minimizing the risk of contamination.
- **Separate Zones:** The space is typically divided into different zones, such as decontamination, preparation, packaging, sterilization, and storage. Each zone has specific requirements and is designed to prevent cross-contamination.

ENVIRONMENTAL CONDITIONS

- **Temperature and Humidity Control:** Maintaining optimal temperature and humidity levels is essential to prevent the growth of microorganisms and maintain the efficacy of sterilization processes.
- **Air Quality:** High-efficiency particulate air (HEPA) filtration systems are used to ensure the air is free from contaminants. Positive pressure is often maintained to prevent outside air from entering.

CLEANING & DECONTAMINATION:

- **Cleaning Area:** A designated area for initial cleaning and decontamination of used instruments. This may include sinks, ultrasonic cleaners, and enzymatic solutions to remove biological debris.
- **Personal Protective Equipment (PPE):** Staff working in the sterile core space must wear appropriate PPE, including gowns, gloves, masks, and eye protection, to prevent contamination.

EQUIPMENT & WORKSTATIONS

- **Sterilization Equipment:** Autoclaves, ethylene oxide (EtO) sterilizers, or other sterilization equipment should be present in the designated sterilization zone.
- **Packaging Stations:** Workstations for the proper packaging of sterilized items, including the use of sterilization wrap, pouches, or containers.

WORKFLOW & TRAFFIC FLOW

- **Unidirectional Flow:** Design the space to allow for a logical, unidirectional flow of materials and personnel to minimize the risk of contamination.
- Segregation of Dirty and Clean Areas: Ensure a clear separation between areas for dirty (contaminated) and clean (sterile) instruments.

MONITORING & QUALITY ASSURANCE

- **Biological and Chemical Indicators:** Regular use of biological and chemical indicators to monitor and verify the effectiveness of sterilization processes.
- **Documentation:** Proper documentation of processes, including sterilization parameters, lot numbers, and expiration dates, is crucial for quality assurance.



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Sterile Spaces (Cont'd)

Adherence to industry standards and guidelines, such as those provided by organizations like the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Disease Control and Prevention (CDC), is essential to ensure the proper design and maintenance of a sterile core space.

The main aspects are:

CLEAN STERILE CORE

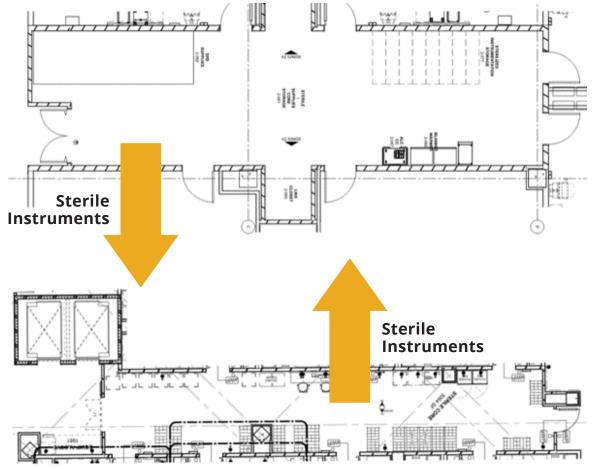
- The clean sterile core refers to a designated area within a healthcare facility where sterile instruments and supplies are prepared and organized for surgical procedures.
- This area must adhere to strict cleanliness and sterilization standards to ensure the integrity of the instruments and supplies.

OPTIMUM LOCATION

- The clean sterile core should be strategically located within the hospital to facilitate quick and efficient access to operating rooms.
- Proximity to the operating rooms minimizes the transportation time of sterile items, reducing the risk of contamination.

CASE CART VS. ASSEMBLY

- Case carts and assemblies both refer to the organized arrangement of surgical instruments and supplies needed for a specific surgical procedure.
- A case cart typically consists of a mobile cart loaded with pre-sterilized instruments and supplies for a specific surgery.
- Assembly may involve preparing the necessary items in a dedicated clean area, which can then be transported to the operating room.



Clean "Sterile" Core Immediately adjacent to OR



Sterile Spaces (Cont'd)

CONSUMABLES (IMMEDIATE NEED SURGICAL SUPPLIES)

- Consumables refer to disposable items used during surgical procedures, such as gauze, drapes, and gloves.
- The clean sterile core must ensure an adequate and timely supply of consumables to meet the immediate needs of surgical teams.

INSTRUMENTATION

- Instrumentation includes surgical tools and equipment required for specific procedures.
- Proper cleaning, sterilization, and organization of instruments are essential in the clean sterile core to prevent infection and ensure surgical success.

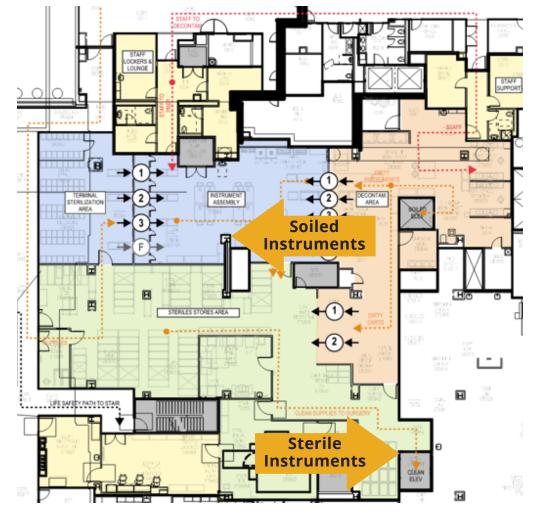
EQUIPMENT

- Equipment in this context may refer to sterilization equipment, such as autoclaves, used to ensure that instruments are free from pathogens.
- Regular maintenance and validation of sterilization equipment are crucial for the effectiveness of the sterile processing area.

CONNECTION TO SPD (STERILE PROCESSING DEPARTMENT)

- The clean sterile core is often part of or closely connected to the Sterile Processing Department (SPD).
- SPD is responsible for the overall sterilization and preparation of surgical instruments, ensuring they are ready for use in the clean sterile core and subsequently in the operating rooms.

The clean sterile core is a critical component of the surgical workflow, ensuring that instruments and supplies are prepared, organized, and maintained in a sterile environment to support successful surgical procedures. The connection to SPD is integral for the overall coordination of sterilization processes.



Sterile Processing Department Vertically adjacent (above/below) OR Elevator down from OR brings soiled instruments to decontam. Elevator up to OR takes sterile instruments to surgery.



Design Considerations

UNRESTRICTED AREAS

Unrestricted areas are the initial entry points in the sterile processing department where general activities occur without stringent controls. These areas are typically open to all staff and visitors.

- No special attire required.
- Free movement of personnel.
- Activities include administrative tasks, receiving of contaminated instruments, and storage of non-sterile supplies.

Typical Activities:

- Reception of soiled instruments from clinical areas.
- Initial sorting and documentation.
- General office work and administrative tasks.

SEMI-RESTRICTED AREAS

Semi-restricted areas act as transitional zones between unrestricted and restricted areas. Access is controlled, and specific attire is required to minimize contamination risks.

- Staff must wear surgical scrubs, caps, and shoe covers.
- · Limited access to authorized personnel only.
- Physical barriers or signage usually mark the boundary.

Typical Activities:

- Decontamination and cleaning of instruments.
- Preparation and assembly of instrument trays.
- Packaging of instruments for sterilization.

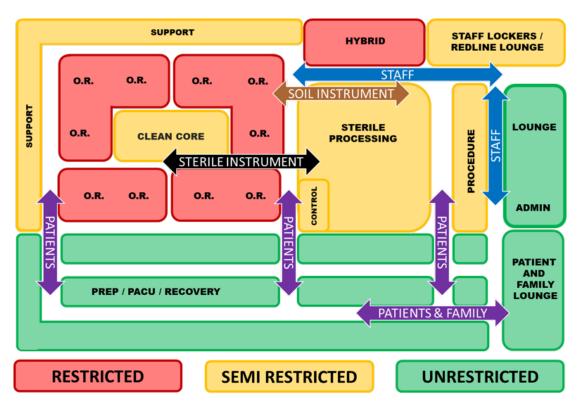
RESTRICTED AREAS

Restricted areas are the most controlled environments within the sterile processing department. These zones are critical for maintaining sterility and require strict adherence to protocols.

- Staff must wear full protective attire, including surgical scrubs, caps, masks, and shoe covers.
- Highly controlled access, often requiring key cards or other forms of authorization.
- Strict environmental controls (e.g., air filtration, temperature, and humidity).

Typical Activities:

- Sterilization of instruments using autoclaves or other sterilization methods.
- Quality control checks to ensure instruments are sterile.
- Storage of sterile instruments until they are needed for use.



Design Considerations

FLOW OF INSTRUMENTS & PERSONNEL

Unrestricted to Semi-Restricted:

- Instruments move from the receiving area (unrestricted) to the decontamination area (semi-restricted).
- Staff don appropriate attire before entering the semi-restricted area.

Semi-Restricted to Restricted:

- Cleaned and prepared instruments move from the preparation area (semi-restricted) to the sterilization area (restricted).
- Staff ensure all protocols are followed to maintain sterility.

Restricted to Use Areas:

- Sterilized instruments are stored in the restricted area until they are needed.
- Instruments are then transported to operating rooms or other clinical areas, maintaining sterility during transport.

In summary, the flow associated with sterile processing in healthcare facilities involves transitioning instruments and personnel through increasingly controlled environments to ensure that all instruments are appropriately sterilized and safe for patient use. Each area has specific protocols and attire requirements to maintain the integrity and sterility of medical instruments.

FLOW OF PATIENTS AND/OR VISITORS

The flow of patients through areas with different levels of restriction in a healthcare facility, particularly around surgical and sterile processing areas, is carefully managed to maintain sterility and minimize infection risks. Here's how patients move through unrestricted, semi-restricted, and restricted areas:

Unrestricted Areas

- Patients arrive and check-in at reception or administrative offices.
- They wait in waiting rooms until called for preoperative procedures.

Semi-Restricted Areas

- Patients are transported from unrestricted areas to pre-operative holding areas, which are semi-restricted.
- Here, patients change into surgical gowns and are prepped for surgery (e.g., IV insertion, vital signs monitoring).

• Patients might wait in the pre-operative holding area until the operating room is ready.

Restricted Areas

- Patients are moved from the semi-restricted pre-operative holding area to the restricted operating room.
- Transport must ensure minimal exposure to contamination (e.g., through sterile corridors or using covered transport mechanisms).
- After surgery, patients are moved to a postanaesthesia care unit (PACU), which can be semi-restricted or restricted depending on the facility's design.

POST-SURGERY FLOW

1. Post-Anaesthesia Care Unit (PACU):

- After surgery, patients are moved to the PACU, where they recover from anaesthesia.
- This area might have semi-restricted access, requiring staff to wear appropriate attire and follow infection control protocols.
- Patients are monitored closely until they are stable enough to move.

2. Transfer to General Wards or Discharge:

- Once stable, patients are transferred from the PACU to general hospital wards (unrestricted) or discharged directly home.
- If transferred to a ward, patients move through semi-restricted areas back to unrestricted areas.
- Discharge instructions and follow-up care plans are provided in unrestricted areas.

SUMMARY OF PATIENT MOVEMENT

- Unrestricted Area: Entry, check-in, and waiting.
- Semi-Restricted Area: Pre-operative preparation and holding.
- Restricted Area: Operating room and immediate post-operative care in PACU.
- Back to Semi-Restricted/Unrestricted: Recovery monitoring and transfer to general wards or discharge.

This controlled movement of patients through different areas ensures that sterility is maintained in critical zones while providing efficient and safe care throughout their surgical journey.

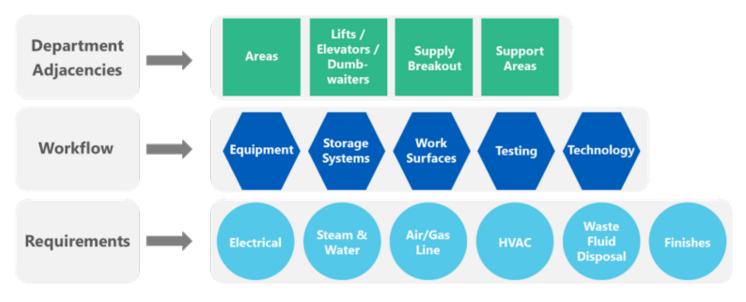


Questions and Considerations for the Ideal Future State

Sterile processing includes both central and satellite sterile processing areas. As you evaluate the needs of the sterile processing department (SPD), you will note that many of the questions that apply to the OR also apply to the SPD. The questions asked may apply to only one area or both, depending on the configuration of the unit.

The sterile processing area consists of a minimum of two separate areas: the clean area and the decontamination area. These two areas should be separated with a wall containing a doorway or a passthrough window to move instruments efficiently from the decontamination side to the clean side. In a very small facility in which a limited number of instruments are sterilized and there is only a small sterilizer such as a table top unit, the wall can be removed as long as there is at least 4 ft of separation between the sink in which the instruments are washed and the beginning of the clean side. A partial wall may also be used as the means of separation as long as it is at least 4 ft high.

The size of the area will be determined by several factors including the number of ORs, the amount of equipment to be stored, the amount of nonsurgical equipment to be reprocessed, and the use of case carts.



The design process will require answers to the following questions. Begin by making decisions about department adjacencies, then follow with workflow functionality and the requirements of support functions.



Getting to Know Your Department Adjacencies

AREAS

- Will sterile processing be centralized, will there be satellite sterile processing areas, or a combination of both?
- If satellite areas will be used, how many are needed?
 - » Note: Old standards dictated one satellite area between every two ORs. This requirement has been removed in the new standards.
 - » Determine the number of satellite areas needed after determining the amount of immediate use steam sterilization performed on each unit requesting a satellite area.
 - » The endoscopy department may also have a satellite area to be used for reprocessing endoscopy scopes.



LIFTS/ELEVATORS/ DUMB WAITERS

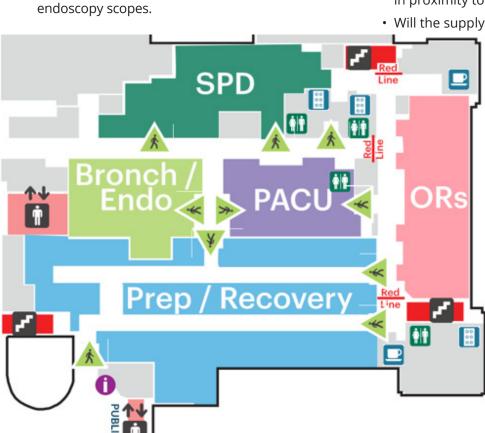
- Are lifts/ elevators/dumb waiters required?
 - » If so, they should be dedicated to either decontamination or clean; the same lift/elevators/ dumb waiters should not be used for both.

SUPPLY BREAKOUT ROOM

- Where should the supply breakout room be located in proximity to the SPD?
- Will the supply breakout room be used
 - for unpacking loaner instruments?
 - What method will be used for handling packing cartons and supplies after the cartons are emptied?

SUPPORT AREAS

- Can locker rooms and other staff support areas be shared with the surgical department?
- If not, how will scrubs be dispensed, and where will the locker room be located?
- Are staff bathrooms needed in addition to those located in the locker rooms?
- Where will SPD offices be located?
- Will there be dedicated access to the OR (corridor, elevator, dumb waiter)?
- Is a multipurpose room or classroom required, or can one be shared with another department?
- Is there room for expansion?



Getting to Know Your Workflow

Workflow

Equipment

Storage Systems Work Surfaces Testing

Technology

EQUIPMENT

Which type or combination of types of sterilizer will be used (eg, steam, ethylene oxide, hydrogen peroxide plasma, ozone)?

- Is a steam source required for the sterilizer, or will the sterilizer have a steam generator?
- What is the required sterilizer capacity, and how many will there be of each size sterilizer?
- What sterilizer associated equipment (eg, carts, accessories) is required?
- Is a sterilizer equipment room required?
- Are there special ventilation requirements (eg, ethylene oxide)?
- What are the utility requirements?
- What are the recommendations for water and steam quality?
- What quantity of steam is required?

Will high-level disinfection be performed?

- Where will this occur?
- What are the utility and water quality requirements?
- Where will the monitoring equipment/supplies be stored?

Will there be a mechanical endoscope processor?

- Where will this be located?
- What are the utility and water quality requirements?
- Will there be a cart washer?
- What are the utility and water quality requirements?

Will there be a washer/sterilizer or washer/disinfector?

- Are these pass-through units, or is the entrance and exit in one room?
- Will there be a detergent management system?
- What are the utility and water quality requirements?
- Does the equipment require reverse osmosis or deionized water

Will there be a pass-through window for hand-washed instruments?

Will there be a door to allow personnel to pass back and forth from the decontamination to the clean side?

Will there be an ultrasonic device?

Will there be borescope equipment (eg, camera, light source, video monitor)?

Will there be an insulation testing device?

How many sinks are required (eg, hand washing, instrument cleaning), and where will they be placed?

How many eyewash stations are required, and where will they be placed?

Will textiles be used?

• Do the textiles have special requirements (eg, special handling, ventilation, a light table)?

STORAGE SYSTEMS

- Will fixed or mobile storage systems be used?
- Where will clean case carts be stored?
- Where will sterilized instruments and other sterile or clean supplies be stored?
- Where will supplies associated with decontamination, packaging, and sterilizing, including personal protective equipment (PPE) be stored, and how much space is required for storage?
- Where will instruments awaiting assembly (after being removed from the washer/disinfector) be stored?
- Where will reserve instruments be stored?
- Where will instruments awaiting repair be stored?
- Where will vendor trays be dropped off, picked up, and assembled?
- Where will PPE be stored, donned, and doffed in the decontamination area?
- Will medical equipment (eg, IV pumps, feeding pumps, crash carts) be disinfected and/or stored in the sterile processing area?



Getting to Know Your Workflow

Workflow

Equipment

Storage Systems

Testing Surfaces

Work

Technology

WORK SURFACES

- Will fixed or mobile work surfaces be used?
- How much work surface is required?

TESTING

- · Where will chemical and biological testing be performed?
- Where will chemical and biological testing supplies be stored?
- How much work surface is required?
- · How many incubators are needed?
- Where will documentation of testing be stored?

TECHNOLOGY REQUIREMENTS

- · What equipment is required (eg, computers, integrated alarms, tracking systems, printers)?
- What are the documentation requirements



Getting to Know Your Requirements

Requirements

Electrical

team & Water

Air/Gas

Line

HVAC

Waste Fluid Disposal

Finishes

ELECTRICAL REQUIREMENTS

What quantity and type of electrical outlets are needed?

- Where will equipment be located?
- Will equipment require wiring or outlets?
- What is the amperage requirement of equipment?
- What is the allowable amperage per electrical panel?
- How will the electrical plugs on the wall or boom be organized?

What medical equipment requires special electrical considerations (eg, 220 volts, unique safety plug)?

Where will emergency outlets and non-emergency outlets be located?

Is a universal power source (UPS) backup needed for computer-based medical equipment?

- Does new equipment have battery backup capability?
- What new equipment requires UPS?
- What are the UPS requirements for mission-critical equipment (eg, washer/disinfector and sterilizers)?
 - » Is full-room UPS needed?
 - » Is equipment-only UPS needed?
- Is special lighting needed for instrument inspection?
- Do some areas need enhanced lighting?

STEAM AND WATER REQUIREMENTS

- For washer/disinfectors, steam sterilizers, ultrasonic cleaners, and other high-level disinfection equipment, what are the manufacturers' recommendations/ requirements for:
- water and drainage capacity?
- reverse osmosis/deionizing?
- water quality?
- need for a water softener or other pre-treatment?

Does any equipment require a dedicated water supply?

How will steam be generated?

- Is one or more steam generators required to provide steam for all steam sterilizers in the SPD and OR?
- What type of piping will be used from the steam generator to the sterilizer?
 - » If using stainless steel pipe for steam, it will be considered sterile steam.
 - » If using black pipe for steam, it will be considered "dirty" steam.
- Will sterilizers have an internal steam generator?

Will spray guns be used on the decontamination sinks?Is there enough water pressure for the spray guns

AIR/GAS LINE REQUIREMENTS

What equipment requires air/gas ports?

How many air/gas ports are required?

What needs to be delivered through the ports (eg, instrument air, nitrogen, vacuum)?

What are the pressure requirements of the air system?

HVAC REQUIREMENTS

Are you meeting the heating, ventilation, and air conditioning requirements as defined by ASHRAE, FGI, and AORN?



Getting to Know Your Requirements

Requirements

Electrical

Steam & Water

Air/Gas Line нуас

Waste

Fluid

Disposal

Finishes

WASTE REQUIREMENTS/FLUID DISPOSAL

Where will equipment be located, and what equipment requires connections to the waste system?

What method will be used for handling solid waste/ garbage from the OR?

Is a waste holding area required?

Will fluids be disposed of in the SPD or in the OR?

Will fluids be disposed of using a solidification agent?

Will fluids be dumped into the sewer system (using a clinical rim flushing device [ie, a hopper])?

Will fluids be disposed of using an integrated fluid waste management system?

FINISHES

Are all the chosen surfaces (eg, floors, walls, ceilings, cabinets):

- durable, smooth, and cleanable?
- able to withstand cleaning chemicals?

Are floors designed to have either no seams or sealed seams and a cove base?

Is the chosen flooring:

- durable enough to handle movement of heavy equipment?
- easy to clean? a slip-proof surface?

Are the walls designed to be smooth with no seams or with sealed seams?

• Will wall protectors be used to decrease the potential for the wall being punctured by carts and other equipment?

Do the chosen cabinets have a smooth surface that is made of laminate, stainless steel, or glass? Absorbent materials, such as exposed wood, should not be used.

Will ceilings be smooth and monolithic or have dropin ceiling tiles?

Are the doors designed to be:

- constructed from durable material that resists damage from impacts with carts and back tables? free of thresholds?
- easy to open, following the one-way directional workflow?



Infection Prevention and Control

In the context of sterile processing, infection prevention and control measures are crucial to maintaining a sterile environment and ensuring the safety of patients and healthcare workers. Sterile processing is a critical component of healthcare facilities where medical instruments and equipment are cleaned, disinfected, and sterilized to prevent the transmission of infections. Here are some key infection prevention and control measures in relation to sterile processing:

Standard Precautions

Adherence to standard precautions is essential in all healthcare settings. This includes the use of personal protective equipment (PPE) such as gloves, gowns, masks, and eye protection to minimize exposure to blood, body fluids, and other potentially infectious materials.

Hand Hygiene

Proper hand hygiene is crucial for preventing the spread of infections. Sterile processing personnel must follow strict handwashing protocols before and after handling instruments, as well as after removing gloves.

Cleaning and Decontamination

Thorough cleaning and decontamination of medical instruments and equipment are essential steps in the sterile processing workflow. This involves the removal of organic material, debris, and contaminants before proceeding to the sterilization process.

Sterilization

Sterilization is a critical step in the process of eliminating all forms of microbial life from instruments and equipment. Common sterilization methods include steam sterilization, ethylene oxide gas sterilization, and hydrogen peroxide gas plasma sterilization.

Validation and Monitoring

Regular validation and monitoring of sterilization processes are essential to ensure their effectiveness. This includes routine testing of equipment, such as autoclaves, to verify that they are consistently achieving proper sterilization.

Environmental Controls

Maintaining a clean and controlled environment in sterile processing areas is crucial. This involves proper ventilation, air filtration, and temperature controls to minimize the risk of microbial contamination.

Education and Training

Ongoing education and training programs for sterile processing personnel are essential to ensure that they are knowledgeable about the latest guidelines and best practices in infection prevention and control.

Documentation and Recordkeeping

Accurate and detailed documentation of all sterile processing activities, including cleaning, disinfection, and sterilization processes, is important for accountability and quality assurance.

Quality Assurance and Audits

Regular audits and quality assurance programs help identify areas for improvement and ensure compliance with infection control protocols.

Personal Responsibility

Healthcare workers involved in sterile processing must take personal responsibility for their actions and adhere to established protocols. This includes reporting any breaches in infection prevention measures and actively participating in continuous improvement efforts.

By implementing these infection prevention and control measures, healthcare facilities can minimize the risk of infections associated with medical procedures and contribute to overall patient safety.





Outsourcing Sterile Processing

Outsourcing sterile processing in hospitals involves contracting external service providers to handle the cleaning, disinfection, and sterilization of medical instruments and equipment. This can be a strategic decision for hospitals to ensure efficient and costeffective management of sterile processing while maintaining compliance with regulatory standards. Below is a detailed explanation of how hospitals can organize outsourced sterile processing:

Assessment of Sterile Processing Needs

- Identify the volume and types of medical instruments and equipment that require sterile processing.
- Evaluate current in-house capabilities and limitations in terms of staffing, equipment, and infrastructure.
- Determine the specific standards and regulations that need to be adhered to (e.g., guidelines from organizations like the Centers for Disease Control and Prevention, Association for the Advancement of Medical Instrumentation, and regulatory bodies).

Define Scope and Requirements

- Clearly define the scope of sterile processing services needed, including the types of instruments, frequency, and turnaround time.
- Establish specific requirements for cleaning, disinfection, and sterilization processes to meet industry standards and regulations.

Identify Potential Service Providers

- Conduct thorough research to identify reputable sterile processing service providers.
- Consider factors such as experience, certifications, compliance with regulations, reputation, and references from other healthcare facilities.
- Evaluate the service provider's capacity to handle the hospital's volume of instruments.

Request for Proposals (RFP)

- Develop a detailed Request for Proposals (RFP) outlining the hospital's requirements, expectations, and evaluation criteria.
- Distribute the RFP to potential service providers and allow them to submit proposals.
- Evaluate proposals based on factors such as cost, quality assurance processes, technology, and compliance with regulatory standards.

Validation and Monitoring

• Regular validation and monitoring of sterilization processes are essential to ensure their effectiveness. This includes routine testing of equipment, such as autoclaves, to verify that they are consistently achieving proper sterilization.

Environmental Controls

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Outsourcing (Cont'd)

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 Accurate and detailed documentation of all sterile processing activities, including cleaning, disinfection, and sterilization processes, is important for accountability and quality assurance.

Quality Assurance and Audits

• Regular audits and quality assurance programs help identify areas for improvement and ensure compliance with infection control protocols.

Personal Responsibility

 Healthcare workers involved in sterile processing must take personal responsibility for their actions and adhere to established protocols. This includes reporting any breaches in infection prevention measures and actively participating in continuous improvement efforts.

By implementing these infection prevention and control measures, healthcare facilities can minimize the risk of infections associated with medical procedures and contribute to overall patient safety

Request for Proposals (RFP)

- Develop a detailed Request for Proposals (RFP) outlining the hospital's requirements, expectations, and evaluation criteria.
- Distribute the RFP to potential service providers and allow them to submit proposals.
- Evaluate proposals based on factors such as cost, quality assurance processes, technology, and compliance with regulatory standards.

Validation and Monitoring

• Regular validation and monitoring of sterilization processes are essential to ensure their effectiveness. This includes routine testing of equipment, such as autoclaves, to verify that they are consistently achieving proper sterilization.

Environmental Controls

• Maintaining a clean and controlled environment in sterile processing areas is crucial. This involves proper ventilation, air filtration, and temperature controls to minimize the risk of microbial contamination.



Outsourced Sterile Processing Workflow



Disposables / Reusables

Sustainability practices in hospitals, including the usage of **disposables**, are gaining attention globally. However, specific guidelines and regulations may vary. Here are some general principles and guidance that are relevant:

Regulations and Guidelines

- The Environmental Protection Agency (EPA) in the United States provides guidelines and resources related to healthcare sustainability. Hospitals may need to comply with federal, state, and local regulations regarding waste management and environmental impact.
- The Healthcare Plastics Recycling Council (HPRC) is a resource that provides guidance on sustainable practices for healthcare plastics.

Green Building Standards

• Some hospitals may follow green building standards, such as LEED (Leadership in Energy and Environmental Design), which can encompass sustainable practices in construction, operation, and waste management.

Waste Reduction and Recycling

 Hospitals can implement waste reduction and recycling programs to minimize the environmental impact of disposables. This may include recycling plastics, paper, and other materials commonly used in healthcare settings.

Single-Use Device Reprocessing

 Some hospitals explore the possibility of reprocessing and reusing certain single-use medical devices that are designed for such purposes. Reprocessing can reduce waste and save costs.

Sustainable Procurement

• Hospitals can adopt sustainable procurement practices by choosing products with lower environmental impact. This includes considering the life cycle of products, their recyclability, and the use of environmentally friendly materials.

Education and Training

• Healthcare professionals can be educated about the environmental impact of disposables and trained to use resources more efficiently. This can contribute to a culture of sustainability within healthcare facilities.

Collaboration and Certification

• Hospitals may collaborate with organizations focused on healthcare sustainability. Certification programs, such as Practice Greenhealth, offer recognition for healthcare facilities that demonstrate a commitment to environmental stewardship.

Monitoring and Reporting

• Regular monitoring and reporting of resource usage and waste generation can help hospitals track their progress and identify areas for improvement in sustainability practices.

It's important to check with relevant authorities, industry organizations, and hospital management for the most up-to-date information and specific guidelines in your region. Additionally, hospital policies and practices may vary, so it's advisable to contact individual healthcare facilities for details on their sustainability initiatives and guidelines regarding the usage of disposables.



Sustainability

Various organizations and agencies provide guidance on sustainability in the usage of <u>reusables</u> in hospitals in the USA. Here are some general sources of guidance:

Practice Greenhealth: Practice Greenhealth is a leading organization that provides resources and support for sustainability in healthcare settings. They offer tools, webinars, and best practices for implementing environmentally friendly practices, including the use of reusables.

Healthier Hospitals Initiative (HHI): HHI is a collaborative initiative of major health systems across the USA. It focuses on promoting sustainability in the healthcare sector. HHI provides guidance on reducing waste, conserving energy, and adopting environmentally preferable purchasing practices, including the use of reusable materials.

U.S. Environmental Protection Agency (EPA): The EPA offers resources and tools to help healthcare facilities implement sustainable practices. Their "WasteWise" program, for example, provides guidance on waste reduction and recycling, which can include strategies for using reusables.

Centers for Disease Control and Prevention (CDC):

While the CDC primarily focuses on public health, it may provide guidelines or recommendations related to the use of reusables in healthcare settings, especially during public health emergencies. **American Hospital Association (AHA):** The AHA may provide information and resources related to sustainability practices in hospitals, including guidance on the use of reusables.

Local and State Health Departments: State and local health departments may also provide guidance on sustainable practices for healthcare facilities. They may have regulations or recommendations regarding the use of reusables.

Professional Associations and Networks: Various professional associations related to healthcare, such as the American Nurses Association (ANA) or the Association for Healthcare Resource & Materials Management (AHRMM), may offer guidance or resources on sustainability practices, including the use of reusables.

For the most up-to-date and specific guidance, it is advisable to check the websites of these organizations or contact them directly. Healthcare facilities may also collaborate with sustainability experts or consultants to tailor strategies to their specific needs and regulations.

