MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

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5.20: UMH HEALTHCARE INSTRUMENT PROCESSING REQUIREMENTS

GENERAL

This guideline applies to new construction and renovation of spaces used for the disinfection, cleaning, processing of reusable medical devices, as well as the staging and storage of reusable and disposable medical devices, within University of Michigan Health (UMH) inpatient and outpatient facilities, owned or leased.

The information expressed herein is meant to standardize the design and performance of sterile processing room types across the UMH campuses and is based on close coordination with the UMH Systems Sterilization Group, UMH High Level Disinfection (HLD) System Group, UMH Hospital Maintenance Sterilizer Group, UMH Safety Management Services (SMS), UMH Infection Prevention and Epidemiology Department (IPE), UMH Operating Rooms and UMH Facilities Planning & Development (FPD), along with industry-wide best practices. Where the information in this guideline exceeds that of regulating healthcare codes, the Architect/ Engineer (A/E) shall nevertheless utilize the information expressed herein. Where the information in this guideline would serve to conflict or be in direct violation of regulating healthcare codes, the A/E shall bring this to the attention of the University Project Manager and FPD. At no time shall governing healthcare codes be violated.

All projects involving sterile processing shall involve Facilities, Planning and Development (FPD), UMH Supply Chain/ Materials Management, OR Leadership, UMH Accreditation and Regulatory, ACS Central Sterile Processing, UMH Maintenance Sterilizer Group and the UMH Infection Prevention and Epidemiology (IPE) Department in the determination of project requirements and equipment selections.

Please refer to SBA 5.16 "MM Requirements for Critical Pressure Sensitive Rooms" for information on room construction detailing and other requirement where air pressure is critical.

QUALITY CONTROL/ COMPLIANCE

Governing Codes:

- MICHIGAN HEALTH FACILITIES ENGINEERING SECTION (HFES) DESIGN CODE, INCORPORATING FACILITY GUIDELINES INSTITUTE (FGI)- *GUIDELINES FOR DESIGN AND CONSTRUCTION OF HOSPITALS*, *2018* AND *GUIDELINES FOR DESIGN AND CONSTRUCTION OF OUTPATIENT CLINICS, 2018*
- ASHRAE STANDARD 170- 2017- *VENTILATION OF HEALTH CARE FACILITIES*
- NFPA 99- *HEALTHCARE FACILITIES*
- AAMI ST79- *COMPREHENSIVE GUIDE TO STEAM STERILIZATION AND STERILITY ASSURANCE IN HEALTH CARE FACILITIES, 2017 along with 2020 AMENDMENTS*
- AAMI ST91- *FLEXIBLE AND SEMI-RIGID ENDOSCOPE PROCESSING IN HEALTH CARE FACILITIES, 2021*
- AAMI ST108 (replaced TIR34): W*ATER FOR THE PROCESSING OF MEDICAL DEVICES, 2023*

UMH Policy (Only available internal to UMH, request copy thru FPD):

- UMH Infection Prevention for Handling, Transport and Storage of Soiled/Contaminated Devices, Items, and Supplies Policy
- UMH Infection Prevention Handling, Storage, and Monitoring of Clean/Disinfected/Sterile Supplies
- Central Sterile Processing Department & Central Endoscope Reprocessing Department SharePoint Site

PROCESS

In general, UMH prefers a centralized approach to sterile processing. Processing of reusable medical devices at UMH can take one of two paths, Sterilization or High Level Disinfection (HLD), depending on the device's Instructions For Use (IFU) and how it is to be used clinically.

Programming on projects should anticipate the following sterile processing space requirements:

1. Staging of dirty medical devices: Staging of dirty medical devices is decentralized and needs to be accommodated at the clinic level. All staging of dirty medical devices should be within site specific Soiled Holding rooms or Soiled Workrooms. Occasionally requires an initial processing of the dirty instrument at the clinic level (i.e. spray and send) for transfer to a centralized CSPD for further processing.
2. Processing of medical devices: The use of sterilization or High-Level Disinfection (HLD), via manual or automated means, to clean devices suitable for patient care. Typically centralized as part of a CSPD, in conjunction with decontamination.
3. Staging and storage of clean medical devices: Staging of clean medical devices is typically decentralized and needs to be accommodated at the clinic level, however some staging of clean devices may be accommodated within a centralized CSPD, if present. All storage of clean medical devices should be within site specific Clean Holding rooms, Clean Workroom, or Sterile Storage rooms. All clean endoscopes should be stored within a dedicated endoscope hanging storage cabinet, ideally located within the Clean Holding/ Workroom.

DEFINITIONS

IFU: Instructions For Use. Published by equipment manufacturers to provide guidance on use and care. Written recommendations developed, validated, and provided by the manufacturer of a device that provide instructions for operation and safe and effective processing.

Soiled Holding: This location is used exclusively for temporary storage of soiled materials and/or supplies prior to their removal from the unit. An area where soiled medical devices are held, in separate, covered containers. Disposal of fluids are not allowed in a Soiled Holding and instead should be performed in a Soiled Workroom. See State of MI Healthcare code for definition and requirements. At a minimum, this room shall contain the following:

- Hand-washing station or hand sanitation station
- Space for separate covered containers for waste and soiled linen

Allowable functions to be considered:

- Linen holding
- Safe patient handling laundry

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- Waste (landfill waste bin, pharmaceutical waste bin, controlled substance waste bin, regulated medical waste bin, trace hazardous drug waste, battery waste bin and empty glass waste bin) holding. Review special waste requirements with clinic.
- Personal Protection Equipment (PPE) storage
- Spill Kit storage
- Enzymatic spray/ disinfectant wipe storage
- Signage for biohazard storage
- Soiled medical device (including scope) holding

Soiled Workroom: Soiled items may be handled in a soiled workroom to prepare them for subsequent cleaning, disposal, or reuse (e.g., emptying and rinsing bedpans or emesis basins, emptying or solidifying suction canisters, rinsing and gross cleaning of medical instruments). Also, this room provides temporary storage for soiled items prior to their removal from the unit. At a minimum, this room shall contain the following:

- Hand-washing station
- Work counter
- Space for separate covered containers for waste and soiled linen
- Emergency eyewash may be required, confirm with UMH Safety Management
- Flushing-rim sink w/ splash guard
- All Soiled Holding functions

Clean Workroom: Where the room is used for preparing patient care items, it shall contain the following:

- Work counter
- Hand-washing station
- Storage facilities for clean and sterile supplies

Clean Supply Room: A room used only for storage and holding as part of a system for distribution of clean supplies. Does not require a work counter or a hand-washing station.

Sterile Storage: An area where clean instruments are staged post sterilization/ disinfection, ready for clinical use. See State of MI Healthcare code for definition and requirements.

Deliveries and Breakdown Room: An area where medical supplies are delivered in cartons and require unpacking, inspecting, logging, and distribution.

Sterile Delivery and Unpacking: An area at Clinical Point-of-Use site where the CSPD Sterile Travel Carts are delivered; Travel Carts are unpacked, and Sterile Items stored on wire racks in the Sterile Supply room. Case Carts have the wheels wiped down and moved into Sterile Supply Staging area for use in the OR/Procedure Room.

Decontamination: The use of physical or chemical means to remove or destroy pathogens on surfaces. A required precursor to effective sterilization or HLD.

Preparation and Packaging: A clean workroom used for the preparation and packaging of clean and sterile instruments.

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Sterilization: A validated process used to render a product free from viable microorganisms. Typically uses a sterilizer, autoclave, or ETO.

High Level Disinfection (HLD): Process used for reprocessing various types of scopes that kills all microbial pathogens but not necessarily high numbers of bacterial spores. An alternative to sterilization as determined by classification. Examples of chemicals used includes glutaraldehyde, OPA or hydrogen peroxide. Can be by manual or automated with the use of Automated Endoscope Reprocessor (AERs), Trophons or TEE processors. Can be standalone, dedicated HLD or integrated with sterilization within a separate room at the main CSPD Facility. *Note: There is a round-trip travel time limitation with the HLD Reprocessing of Medical Instruments, consult with UMH CSPD HLD Department. The travel time must be considered when determining location of HLD CSPD point-of-use location.*

Central Sterile Processing Department (CSPD): A group of rooms dedicated to high-volume, high-level disinfection (HLD) and/ or sterilization of medical devices, incorporating physical separation between clean and dirty processes. Typically, a centralized medical device processing function serving a multitude of clinics/ departments.

FGI 2018 requires that these facilities follow two separate Design Guidelines paths, either FGI 2018 Design Guidelines for Inpatient (Hospitals) or FGI 2018 Design Guidelines for Outpatient Clinics. The core medial equipment's of the two-room reprocessing support rooms and functions is the same for Hospitals and Clinics except they deviate in allowed shared support staff rooms and functions.

Consists of the following distinct, separate room types:

Inpatient Hospitals: (Contained behind Semi-Restricted Area)

- CSPD Support areas:
  - Locker Rooms and Offices
  - Delivery and Break Down
- Decontamination (Instrument Reprocessing & HLD Reprocessing)
- Sterile Preparation and Packaging
  - General medical instruments and HLD endoscopes will be processed in separate areas.
  - Sterilization Preparation and Packaging
    - General Medical Instruments
      - HLD endoscopes will be processed in separate area.
    - Sterilization Area
      - Sterilizer Loading/ Unloading
      - Sterilizer Equipment Room (Optional, Dependent on Selected Equipment)
- Sterile Storage
- Case Cart Staging/ Distribution

Outpatient Clinics:

- CSPD Support areas: (Shared with Business & Medical areas)
  - Locker Rooms, Break Room, Offices
  - Delivery and Break Down
- Contained behind Semi-Restricted Area:
  - Decontamination (Instrument Reprocessing & HLD Reprocessing)

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- Sterile Preparation and Packaging
  - General Medical Instruments
    - HLD Endoscopes will be processed in separate area.
  - Sterilization Area
    - Sterilizer Loading/ Unloading
    - Sterilizer Equipment Room (Optional, Dependent on Selected Equipment)
- Sterile Storage
- Case Cart Staging/ Distribution

ROOM TYPE REQUIREMENTS

General

AE shall design space for unidirectional workflow of decontamination to clean to sterile storage. Workflow shall not require that clean medical devices pass through decontamination.

Soiled Workrooms and Soiled Holding rooms shall be separate from and have no direct connection with either Clean Workrooms or Clean Supply rooms.

Soiled Holding/ Workrooms are NOT used for medical device decontamination. Soiled Holding/ Workrooms can be used for dirty instrument staging, as defined above.

Medical device processing spaces shall be restricted to authorized personnel by using access control (card readers) at all doors into the space. In addition, provide additional access control to restrict access to the Sterilizer Loading/ Unloading area.

All utilities not directly serving the CSPD should not be routed over the CSPD area. Where unavoidable, AE should consider the use of a mezzanine structure above CSPD to allow maintenance access if ceiling cavity permits.

Healthcare code allows single room CSPD designs when use is limited to a table-top or similar sized sterilizer. **UMH does not allow the use of single room sterile processing facility of medical devices and instrument**. Single room HLD is allowable, as long as a unidirectional flow of dirty to clean is maintained.

Refer to “Table 1: UMH CSPD Minimal Areas Summary Requirements” and Example Floor Plan SK-01 & 02. Note that minimum space and equipment requirements were based on a CSPD supporting (6) six Operating Rooms and include some equipment redundancy (i.e. N+1 sterilizers, etc.).

Note that these current minimum standards reflect a HLD sharing space with CSPD supporting a maximum of 6 OR’s. For CSPD applications supporting more than 6 OR’s, UMH requires a centralized, standalone HLD (i.e. Centralized Endoscope Reprocessing Department (CERD)) independent of CSPD.

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TABLE 1: UMH CSPD MINIMAL AREAS SUMMARY REQUIREMENTS

Access Restrictions	Minimum Room Size (Clear Square Footage) Actual size determined by Equipment Plan	Min. Room Ceiling Height (ft)	Floors Monolithic	Base	Walls
Vendor Deliveries & Break Down	375 sq. ft. min. clear	10'-0"	Yes	Integral	FRP
Decontamination Secure Airlock Vestibule with restricted access control Hallway with direct access to Janitors Closet, Staff Toilet, Air Compressor/ Water Treatment Rooms	175 sq. ft. min. clear Janitors Closet 80 sq. ft clear. Staff Toilet 100 sq. ft clear. Air Compressor/ Water Treatment Room 180 sf. ft clear	8'-6" to 10'-0"	Yes	Integral	FRP
Decontamination Room	2,200 sq. ft. min. Equipment layout and maintenance clearances, circulation clearances, dirty travel/case carts staging will dictate room size. Note 1.	10'-0"	Yes	Integral	FRP
Decontamination Storage Room	200 sq. ft. min. Storage Racks, fire-rated metal cabinet for HLD Chemicals, an ATP Fridge. Require Storage will dictate size.	9'-0"	Yes	Applied	FRP
Cart Washer w/ Drying Cart Area	300 sq. ft. min. Cart Volume thruput may require additional space on Drying side cart washer	10'-0"	Yes	Integral	FRP
HLD Decontamination Area Open to Main Instrument Decontamination room	850 sq. ft. min. Includes area for ARE Hook-ups, Tee Probe, Trophon w Printer, Conductivity Test Table access to 2 Pass Thru AERS and 2 pass-thru windows (1) for Clean Scopes & (1) for Failed Dirty Returns.	10'-0"	Yes	Integral	FRP
Clean Scopes Room	500 sq. ft min clear Dependent upon equipment. Room sized for 2 PASS-THRU AERs. If additional AER capacity is required, then separate significantly larger HLD Area would be required.	10'-0"	Yes	Integral	FRP

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Sterile Preparation and Assembly Includes space for Sterilizes and Cart Cooling	1940 sq. ft min clear	10'-0"	Yes	Integral	FRP
Steam Sterilizers	230 sq. ft min clear Minium size to maintain 3 Steam Sterilizer w/ maintenance access from corridor or non-sterile area	10'-0"	Exp Conc Sealed	Applied	Gypsum
Sterile Storage/ Circulation Includes space for Case & Travel Cart Staging Storage racks for Sterilize Supplies	1076 sq. ft min clear Minium size to serve 6 OR Rooms. Dependent on daily Sterile Supply Demand, review with CSPD Manager.	10'-0"	Yes	Integral	FRP
Main CSPD Offices CSPD Supervisor Office CPSD Manager Office Teams Work Room Conference Room/ Training	150 sq. ft 120 sq. ft 180 sq. ft (3 staff) 245 sq. ft	8'-6"	Yes	Applied	FRP
HLD CSPD Offices CSPD Supervisor Office	120 sq. ft. (2 Staff)	8'-6"	Yes	Applied	FRP
Corridor Circulation Hospital – Restricted Access only used for CSPD Functions. Clinic – Shared with other Clinical areas and should be restricted	Area dependent on meeting Code require egress from CSPD Areas to access an exit access corridor. Include space for Staff Scrub Dispensing Machine and PPE for visiting Staff and Vendors	10'-0"	Yes	Integral	FRP

References:

- Minimum Design Standards for Healthcare in Michigan, FGI 2018
- ASHRAE/ASHE Standard 170- Ventilation of Health Care Facilities

Note:

1. Allow extra space to accommodate Dirty Elevator when CSPD Program requires.
2. Allow extra space to accommodate Clean Elevator when CSPD Program requires.

Soiled Holding/ Soiled Workroom, Sterile Storage (Supply) and Breakdown Room for Receiving/ Unpacking Clean/Sterile Supplies):

Refer to State of Michigan Healthcare FGI Guidelines for requirements.

Central Sterile Processing Department (CSPD): Applies to Inpatient Hospital Facilities and Outpatient Facilities

A/E shall coordinate program needs including anticipated case volumes, staffing, medical device processing technology (current and potential future), staging requirements for cart holding and sterile storage & distribution needs. Consider need to undergo LEAN process and mockup to streamline process flow and provide a safe working environment.

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Support areas (Required to be CSPD dedicated spaces by FGI 2018 for Inpatient Hospitals):

- Locker Rooms: provide male & female locker rooms and toilets, of sufficient size for anticipated staff, with access off corridor, allowing direct access to Preparation & Packaging (*FGI 2.1-5.1.2.5).*
- Break Room: size required to meet the needs of Staff.
- Offices: Review office needs with design manager. At a minimum, provide offices for CSPD department Manager and HLD Manager, with direct access to general corridor through air lock vestibule. CSPD Manger Office requires viewing windows into sterile storage and decontamination areas.
- Training/ Conference Space: Review with design manager means with which staff will undergo meetings and training. Typically, larger CSPD's should facilitate meetings and training outside of the CSPD environment, which can be noisy and hazardous for this function.
- Janitor's Closets: Provide (2) dedicated janitor's closet within the CSPD area, one on the dirty side and one on the clean side.
- Medical Equipment Repair Specialist: Review with design manager need for dedicated space for repair staff and parts stock/ storage. Generally, the Vendor Breakdown room will meet these requirements.
- Water Treatment Room: Provide dedicated, restricted access room for water treatment equipment serving CSPD (i.e. RO/ DO systems, filtration, backflow prevention, etc.), see Plumbing section requirements below. For Outpatient Facilities, room shall be accessible from outside the regulated medical device processing space and can share space in a mechanical room with other infrastructure equipment. For Inpatient Facilities, room shall be accessible from the Decontamination airlock and be dedicated for CSPD water treatment.
- Hazardous Chemical Storage- driven by building code and would be inside a separate room.

Support areas (Required by FGI 2018 in Outpatient Facilities, can be shared with other departments):

- Staff Locker Rooms/ Showers / Toilet areas can be shared with other Staff facilities that serve other Clinical Departments (*FGI 2.1-4.3.2.5).*
- Breakroom – Shared room with other Clinical departments.
- Toilets – shared with other Staff Toilets. Public and Patient toilets must be separate.
- Offices – Shared with other Staff Offices spaces.
- Hazardous Chemical Storage - driven by building code and would be inside a separate room but could be shared with other similar Hazardous storage rooms.
- Water Treatment Room – Shared with an available mechanical room.

Deliveries and Breakdown Room:

- A dedicated room for receiving and breakdown of packaging of received medical supplies, and Vendor Instruments on consignment.
- Provide space for wall mounted Workstation to inventory received items and printer.

- Provided table for unpacking deliveries. Table would be used to inspect medical devices unpacked prior to sterile processing and/or by Instrument Vendors to inspect medical devices on consignment.
- Provide space for linen and waste carts (1 each minimum) confirm size with CSPD Department.
- Provide space for 2 – 48" x 24" x 4 shelf wire shelving carts, and space for a 36" x 24" Outbound Package pick-up table.

Decontamination:

- Air-Lock Entrance:
  - Provide automated double-door entry, large enough for carts and medical devices being processed. Provide double-door vestibule airlock to ensure control of room negative pressure. Entrance vestibule shall incorporate space for the following:
    - PPE storage, coat hooks, gowning
    - Janitors closet for Staff behind the Redline can readily access.
    - Single Staff Toilet (no shower) for Decontamination Staff
  - For Inpatient Hospitals, access to Water Treatment Room would be off this vestibule. Decontamination Staff must have access to this room without leaving the Decontamination Secure area.
- Decontamination Room Internal Entrance Area:
  - Area is defined with Redline at core decontamination room which permits EVS to enter the decontamination room to remove/replace waste and linen bins. Provide space for hazardous (red) and standard trash receptacles.
  - Provide emergency shower/ eyewash consistent with AAMI requirements- review with Safety Management Services based on disinfectants used. Provide floor drain in immediate vicinity of emergency shower.
  - Handwash sink w/ PT, soap, and waste. Mirror is optional, verify with users.
- Direct access to Decontamination room: Building where OR's and/or Procedure rooms are located on other floors, consider the need for dedicated dirty elevator for medical device transportation. When used, consider need for air lock at elevator loading/ unloading within CSPD, as the "piston effect" of elevators has proven to be problematic in room pressure control.
- Provide adequate floor space for dirty instrument cart staging at each sink lane and additional staging area refer to floor plan rack for instrument trays, and a counter and computer workstation for logging.
- Provide back-to-back sink lanes consisting of seamless, stainless steel, powered-height-adjustable three bowl sinks. Sink bowls shall be a minimum of 16"x30"x 10" deep with externally operated drain release mechanism. Underneath of sinks should be open and exposed; cabinets enclosing the underside of the sinks are not allowed.
  - Adjacent to sinks, provide dedicated 36" long countertop for soiled holding on one end and 36" long dedicated countertop for drying on the other.
  - Laser-engraved volume measurements inside of sink bowls, all three bowls.
  - Provide see-thru Plexiglas splash guard between sink and PC Logging Workstation at input side of the sink lane.
  - Provide with domestic HW/CW flexible hose sprayers/ gooseneck faucets and water gun, RO/DI gooseneck faucet, and instrument compress air (ICA) gun.

Coordinate layout to facilitate initial washing with HW/CW, rinsing with RO/DI and drying with ICA. Provide signage at each sink indicating "Non-potable water, do not drink".
    - Provide local pressure regulators for water and Instrument compressed air.
    - Coordinate receptacle power requirements at sink lanes for PC Workstation, automated leak tester, flushing devices, magnifiers, etc.
    - Provide space for full size trash bin.
    - Provide space, power & data for dedicated computer workstation, mounted on GCX bracket with a splash guard between PC & sink.
- Provide at minimum 3 Automated washers with conveyor on each side of at each washer. Confirm with CSPD Department if the washer equipment will use conveyors. At minimum conveyor is required on prep-assembly side of washer. (*Note: Conveyors do provide a benefit in that they provide space for queuing of cleaned instruments prior to washing and space for cooling/staging of instrument baskets on prep-assembly side.*)
  When used, configure washers in the demising wall between Decontamination and Sterile Preparation & Packaging with a return pass-thru conveyor lane. All openings for equipment shall utilize a hard, airlock door system to prevent bleed-thru of pressurization. Designs that utilize plastic "fingers" or other soft passageways shall not be allowed.
    - Provide power & data connection to washers, verify with manufacturer requirements.
    - Provide non-potable HW/CW, RO/ DI, steam, instrument compressed air and exhaust connection to washers, verify with manufacturer requirements.
    - Provide a stainless-steel welded exhaust hood(s) with welded stainless steel exhaust ductwork to capture steam that escapes from steam sterilizers/ washers.
    - Provide in the demising wall a 36" wide pass-through window that is auto opening and self-closing.
    - Provide 4'-0"w x 5'-0"h pair of doors for returning mobile carts.
- Provide counter space for maintaining logs/ paperwork in an area away from the sink lanes.
- Clinical flushing-rim sinks are <u>not</u> required in the Decontamination space. UMH CSPD uses an alternate method for handling solid bio-waste.
- Provide floor drains to allow cleaning of space and for draining of decontamination equipment.
- Provide dedicated adequate space for soiled cart staging at Cart Washing Area. This space is dependent on volume of instrument travel carts and other cart types brought and used within the decontamination room. Drying area on output side of cart washer needs to be of similar size open to Sterile Storage side.
- Provide dedicated fire rated Storage Room for chemical storage, including flammable storage cabinets, if needed. Review need with Safety Management Services (SMS) based on anticipated volumes of chemicals used and design accordingly to meet Building Codes.
- Detergents Room: provide room to place detergent pumps with point of use storage. Additional detergent storage can be in a separate storage room located inside the decontamination room.
- <u>HLD Endoscope Reprocessing Area</u>:
    - Provide a HLD Endoscope Reprocessing Area as a part of CSPD.
    - Decontamination Area:

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        - Provide back-to-back 3 compartment sinks lanes as describe above.
        - Provide dedicated soaking lane with a single bowl sink with soaking tables on each side of the sink for manual cleaning and leak testing of specialized endoscopes that cannot be placed in the AER's. Provide non-potable CW & HW faucet, RO/DI faucet, and instrument compressed air gun w/ regulator. Provide signage at each sink indicating "Non-potable water, do not drink".
        - At clean end of 3 compartment sink lanes provide a shared 6 FT x 3 FT stainless steel table w/ Helmer Fridge below table with testing supplies.
    - Automated Endoscope Reprocesses (AERs). Pass through, in-wall AER's are the standard in the demising wall between HLD Decontamination and the Clean Scope Room.
        - No door is to be provided between the HLD Decontamination side and Clean Scope Room.
        - Provide two pass-through windows (26" x 30"): One for HLD Clean Instruments that cannot be placed in the AERs and the same size pass through window for failed scope instruments sent back for additional HLD cleaning. These windows need to be separated to prevent cross contamination between clean/dirty and have shelves each side (24" x 34").
        - Provide adequate working clearance around AER's for loading/ unloading.
        - Provide dedicated, wall-mounted pre-filters and mixing valves, non-potable CW & HW water and instrument air services in accordance with AER manufacturer IFU.
        - Provide exhaust, power & data connection to AER's, in accordance with AER manufacturer IFU.
    - Provide HLD Wire Supply Cart (24 x 48 x 4 shelves) for disposable cleaning accessories.
    - Provide HLD Wire Supply Cart (24 x 48 x 4 shelves) for PPE Supplies.

<u>Preparation and Packaging</u>: (Medical Instruments)

- Provide 6 medical device assembly workstations:
    - Adjustable height 6 ft x 4 ft stainless steel table w/ seamless and smooth surface construction and locking wheels.
    - Eye-level bin storage for parts needed in assembly with magnetic bar and light.
    - Storage for consumable materials needed in processing (labels, etc.).
    - CPU workstation & printer for documentation and medical device tracking.
    - Provide compressed instrument air guns w/ regulator workstations.
    - 24" x 24" (min) mobile tools cabinet w/ drawers and locking wheels.
    - 36" x 4ft stainless steel end table each end of a pair of stations.
    - Provide hospital grade power bars (min 4 duplexes).
- Provide adequate areas for cart holding and queuing and medical device containers.
- Provide storage space for test equipment, scanners and the various wrappers used.
- Provide wire storage racks for storage of cleaned instrument baskets.
- Wire storage racks for bulk materials, spare instrument parts, etc.
- Provide space for covered soiled linen disposal and general trash receptacles.
- Provide separate, dedicated handwashing sink near the entrance/ exit to the room.

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- Provide floor drains near washer-disinfectors. Provide with hinged, stainless-steel grates for periodic cleaning of drain body.
- Provide (2) LED display monitors easily viewable from workstations.
- Medical instrument repair: Provide a 12 ft long stainless-steel counter w/ base cabinet and upper cabinets.
- Provide space one free standing network printer w/ power & data.

Sterilization Area:

- Provide fully recessed and enclosed, N+1 steam sterilizers to support the intended OR's (i.e. a minimum of 3 steam sterilizers to support 6 OR's).
  - Dependent on sterilizer equipment selected, provide a separate room behind sterilizers for servicing, access of which must be from corridor not through Sterile Preparation and Packaging area. Conform with sterilizer manufacturer requirements with spacing between sterilizer and to adjacent walls/ obstructions, in order to ensure safe working conditions in servicing sterilizers.
- The sterilization area shall consist of the following:
  - Sterilizer Loading/ Unloading area.
  - Provide space for wall mounted workstation for documentation and medical device tracking integration.
  - Provide space for staging sterilizer carts prior to be processed.
  - Space for staging of atypical sterilizer process (low temp, Bowie-Dick test packs, incubators, etc.)
  - Provide staging area for carts to cool down after processing.
  - Space for dedicated cart for devices held in quarantine.
  - Provide adequate space and path to remove and replace each sterilizer.
  - Confirm number and types of sterilizers to be utilized with CSPD Manager.
  - Confirm number of HLD sterilizers required for sterilizing medical instruments that cannot withstand high heat steam sterilizer process.

Sterile Storage:

- Provide adjacent to the Sterilization Area a defined storage room. Access should be limited and controlled to prevent contamination with non-sterile items, maintain safety, accuracy, and security.
- Provide adequate space for cart holding and queuing for distribution.
- Provide workstation with printer for medical device tracking and documentation.
- When used for endoscopes, provide dedicated, HEPA-filtered endoscope drying cabinet, sized to fit scopes used.
- Provide accommodations for logging workstation with scanner on mobile cart.
- Doctors Case Card Order Station:
  - 5ft x 24" stainless steel counter, workstation w/ dual monitors, printer on cart, wall phone
  - Wall above – provide 2 LED Large Screen monitors for tracking and education.
- Clean Cart Drying area is directly accessible from Sterile storage. Drying areas needs to be placed minimum 10 ft to 12 ft from Sterile Storage racks.

Travel/ Case Cart Staging/ Distribution:

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- Size to meet peak demand staging requirements, with adequate access.

Architectural

CSPD room finishes should be cleanable, smooth, monolithic, and as joint free as possible. Materials used should be resistant to frequent use of cleaning chemicals, impervious to water and resistant to abuse.

- Walls:
  - Walls to be full height to underside of floor slab deck and/or roof deck with average height of 14 ft to accommodate 10 FT ceiling height. All walls around CSPD Main Room areas, Decontamination, Sterile Preparation and Packaging and Sterile Storage, are min 1 HR fire rated to deck.
  - Wall finish - monolithic smooth faced FRP panels with flush-tooled polyurethane sealant joints. Stainless steel wrapped columns & corner guards.
- Flooring:
  - Smooth and seamless epoxy flooring (with grit to prevent slipping- AE shall require sample of epoxy floor that shall be approved by CSPD department to ensure floor is cleanable) with integral coved base. Needs to be durable to handle repeated heavy cart loads. Provide anti-fatigue mats where prolonged standing is required (i.e. sink lanes, etc.).
- Ceilings: 10 FT Min height (new construction), existing buildings 8'-6" min.
  - Hard gypsum board suspended ceilings w/ two-part epoxy painted finish.
    - Existing buildings may require multiple access points to above ceiling existing MEP systems. In these cases, a sealed ACT tile ceiling could be utilized. Verify case for ACT with UMH FPD.
  - Recessed light fixtures with gaskets and seals.
  - Stainless steel access doors w/ gaskets strategically coordinated above clear floor access space to maintain equipment/ devices in ceiling plenum above. Coordinate above ceiling MEP systems with CSPD reprocessing equipment to provide clear working access from below.
- Doors:
  - Seamless, stainless-steel doors with view window sized per code, welded stainless steel frame and no thresholds. For single doors, provide minimum of 48" width. Provide pair of doors, 88" clear width, at all main entrances with positive latching, automatic operators, and access control. Provide automatic door operators on all doors used for cart passage, review with client. At airlock vestibule provide interlock to prevent simultaneously opening of both doors to maintain air pressure within Sterile Areas. All doorways into pressurized spaces shall have closers and automatic drop seals at floor to maintain room pressurization.
- Countertop surfaces/ shelving: Seamless stainless steel. Mobile carts under counters should be limited, provide stainless steel base cabinets w/ doors & drawers, min 6" base.
  - Mobile carts tend to promote clutter which creates cleaning issues.
- All pass-thru's (windows/doors) used in demising walls between pressurized rooms shall be seamless stainless steel. Confirm pass-thru size with users.

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The AE shall design and detail the room envelope of all pressurized medical device processing rooms to be airtight. All partition walls that form the room envelope shall be built up to the floor/ roof structure above and sealed. All penetrations of these walls shall be sealed airtight, including electrical raceways like light switches, receptacles, etc. CSPD shall conform to Special Building Area (SBA) 5.16: UMHS - REQUIREMENTS FOR CRITICAL PRESSURE SENSITIVE ROOMS. AE shall coordinate with washer/ disinfector/ sterilizer equipment manufacturers to provide adequate sealing of equipment within walls separating pressurized spaces.

HVAC

Maintaining instrument processing is critical to maintaining OR operations. The A/E of record shall provide the mechanical equipment serving CSPD's with the same level of redundancy (i.e. N+1) as the mechanical equipment serving the operating rooms (ORs) within the same facility.

See mechanical requirements under Special Building Area (SBA) 5.16: UMHS - REQUIREMENTS FOR CRITICAL PRESSURE SENSITIVE ROOMS for all instrument processing spaces.

HVAC systems shall be designed to meet requirements set forth in the table below:

TABLE 2: UMH HVAC REQUIREMENTS

Room Type	Room Air Pressure (1)	Min OA ACH	Min Total ACH	Fully Exhausted	Recirc. Air Units	Design Temperature	Design Humidity (%RH)
Support Space- Soiled Holding/ Workroom	Negative	2	10	Yes	No	NR	NR
Support Space- Clean Holding/ Workroom/ Supply	Positive	2	4	NR	NR	NR	NR
CSPD-Decontamination Room, includes HLD	Negative	2	6	Yes	No	62°F (new facilities) 69°F (existing facilities)	60% max
CSPD- Preparation & Packaging (Clean Workroom), includes HLD	Positive	2	6	NR	NR	68-73°F	60% max
CSPD- Sterilizer Equipment Access (2)	Negative	NR	10	Yes	No	NR	NR
CSPD- Sterilization Loading/ Unloading (2)	Positive	2	6	Yes	No	68-73°F	60% max
CSPD- Sterile Storage, Case Cart Staging/ Distribution	Positive	2	4	NR	NR	<75°F	60% max

References:

- ASHRAE STANDARD 170 2017- VENTILATION OF HEALTH CARE FACILITIES
- AAMI ST79- COMPREHENSIVE GUIDE TO STEAM STERILIZATION AND STERILITY ASSURANCE IN HEALTH CARE FACILITIES

Notes:

1. Room air pressure requirements noted as "positive" or "negative" shall be designed to maintain directional airflow with verification thru flutter strips or smoke trail. Room air pressure requirements noted with a room pressure differential (i.e.

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+0.01") are minimum required for compliance. AE shall design the HVAC to maintain room pressure above minimum compliance value at all doorways into room, with verification by differential pressure reading. See Special Building Area (SBA) 5.16: UMHS - REQUIREMENTS FOR CRITICAL PRESSURE SENSITIVE ROOMS.

2. If ethylene oxide (EO) sterilizers are used, AE shall design ventilation system to comply with OSHA regulations and EO sterilizer requirements, including the use of a local EO monitoring and alarm system.
3. NR= No Requirement

HLD chemicals that are heavier than air (ie glutaraldehyde) shall be provided with a low backsplash exhaust where chemical is used and stored.

Provide a wall mounted Human Machine Interface (HMI) to digitally display and alarm relevant room environmental conditions (temperature, humidity, room pressure) in CSPD Decontamination, CSPD Preparation & Packaging and CSPD Sterile Storage spaces.

Exhaust serving washers, sterilizers and other wet exhaust systems shall be all stainless steel. Exhaust connections to sterilizers and washers shall be pitched and trapped with drains to prevent accumulation of steam condensate within the ductwork.

Provide stainless steel exhaust hoods over sterilizer doors to capture steam that escapes from the sterilizer when opened. Consider the same for large, in- wall instrument washers.

Plumbing

Maintaining instrument processing is critical to maintaining OR operations. The A/E of record shall provide the plumbing equipment serving CSPD's with N+1 redundancy to allow serving of equipment without disrupting CSPD operations (i.e. redundant RO/DI pumps, redundant instrument air sources, redundant backflow preventors, etc.).

For all new construction, all water (Utility Water, Critical Water, Steam) used for medical device reprocessing shall meet the water quality requirements set forth in AAMI ST108: WATER FOR THE PROCESSING OF MEDICAL DEVICES, 2023, Table 2 (Section 6.2, page 18) as well as the manufacturer equipment requirements (washers, sterilizers, etc.). Steam feedwater shall be critical water as defined in the table. For renovations of existing instrument processing areas where the existing plumbing distribution system is not part of the project (e.g., point-of use renovations, areas served by campus power plant steam, etc.), compliance with AAMI ST108 Table 2 should be the goal, but may not be required.

All water treatment equipment required to meet instrument processing applications shall be located within a separate, restricted access mechanical room, accessible from outside of the CSPD space. Room shall be designed with finishes to accommodate a wet environment, with adequate floor drains for maintenance and to contain potential leaks. All critical parameters of water treatment, like deionizer exhaustion or low water levels in a storage tank, shall be monitored and alarmed thru the hospital's Building Management System (BMS).

Provide non-potable water services to CSPD. The AE shall centrally locate all backflow prevention devices in a dedicated mechanical room; equipment shall not be located above the ceiling of CSPD. AE shall design a dedicated, restricted access room to house this equipment, accessible from outside the regulated medical device processing space. Do not provide dedicated backflow prevention for each piece of equipment. Instead, unify and centralize these services as code allows to consolidate the quantity, space requirement and maintenance of this equipment.

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All piping, fittings and various hydronic specialties used in treated water systems (i.e. RO/ DI) shall be suitable for the application, i.e. HDPE, etc., and shall be looped to ensure continuous flow (3 to 5 fps per AAMI ST108 requirements (section 8.3.3)). See AAMI ST108, Annex F.

Compressed air needs within medical device processing rooms typically consist of a) benchtop stations for air guns used for flushing lumened devices, b) AERs and c) washers and sterilizers. Medical Air is not allowed to be used for this purpose. A separate instrument compressed air system shall be provided, sized to meet program demands, consisting of dedicated compressed air tank manifolds or, where demand dictates, an air compressor system. Provide N+1 redundancy. At a minimum, compressed air systems shall be sized to deliver 40-60 psi and meet AAMI ST79 requirements (i.e. meet the requirements for "Instrument Air" as defined by NFPA 99 2015: oil-free, minimum 0.01 micron filtration, -40°F dewpoint, free of liquids and hydrocarbons, ANSI/ ISA S-7.0.01 compliant). Confirm compressed air requirements with equipment served and client needs. Provide pressure regulators based on maximum pressure requirements of loads. AE shall consider the use of all stainless steel compressed air piping downstream of the air dryer and filters.

See design guideline 220010-H SUPPLEMENTAL PLUMBING SPECIALTIES for handwashing sink requirements.

All floor drains/ trench drains within Decontamination and Preparation & Packaging shall utilize hinged stainless-steel grates and be removable for cleaning.

AE shall not assume diversity in sizing services for medical device processing equipment.

Steam for sterilizers shall meet AAMI ST79 requirements. These requirements include:

- 97%-100% steam dryness
- Non-condensable gases less than 3.5% v/v condensate
- Superheat of steam less than 77°F
- Additives and conditioners in steam shall be FDA approved (21 CFR 173.310 & 21 CFR 200.11)

Steam boilers serving instrument processing applications shall have boiler make-up water and steam condensate monitoring meeting requirements in AAMI ST108: WATER FOR THE PROCESSING OF MEDICAL DEVICES, 2023. Require dedicated clean steam just for CSPD applications.

Provide point-of-use steam filters at each sterilizer steam connection. Filter to be all stainless-steel construction, 98% efficient at 0.1 micron, based on Balston 23/ 75R. All steam piping, fittings and valves between the filter and sterilizer shall be stainless steel. Provide full-size, valved bypass around filter.

All steam piping, fittings, valves and other steam specialties fed by a boiler system with Critical Water (per AAMI ST108) make-up shall be stainless steel. Boiler wetted parts shall also be stainless steel.

All chemical treatment meant to passivate and maintain the integrity of the steam/ boiler system (i.e. amines) shall inject chemical into the boiler feedwater system, not the steam distribution system. Provide sample test port to allow chemical treatment vendor to validate the boiler system chemical treatment. AE shall review chemical injection and sampling plan with chemical treatment provider to ensure compliance with AAMI ST108.

AAMI ST108 requires meeting stringent water and steam quality requirements. AE shall detail sampling ports/ valves as needed and review layout with UMH FPD and UMH IPE.

- Provide water and steam sampling ports to facilitate regular testing, per AAMI ST108.
- For all water systems, provide sampling ports after the last component at the source (i.e. immediately downstream of the DI tank) and at the point-of-use:
    - For in-line sampling, use a sanitary sampling valve similar to Evoqua model W2T152132.
    - For systems using a final filtration system, provide sampling pre and post filter.
- For all steam systems, provide sampling coolers after the last component at the source (i.e. immediately downstream of the boiler) and at the point-of-use:
    - Sample coolers shall be similar to those manufactured by Sentry.
    - For steam systems using a final point-of-use steam filter, provide sampling cooler immediately downstream of final steam filter.
    - To test treated steam feedwater, a sanitary sampling valve could be placed in-line prior to the boiler.
- Consider installing in-line analyzers for real-time testing of parameters that would be affected by carbon dioxide from the ambient air (i.e. pH, TOC's and conductivity).

Electrical

AE shall design medical device processing spaces to match the emergency power functionality and system redundancy of the programs of which they support. For example, CSPD rooms serving Operating Rooms that are designed to be fully functional on emergency power shall be designed with the same functionality. This emergency power functionality applies to equipment (i.e. washers, sterilizers, etc.) as well as lighting, equipment elevators, HVAC, space pressurization control, etc.

Provide emergency power to sterile processing equipment per AAMI 79

Locate lighting above all work areas so that work is illuminated and not in shadow. All lighting shall be enclosed and cleanable. Provide lighting levels consistent with IES, AAMI ST79 and AAMI ST91. Lighting design to be consistent with U of M AEC Design Guideline 265100 Interior Lighting and U of M MM 265100-H Supplemental Interior Lighting.

AE to coordinate data connections needed in sink workstations, AER's, drying cabinets and assembly. Confirm with department requirements.

Smoke detectors shall be located so as to avoid nuisance trips from steam sources.

Provide an Energy Impact Statement that demonstrates the infrastructure can support loads for each branch of power that is used and that identifies the amount of power for normal and emergency power demanded by design as well as proof of available sources. The table should have existing loads, added loads, and remaining power. Refer to 260510-H Electrical General Requirements on percentage of thermal capacity to remain on each branch of power distribution.

Review with users on the required security to room including card readers and possible AI Phones for entering the room.

Provide Stentofon phones for communication to the OR's if system exists within facility.

All Telecomm Rooms shall conform to UMH design guideline 5.4.1: MM TELECOMMUNICATION ROOMS.

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Equipment

The following is a list of the recommended CSPD equipment for the support of six operating rooms. This is a preliminary list, quantities, and specifications of equipment to be determined and verified by users and equipment vendor.

Central Sterile Processing Department (CSPD) Equipment List

QTY	DESCRIPTION
01	Cart & Utensil Washer/Disinfector
04	3 Bay Reprocessing Sink/120” Long/Height Adjustable
04	Ultrasonic Irrigator
03	Single-Chamber Washer/Disinfector
03	Load/Unload Conveyor System – Single Load/Single Unload
11	Long Chamber Transfer Cart with Auto-Docking
09	Closed Case Cart
04	Container Cart (Travel Cart)
01	Offset Mounted Rack Return
01	Automated Pass-Through Window
06	Prep & Pack Workstation
03	Steam Sterilizer

- Consider need for packaged, self-steam generating sterilizers- review need with FPD to determine if centralized steam can meet AAMI requirements.
- Consider use of water conservation sterilizers when centralized cooling systems are available.

06	Loading Car/Transfer Carriage
02	Low Temperature Sterilization System
02	Wall-Mounted 2-Container Detergent Holding System
01	Detergent Dosing System – Cart Washer
01	Wall-Mounted 3 Container Detergent Holding System
02	Detergent Dosing System – 3 Pumps
17	Wire Shelf Unit

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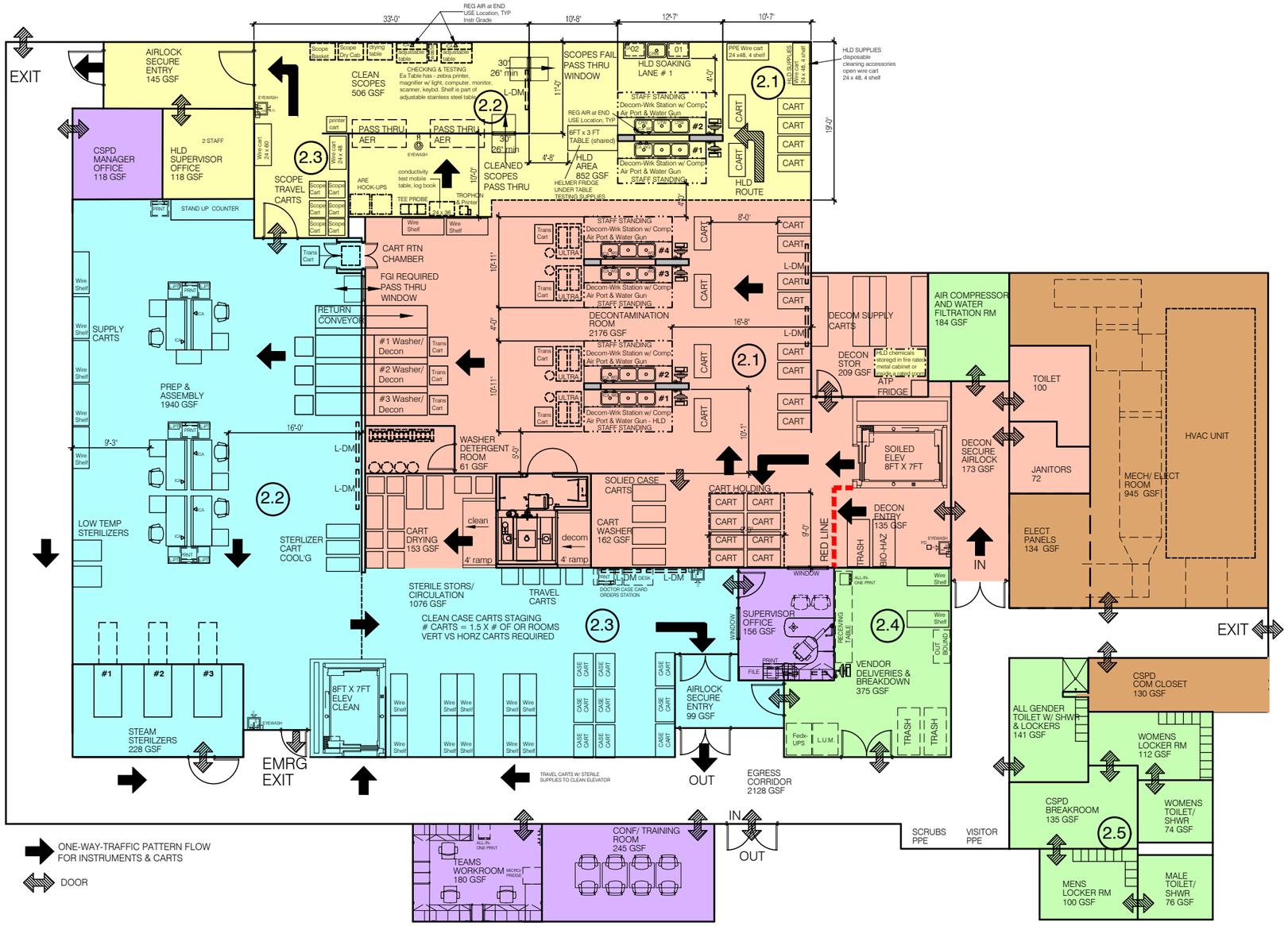
13	Case Carts
20	Carts
03	Prep & Pack Workstation Printer
01	Medical Instrument Repair Printer
01	Doctor Order Station Printer
06	Mobile Tool Cabinet
03	Prep & Pack Worktable
04	Decontamination Sink Lane Computers



1 SK-01 NEW CENTRAL STERILE PROCESING DEPARTMENT (CSPD) BLOCK PLAN
Scale: 1/8" = 1'-0"

0 2' 4' 8'
Scale: 1/8" = 1'-0"

PROPOSED PROGRAM PROBABLE AREAS

MAIN CSPD & OFFICES	= 7,730 GSF
STAFF LOCKER AREA	= 640 GSF
MEP SUPPORT AREA	= 1,210 GSF
HLD AREA	= 1,622 GSF (ONLY INCLUDED FOR MINIMAL HLD REPROCESSING)
EGRESS CIRCULATION AREA	= 2,128 GSF
TOTAL	= 13,330 GSF

NOT INCLUDING MEP SUPPORT AREAS THAT WOULD BE ACCOMMODATED IN AN EXISTING BUILDING
DESIGNED TO MEET FGI 2018 GUIDELINE REQUIREMENTS, MEP AREA LISTED COULD BE REDUCED

FGI 2018
TWO-Room Sterile Processing Facility

(a) The two room sterile processing facility shall consist of a decontamination room and clean workroom that is physically separated by a wall containing a door or pass-through window that can be closed and secured or built-in washer/ disinfector with pass-through door or window.

b) A sterilizer access room for maintaining the equipment shall be provided if required by manufacture

c) Facility shall be design with One-Way Traffic in sterile processing. Decontamination to Packaging/ Sterilization to Sterile Storage

2.1 FGI 2018 - Decontamination

(a) The Decontamination room shall be sized to meet the equipment space and clearances needed for equipment used.

(b) In addition to space for equipment, the decontamination room shall contain the following:

1) Work Counter(s)
2) Hand Washing station
3) Three-basin sink with counter
4) Flushing-rim clinical sink or equivalent fixture unless alternative methods for disposal of bio-waste are provided
5) Space for waste and soiled linen receptacles(s)
6) Documentation area
7) Instrument air outlets for drying instruments
8) Eyewash station if required by safety risk assessment
9) Storage for decontamination supplies and PPE

2.2 FGI 2018 - Clean Workroom

(a) The Clean Workroom shall be sized to accommodate the space and clearances needed for the sterilization equipment used.

(b) In addition to space for equipment, the workroom shall contain the following:

1) Work Counter(s)
2) Hand Washing station
3) Eyewash station if required by safety risk assessment
4) Storage for Sterilization supplies
5) Documentation Area
6) Instrument air outlet as required to dry instruments
7) Steam Sterlizer Locations: Include cooling area for sterilization cart. The sterilizer is loaded/unloaded using a rolling cart

2.3 FGI 2018 - Sterile Storage

(a) A sterile Storage space shall be provided for storage of sterile instruments and supplies
1) This space shall be permitted part of the Clean Workroom or separate room
2) Space for case cart storage shall be provided where/when cast carts are used

2.4 FGI 2018 - Breakdown Receiving/ Unpacking) of Clean/Sterile Supplies

(a) A room shall be provided for receiving/unpacking clean/sterile supplies received from outside the department or facility

b) If facility uses an equipment consignment process, provisions of space should be considered where instrument venders can deliver, inventory, inspect and prepare their consigned equipment for sterile processing.

2.5 FGI 2018 - Support areas for Staff

(a) Separate Male/Female changing areas shall be provided. Provision of All Gender changing room shall be provide.

1) lockers, Toilets, lavatories, space for donning PPE attier
2) provision for separate storage of clean and soiled PPE

CSPD DESIGNGUIDE BLOCK PLAN

5.20 Last Rev 09.25.2024

SK-01

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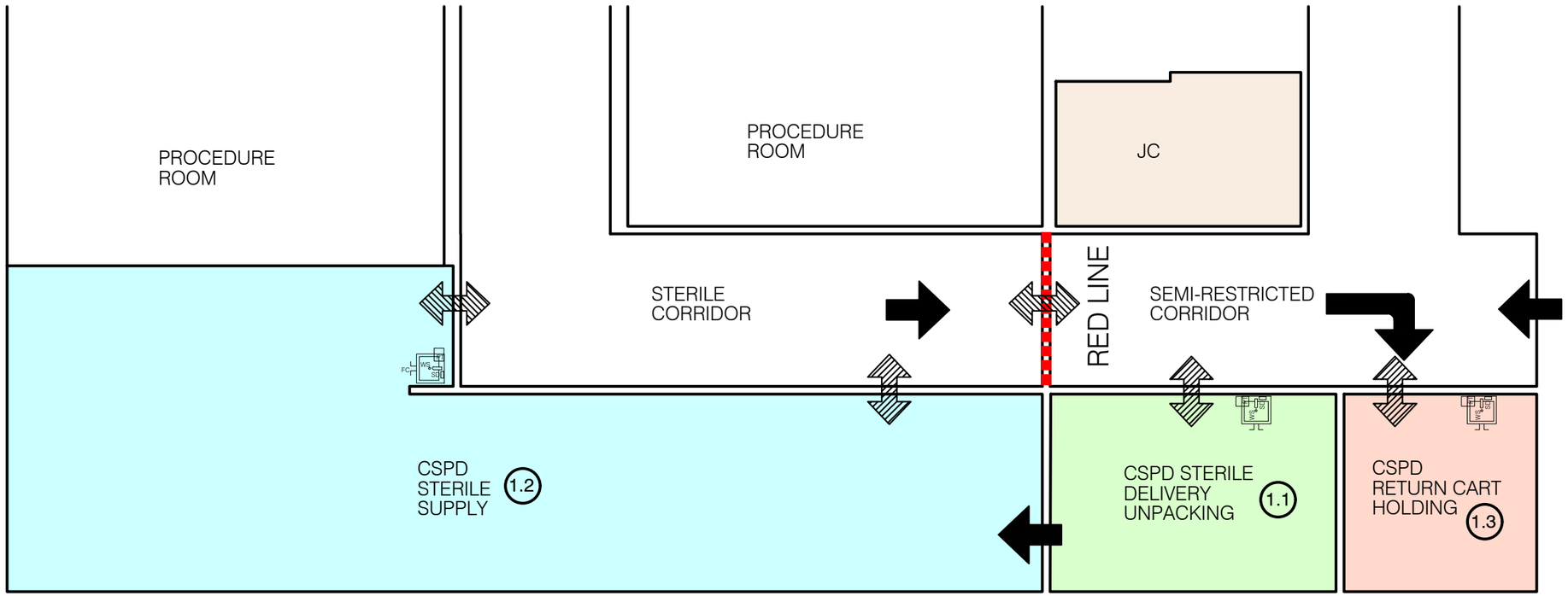

1 / SK-02 POINT OF CARE (CSPD) DELIVERY & STERILE STORAGE BLOCK PLAN

Scale: 3/16

0 1' 2' 4' 8'

Scale: 3/16" =1'-0"

FGI 2018
Supports Areas for Hospitals Using Off-Site Sterile Processing

Where sterile processing services are provided off-site, the following on-site support spaces shall be provided:

1.1 FGI 2018 -
A room for breakdown (receiving/unpacking) of clean sterile supplies.

1) Clean/sterile supply receiving. A room shall be provided for receiving/unpacking clean/sterile supplies & carts received from Off-Site CSPD facility.

1.2 FGI 2018 -
Equipment and Supply Storage
1) Instrument and supply storage. Storage shall be provided for sterile and clean instruments and supplies.
   a) This storage shall be permitted to be separate room or portion of the clean workroom.
   b) Space for case cart storage shall be provided where case carts are used.
   c) Storage for clean/sterile packs shall include provisions to maintain humidity and temperature levels specified by the manufactures of the materials being stored.

1.3 FGI 2018 -
Soiled Return Cart and Instrument Holding
1) Where sterile processing services are provided off-site, the on-site location shall be provided with a soiled Instrument/ return cart holding room which includes the following:
   a) Handwash station
   b) Flushing-Rim clinical service sink
   c) Work Counter
   d) Space to hold covered Case / Travel carts and soiled instruments for re-processing at off-side location

2) Existing (soiled workroom or soiled holding room) shall be permitted for this purpose, provided enough space is available as to not impact existing building operations.

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SK-02

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