

COMPLIANCE CHECKLIST**OP4: Sterile Processing Suites**

The following checklist is intended to be used in the plan review applications for health care facilities submitted to the Massachusetts Department of Public Health. This checklist summarizes and references the applicable requirements from the Licensure Regulations and the 2018 Edition of the FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities. Applicants must verify compliance of the plans submitted to the Department with all referenced requirements from the Licensure Regulations and FGI Guidelines when completing this Checklist. A separate Checklist must be completed for each nursing unit, hospital or clinic department, or clinical suite.

Other jurisdictions, regulations and codes may have additional requirements which are not included in this checklist, such as:

- NFPA 101 Life Safety Code (2012) and applicable related standards contained in the appendices of the Code
- State Building Code (780 CMR)
- Accreditation requirements of The Joint Commission
- CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities
- USP 797
- Regulations of the Massachusetts Board of Registration in Pharmacy
- Accessibility Guidelines of the Americans with Disabilities Act (ADA)
- Architectural Access Board Regulations (521 CMR)
- Local Authorities having jurisdiction.

Instructions:

1. All requirement lines must be completed according to the following instructions and included in the plan submissions for Self-Certification Process or Abbreviated Review Process.
2. This checklist must be completed by the project architect or engineer based on the design actually reflected in the plans at the time of completion of the checklist.
3. Each requirement line (____) of this Checklist must be completed exclusively with one of the following marks, unless otherwise directed in the checklist. If a functional space is not affected by a renovation project, the mark "E" may be indicated on the requirement line (____) before the name of the functional space (associated requirements on indented lines below that name, or associated MEP requirements do not have to be completed in this case). If more than one functional space serves a given required function (e.g. patient room or exam room), that clarification should be provided in the Project Narrative, and the requirement lines are understood to only address the functional spaces that are involved in the project.

X = Requirement is met, for new space, for renovated space, or for existing direct support space for an expanded service.

☒ = Check box under section titles or individual requirements lines for optional services or functions that are not included in the project area.

E = Requirement relative to an existing suite or area that has been *licensed* for its designated function, is *not affected* by the construction project and *does not pertain to a required direct support space* for the specific service affected by the project.

W = Waiver requested for specific section of the Regulations or FGI Guidelines, where hardship in meeting requirement can be demonstrated (a Physical Plant Waiver Form must be completed for each waiver request). An explicit floor plan or plan detail must be attached to each waiver request.

4. All room functions marked with "X" must be shown on the plans with the same name labels as in this checklist.
5. Mechanical, electrical & plumbing requirements are only partially mentioned in this checklist. The relevant section of the FGI Guidelines must be used for project compliance with all MEP requirements and for waiver references.
6. Oxygen, vacuum, medical air, and waste anesthesia gas disposal outlets (if required) are identified respectively by the abbreviations "OX", "VAC", "MA", & "WAGD".
7. Requirements referenced with "FI" result from formal interpretations from the FGI Interpretations Task Group.
8. The location requirements including asterisks (*) refer to the definitions of the Glossary in the beginning section of the FGI Guidelines and reproduced in this checklist.

Facility Name:

DoN Project Number: (if applicable)

Facility Address:

Satellite Name: (if applicable)

Building/Floor Location:

Satellite Address: (if applicable)

Submission Dates:

Initial Date:

Revision Date:

Project Description:

Architectural Requirements**Building Systems Requirements****2.1-4.3 STERILE PROCESSING SUITE****2.1-4.3.2 FACILITIES FOR ON-SITE STERILE PROCESSING**

2.1-4.3.2.2
2.1-4.3.2.1(1)(b) ☐ Two-room sterile processing facility
☐ check if not included in project (only if sterilization equipment is limited to table-top sterilizer)

2.1-4.3.2.1(2) ☐ meets requirements of semi-restricted area

2.1-4.3.2.1(3) ☐ layout allows one-way traffic pattern

(1)(a) ☐ consists of decontamination room & clean workroom that are physically separated by wall

☐ separation wall contains door or pass-through window that can be closed & secured

or

☐ separation wall contains built-in washer/disinfector with pass-through door or window

(2) ☐ decontamination room

(a) ☐ sized to accommodate min. space & clearances needed for equipment used
☐ equipment plan has been submitted to DPH Plan Review

Ventilation:

☐ Min. 6 air changes per hour
☐ Exhaust
☐ Negative pressure
☐ No recirculating room units

Table 8.1

(b) ☐ work counter
☐ handwashing station
☐ three-basin sink with counter
☐ flushing-rim clinical sink or equivalent fixture

or

☐ alternative methods for disposal of bio-waste are described in Project Narrative

☐ space for waste & soiled linen receptacles

☐ documentation area

☐ eyewash station

☐ check if not included in project (only if not required by safety risk assessment)

☐ storage for decontamination supplies & personal protective equipment (PPE)

Architectural Requirements**Building Systems Requirements**

- (3) ☐ clean workroom
- (a) ☐ sized to accommodate space & clearances needed for sterilization equipment used
☐ equipment plan has been submitted to DPH Plan Review

- (b) ☐ work counters
☐ handwashing station
☐ eyewash station
☐ check if not included in project (only if not required by safety risk assessment)
☐ storage for sterilization supplies
☐ documentation area
☐ cooling area for sterilization cart
☐ check if not included in project (only if sterilizer is not loaded or unloaded using rolling cart)

- (4) ☐ sterile storage space
☐ provided for storage of sterile instruments & supplies

- (a) ☐ located in clean workroom
or
☐ located in separate storage room

- 2.1-4.3.2.3 ☐ One-room sterile processing facility
2.1-4.3.2.1(1)(a) ☐ check if not included in project (only if Two-Room Sterile Processing Facility is provided)

- 2.1-4.3.2.1(2) ☐ meets requirements of semi-restricted area

- 2.1-4.3.2.1(3) ☐ layout allows one-way traffic pattern

- (1) ☐ consists of decontamination area & clean work area

- (b) ☐ entrance located approximately equidistant from clean & decontamination sides & allows for one-way traffic flow
or
☐ two entrances provided to allow for one-way traffic flow

Ventilation:

- ☐ Min. 4 air changes per hour Table 8.1
☐ Positive pressure
☐ No recirculating room units

Architectural Requirements**Building Systems Requirements**

- (2) ☐ decontamination area
- (a) ☐ countertop
☐ handwashing station
☐ separate from instrument-washing sink
☐ two-basin sink for washing instruments
☐ storage for supplies
- (b) ☐ instrument-washing sink separated from clean work area by 4'-0" distance from edge of sink
or
☐ instrument-washing sink separated from clean work area by separating wall or screen (extends min. of 4'-0" above sink rim)

Ventilation:

- ☐ Min. 6 air changes per hour Table 8.1
☐ Exhaust
☐ Negative pressure
☐ No recirculating room units

- (3) ☐ clean work area
- (a) ☐ countertop
- (b) ☐ sterilizer as required for services provided
- (c) ☐ storage for supplies

Ventilation:

- ☐ Supply diffuser

- 2.1-4.3.2.4 ☐ Equipment & supply storage
- (1) ☐ storage for sterile & clean instruments & supplies
- (a) ☐ separate equipment & supply storage room
or
☐ designated equipment & supply storage area in clean workroom
- (b) ☐ space for case cart storage
☐ check if not included in project (only if case carts are not used)
- (c) ☐ provisions to maintain humidity & temperature levels
- (2) ☐ clean/sterile medical/surgical supply receiving room or area

Architectural Requirements**Building Systems Requirements****2.1-4.3.2.5 SUPPORT AREAS FOR STERILE PROCESSING STAFF**

☐ check if not included in project
(may be shared with other staff in same facility)

2.1-3.9.4 _____ Staff changing area

2.1-3.9.4.1(1) _____ lockers

2.1-3.9.4.1(2) _____ toilet room

Ventilation:

_____ Min. 10 air changes per hour Table 8.1

_____ Exhaust

_____ Negative pressure

_____ No recirculating room units

(3) _____ handwashing stations

(4) _____ space for donning surgical attire

(5) _____ provision for separate storage for clean
& soiled surgical attire

***LOCATION TERMINOLOGY:**

Directly accessible: Connected to the identified area or room through a doorway, pass-through, or other opening without going through an intervening room or public space

Adjacent: Located next to but not necessarily connected to the identified area or room

Immediately accessible: Available either in or adjacent to the identified area or room

Readily accessible: Available on the same floor or in the same clinic as the identified area or room

Architectural Details & MEP Requirements**2.1-7.2.2 ARCHITECTURAL DETAILS****2.1-7.2.2.2 CEILING HEIGHT:**

_____ Min. ceiling height 7'-10"

2.1-7.2.2.3 DOORS & DOOR HARDWARE:

(1) Door Type:

(a) _____ doors between corridors,
rooms, or spaces subject to
occupancy swing type or
sliding doors

(b) _____ sliding doors

☐ check if not included in project

_____ manual or automatic
sliding doors comply with
NFPA 101

_____ detailed code review
incorporated in Project
Narrative
_____ no floor tracks

(2) Door Opening:

(a) _____ min. 34" clear door width

_____ min. 83.5" clear door height

(3)

(a)

Door Swing:

_____ doors do not swing into corridors
except doors to non-occupiable
spaces (e.g. environmental ser-
vices rooms & electrical closets)
& doors with emergency break-
away hardware

(4)

_____ Lever hardware or push/pull latch
hardware

2.1-7.2.2.8

(3)(a)

HANDWASHING STATIONS:

_____ Handwashing station countertops
made of porcelain, stainless steel,
solid-surface materials or impervious
plastic laminate assembly

(3)(b)

_____ Countertops substrate
☐ check if not included in project
_____ marine-grade plywood (or
equivalent material) with im-
pervious seal

(4)

_____ Handwashing station casework
☐ check if not included in project
_____ designed to prevent storage
beneath sink

- (5) ☐ Provisions for drying hands
☐ check if not included in project (only at hand scrub facilities)
- (a) ☐ hand-drying device does not require hands to contact dispenser
- (b) ☐ hand-drying device is enclosed to protect against dust or soil
- (6) ☐ Liquid or foam soap dispensers

2.1-7.2.3
 2.1-7.2.3.1

SURFACES**FLOORING & WALL BASES:**

- (1) ☐ Flooring surfaces cleanable & wear-resistant for location
- (3) ☐ Smooth transitions provided between different flooring materials
- (4) ☐ Flooring surfaces including those on stairways are stable, firm & slip-resistant
- (5) ☐ Floors & wall bases of all areas subject to frequent wet cleaning are constructed of materials that are not physically affected by germicidal or other types of cleaning solutions
- (6)(a) ☐ Floors are monolithic & integral coved wall bases are at least 6" high & tightly sealed to wall in sterile processing rooms

2.1-7.2.3.2

WALLS & WALL PROTECTION:

- (1)(a) ☐ Wall finishes are washable
- (1)(b) ☐ Wall finishes near plumbing fixtures are smooth, scrubbable & water-resistant
- (2) ☐ Wall surfaces in areas routinely subjected to wet spray or splatter (e.g. environmental services rooms) are monolithic or have sealed seams that are tight & smooth

2.1-7.2.3.3

CEILINGS:

- (1) ☐ Ceilings provided in all areas except mechanical, electrical & communications equipment rooms
- (a) ☐ Ceilings cleanable with routine housekeeping equipment
- (b) ☐ Acoustic & lay-in ceilings where used do not create ledges or crevices
- (2) **Semi-Restricted Areas:**
- (a) ☐ ceiling finishes are scrubbable, non absorptive, non perforated, & capable of withstanding cleaning with chemicals
- (b) ☐ lay-in ceilings
☐ gasketed or each ceiling tile weighs at least one pound per square foot

- (c) ☐ no perforated tegular, serrated or highly textured tiles
- or**
- ☐ monolithic ceilings

2.1-8.2

HEATING VENTILATION & AIR-CONDITIONING (HVAC) SYSTEMS

Part 3/6.4

FILTRATION:

- ☐ One filter bank MERV 7

Part 3/6.7

Part 3/6.7.1

AIR DISTRIBUTION SYSTEMS:

- ☐ Maintain pressure relationships required in tables 7.1 in all modes of HVAC system operation
- ☐ Spaces that have required pressure relationships are served by fully ducted return systems or fully ducted exhaust systems

Part 3/6.7.2

Air Distribution Devices:

- ☐ supply air outlets comply with Table 6.7.2

Part 3/6.8

ENERGY RECOVERY SYSTEMS:

Part 3/6.8.3

- ☐ check if not included in project
- ☐ Energy recovery systems with leakage potential
- ☐ check if not included in project
- ☐ arranged to minimize potential to transfer exhaust air directly back into supply airstream
- ☐ designed to have no more than 5% of total supply airstream consisting of exhaust air
- ☐ not used from these exhaust airstream sources: central medical & surgical supply, soiled or decontamination room

Part 3/7

Part 3/7.1.a

SPACE VENTILATION:

Part 3/7.1.a.1

Part 3/7.1.a.3

- ☐ Complies with Table 8.1
- ☐ Air movement is from clean to less-clean areas
- ☐ Min. number of total air changes required for positive pressure rooms is provided by total supply airflow
- ☐ Min. number of total air changes required for negative pressure rooms is provided by total exhaust airflow
- ☐ Entire minimum outdoor air changes per hour required by Table 8.1 for each space meet filtration requirements of Section 6.4

2.1-8.3 ELECTRICAL SYSTEMS**2.1-8.3.5 ELECTRICAL EQUIPMENT**

- 2.1-8.3.5.1 ☐ Handwashing sinks & scrub sinks that depends on building electrical service for operation are connected to essential electrical system
☐ check if not included in project

2.1-8.3.6 ELECTRICAL RECEPTACLES

- ☐ Receptacles in patient care areas are provided according to Table 2.1-1

2.1-8.4 PLUMBING SYSTEMS

- 2.1-8.4.2 Plumbing & Other Piping Systems:
 2.1-8.4.2.1(3) ☐ no plumbing piping exposed overhead or on walls where possible accumulation of dust or soil may create cleaning problem
- 2.1-8.4.2.5 Heated Potable Water Distribution Systems:
 (2) ☐ heated potable water distribution systems serving patient care areas are under constant recirculation
☐ non-recirculated fixture branch piping length max. 25'-0"
 (3)(a) ☐ no installation of dead-end piping (except for empty risers mains & branches for future use)
 (3)(c) ☐ any existing dead-end piping is removed
 (3)(b) ☐ check if not included in project
 (4)(a) ☐ water-heating system supplies water at following range of temperatures: 105–120°F
- 2.1-8.4.2.6 Drainage Systems:
 (1)(a) ☐ drainage piping installed above ceiling of or exposed in rooms listed below piping have special provisions (e.g. double wall containment piping) to protect space below from leakage & condensation
 - sterile processing facilities
 - electronic data processing areas
 - electrical rooms
- (1)(b) ☐ drip pan for drainage piping above ceiling of sensitive area
☐ check if not included in project
☐ accessible
☐ overflow drain with outlet located in normally occupied area

2.1-8.4.3 PLUMBING FIXTURES

- 2.1-8.4.3.1(1) ☐ Materials used for plumbing fixtures are non-absorptive & acid-resistant
- 2.1-8.4.3.2 Handwashing Station Sinks:
 (2) ☐ sink basins have nominal size of no less than 144 square inches
☐ sink basins have min. dimension 9 inches in width or length
 (3) ☐ sink basins are made of porcelain, stainless steel or solid-surface materials
 (5) ☐ water discharge point of faucets is at least 10" above bottom of basin
 (7) ☐ anchored so that allowable stresses are not exceeded where vertical or horizontal force of 250 lbs. is applied
 (8) ☐ sinks used by staff have fittings that can be operated without using hands (may be single-lever or wrist blade devices)
 (a) ☐ blade handles
☐ check if not included in project
☐ at least 4 inches in length
☐ provide clearance required for operation
 (b) ☐ sensor-regulated water fixtures
☐ check if not included in project
☐ meet user need for temperature & length of time water flows
☐ designed to function at all times and during loss of normal power
- 2.1-8.4.3.5 Clinical Flushing-Rim Sinks:
☐ check if not included in project
 (1) ☐ trimmed with valves that can be operated without hands (may be single-lever or wrist blade devices)
 (a) ☐ handles are at least 6 in. long
 (b) ☐ integral trap wherein upper portion of water trap provides visible seal
 (2)