**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 2022 Edition of the FGI Guidelines for Design and Construction of 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.

**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.

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

**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:

Project Description:

Initial Date:

Revision Date:

| | 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<br>2.1-4.3.2.1(1)(b) | ___ Two-room sterile processing facility<br>☐ check if not included in project<br>(only if sterilization equipment is limited to table-top sterilizer) | | |
| 2.1-4.3.2.1(2) | ___ meets requirements of semi-restricted area (see Page 6) | | |
| 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<br>**or**<br>___ 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<br>___ equipment plan has been submitted to DPH Plan Review | Ventilation:<br>___ Min. 6 air changes per hour<br>___ Exhaust<br>___ Negative pressure<br>___ No recirculating room units | Table 8-1 |
| (b) | ___ work counter<br>___ handwashing station<br>___ three-basin sink with counter<br>___ flushing-rim clinical sink or equivalent fixture<br>**or**<br>___ alternative methods for disposal of bio-waste are described in Project Narrative | | |
| | ___ space for waste & soiled linen receptacles<br>___ documentation area<br>___ eyewash station<br>☐ check if not included in project<br>(only if not required by safety risk assessment)<br>___ 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<br>___ equipment plan has been submitted to DPH Plan Review | Ventilation:<br>___ Min. 4 air changes per hour<br>___ Positive pressure<br>___ No recirculating room units | Table 8-1 |
| (b) | ___ work counters<br>___ handwashing station<br>___ eyewash station<br>☐ check if not included in project (only if not required by safety risk assessment)<br>___ storage for sterilization supplies<br>___ documentation area<br>___ cooling area for sterilization cart<br>☐ check if not included in project (only if sterilizer is not loaded or unloaded using rolling cart) | | |
| (4) | ___ sterile storage space<br>___ provided for storage of sterile instruments & supplies | | |
| (a) | ___ located in clean workroom<br>**or**<br>___ located in separate storage room | | |
| 2.1-4.3.2.3<br>2.1-4.3.2.1(1)(a) | ___ One-room sterile processing facility<br>☐ 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 (see Page 6) | | |
| 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<br>**or**<br>___ two entrances provided to allow for one-way traffic flow | | |
| (2) | ___ decontamination area | | |
| (a) | ___ countertop<br>___ storage for supplies<br>___ handwashing station<br>___ separate from instrument-washing sink | Ventilation:<br>___ Min. 6 air changes per hour<br>___ Exhaust<br>___ Negative pressure | Table 8-1 |

| | Architectural Requirements | Building Systems Requirements | |
|---|---|---|---|
| | ___ two-basin instrument-washing sink | ___ No recirculating room units | |
| (b) | ___ separated from clean work area by 4'-0" distance from edge of sink<br>**or**<br>___ separated from clean work area by separating wall or screen (extends a minimum of 4'-0" above sink rim) | | |
| (3) | ___ clean work area | Ventilation: | |
| (a) | ___ countertop | ___ Supply diffuser | |
| (b) | ___ sterilizer as required for services provided | | |
| (c) | ___ storage for supplies | | |
| 2.1-4.3.2.4 | ___ Equipment & supply storage | | |
| (1) | ___ storage for sterile & clean instruments & supplies | | |
| (a) | ___ separate equipment & supply storage room<br>**or**<br>___ designated equipment & supply storage area in clean workroom | | |
| (b) | ___ space for case cart storage<br>☐ check if not included in project<br>(only if case carts are not used) | | |
| (c) | ___ provisions to maintain humidity & temperature levels | | |
| (2) | ___ clean/sterile medical/surgical supply receiving room or area | | |
| 2.1-4.3.2.5 | **SUPPORT AREAS FOR STERILE PROCESSING STAFF**<br>☐ check if not included in project<br>(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:<br>___ Min. 10 air changes per hour<br>___ Exhaust<br>___ Negative pressure<br>___ No recirculating room units | Table 8-1 |
| (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
(b) sliding doors
___ 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. 32" clear door width
___ min. 83.5" clear door height
(3) Door Swing:
(a) ___ doors do not swing into corridors except doors to non-occupiable spaces (e.g. environmental services rooms & electrical closets) & doors with emergency breakaway hardware
(4) ___ Lever hardware or push/pull latch hardware

2.1-7.2.2.8 HANDWASHING STATIONS:
(3)(a) ___ 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 impervious 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 **SURFACES**
2.1-7.2.3.1 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:
a. ___ Particulate matter filters, min. MERV-8 provided upstream of first heat exchanger surface of any air-conditioning system that combines return air from multiple rooms or introduces outdoor air.
b. ___ Outdoor air filtered in accordance with Table 8-1
c. ___ Air supplied from equipment serving multiple or different spaces is filtered in accordance with Table 8-1
d. ___ Air recirculated within room is filtered in accordance with Table 8-1
e. ___ Design includes all necessary provisions to prevent moisture accumulating on filters located downstream of cooling coils & humidifiers
h. ___ For spaces that do not permit air recirculated by means of room units & have min. filter efficiency of MERV-14, MERV-16 or HEPA in accordance with Table 8-1, the min. filter requirement listed in Table 8-1, is installed downstream of all wet-air cooling coils & supply fan

Part 3/6.4.1 ___ Filter Bank No. 1 placed upstream of heating & cooling coils
Part 3/6.4.2 ___ Filter Bank No. 2 placed downstream of all wet-air cooling coils & supply fan

Part 3/6.7 AIR DISTRIBUTION SYSTEMS:
Part 3/6.7.1 ___ Maintain pressure relationships required in Table 8-1 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 6-2

Part 3/6.8 ENERGY RECOVERY SYSTEMS:
☐ check if not included in project
Part 3/6.8.1 ___ Located upstream of filters required by Part 3/6.8.4
Part 3/6.8.3 ___ 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 SPACE VENTILATION:
Part 3/7.1.a ___ Complies with Table 8-1
___ Air movement is from clean to less-clean areas
Part 3/7.1.a.1
Part 3/7.1.a.3 ___ 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
Part 3/7.1.a.4 ___ 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

(3)(c) mains & branches for future use)

(3)(b) ___ any existing dead-end piping is removed

☐ 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 Sinks:

☐ check if not included in project

(1) ___ trimmed with valves that can are operated without hands (may be single-lever or wrist blade devices)

(a)

(b) ___ handles are at least 6 in. long

(2) ___ integral trap wherein upper portion of water trap provides visible seal