

**COMPLIANCE CHECKLIST****OP2: Outpatient Laboratory 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.

☒ = 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. "E" must not be used for an existing required support space associated with a new patient care room or 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. Any 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**

2.2-4.1

**LABORATORY SERVICES**

2.1-4.1.1.1

\_\_\_ Facilities for laboratory services provided on-site are located in or immediately accessible\* to outpatient facility

2.1-4.1.1.2

\_\_\_ All laboratory equipment requiring permanent connections to power, water, ventilation or other utility systems are identified in equipment plan  
 \_\_\_ equipment plan & equipment schedule have been submitted to DPH Plan Review

2.1-4.1.2

\_\_\_ Laboratory work area

2.1-4.1.2.1

\_\_\_ separate dedicated room  
 \_\_\_ ☐ check if not included in project (only if laboratory testing in open laboratory is limited to CLIA waived tests)

Ventilation:

\_\_\_ Min. 6 air changes per hour Table 8-2  
 \_\_\_ Negative pressure

2.1-4.1.2.2

\_\_\_ laboratory workstations

(1)(a)

\_\_\_ work counter

(1)(b)

\_\_\_ laboratory sink

(2)

\_\_\_ access to all utility connections required for the equipment

2.1-4.1.2.3

\_\_\_ handwashing station

2.1-4.1.2.4

\_\_\_ all work counters in areas used for specimen handling, preparation of specimens or reagents & laboratory testing are constructed of non-porous materials

Ventilation:

\_\_\_ Min. 6 air changes per hour Table 8-2  
 \_\_\_ Negative pressure

2.1-4.1.2.5(1)

\_\_\_ terminal sterilization provisions before transport

☐ check if not included in project

(a)

\_\_\_ facilities & equipment (autoclave or electric oven) provided for terminal sterilization of bio-hazardous waste

(b)

\_\_\_ biosafety Level III laboratory  
☐ check if not included in project  
 \_\_\_ decontamination methods conform to Section IV of *CDC Biosafety in Microbiological & Biomedical Laboratories*.

2.1-4.1.8

**SUPPORT AREAS FOR LABORATORY**

2.1-4.1.8.1

\_\_\_ Storage cabinet or closet

(1)

\_\_\_ storage for reagents specimens flammable materials acids bases & other supplies used in laboratory

**Architectural Requirements****Building Systems Requirements**

- 2.1-4.1.8.2 \_\_\_ Specimen collection facilities
- (1) \_\_\_ urine or feces specimen collection  
       \_\_\_ ☐ check if not included in project  
       \_\_\_ dedicated specimen toilet room  
           \_\_\_ handwashing station  
           \_\_\_ staff-controlled access
- 2.1-4.1.8.2(2) \_\_\_ drug screening requiring Chain of Custody  
       \_\_\_ ☐ check if not included in project  
       \_\_\_ handwashing station meets requirements established in "Department of Health & Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs" (including securing water supply)
- (3) \_\_\_ blood collection facilities
- (a) \_\_\_ work counter
- (b) \_\_\_ seating space for patients
- (c) \_\_\_ handwashing station
- (d) \_\_\_ supply storage
- 2.2-4.1.8.2 \_\_\_ Specimen storage
- (1) \_\_\_ accommodations for storage of blood urine & other specimens
- (2) \_\_\_ blood storage facilities meet requirements of CLIA standards for blood banks
- §493.1103(c)(1) \_\_\_ blood specimen stored in monitored refrigerator  
       **or**  
       \_\_\_ blood storage conditions including temperature are appropriate to prevent deterioration of blood specimens
- 2.1-5.3.1 \_\_\_ Environmental services room
- 2.1-5.3.1.1(3) (may serve more than one clinical service area on same floor)
- 2.1-5.3.1.1(1) \_\_\_ min one ES room per floor
- 2.1-5.3.1.1(2) \_\_\_ additional ES rooms provided on floor according to needs of areas served
- 2.1-5.3.1.2(1) \_\_\_ service sink or floor-mounted mop sink
- 2.1-5.3.1.2(2) \_\_\_ provisions for storage of supplies & housekeeping equipment
- 2.1-5.3.1.2(3) \_\_\_ handwashing station or hand sanitation dispenser

## Ventilation:

- \_\_\_ Min 10 air changes per hour Table 8-2
- \_\_\_ Exhaust
- \_\_\_ Negative pressure
- \_\_\_ No recirculating room units

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- \_\_\_ Min 10 air changes per hour Table 8-2
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**Architectural Requirements****Building Systems Requirements**

- 2.1-4.1.8.3 Administrative Area:  
       \_\_\_ space for clerical work filing & record  
       \_\_\_ maintenance/storage
- 2.1-4.1.9 **SUPPORT AREAS FOR LABORATORY STAFF**
- 2.1-4.1.9.2 (may be shared with other clinical services)
- 2.1-4.1.9.1 \_\_\_ Staff lounge & lockers
- \_\_\_ Staff toilet room
- \_\_\_ readily accessible\* for laboratory staff

- Ventilation:
- \_\_\_ Min 10 air changes per hour Table 8-2
- \_\_\_ Exhaust
- \_\_\_ Negative pressure
- \_\_\_ No recirculating room units

**\*LOCATION TERMINOLOGY:**

Directly accessible: Connected to the identified area or room through doorway pass-through or other opening without going through 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**

- |   |   |   |
|---|---|---|
| <p>2.1-7.2.2 <b>ARCHITECTURAL DETAILS</b></p> <p>2.1-7.2.2.1 <b>CORRIDOR WIDTH:</b></p> <p>IBC 1018.2 ___ Min 44"</p> <p><b>or</b></p> <p>___ Detailed code review incorporated in Project Narrative</p> <p>421 CMR ___ Corridors include turning spaces for wheelchairs</p> <p>6.00</p> <p>2.1-7.2.2.2 <b>CEILING HEIGHT:</b></p> <p>(1) ___ Min ceiling height 7'-6" in corridors &amp; in normally unoccupied spaces</p> <p>(2) ___ Min height 7'-6" above floor of suspended tracks rails &amp; pipes located in traffic path</p> <p>___ Min ceiling height 7'-10" in other areas</p> <p>2.1-7.2.2.3 <b>DOORS &amp; DOOR HARDWARE:</b></p> <p>(1) Door Type:</p> <p>(a) ___ doors between corridors rooms or spaces subject to occupancy swing type or sliding doors</p> <p>(b) ___ sliding doors</p> <p>      ___ <input type="checkbox"/> check if <u>not</u> included in project</p> <p>      ___ manual or automatic</p> <p>      ___ sliding doors comply with NFPA 101</p> <p>      ___ detailed code review incorporated in Project Narrative</p> <p>      ___ no floor tracks</p> | <p>(2)</p> <p>(a)</p> <p>(3)</p> <p>(a)</p> <p>(4)</p> <p>(5)</p> <p>(a)</p> <p>(b)</p> | <p>Door Opening:</p> <p>___ min 32" clear door width</p> <p>___ min 83.5" clear door height</p> <p>Door Swing:</p> <p>___ doors do not swing into corridors except doors to non-occupiable spaces (e.g environmental services rooms &amp; electrical closets) &amp; doors with emergency breakaway hardware</p> <p>___ Lever hardware or push/pull latch hardware</p> <p>Doors for Patient Toilet Facilities:</p> <p>___ door that swings outward</p> <p><b>or</b></p> <p>___ door equipped with emergency rescue hardware (permits quick access from outside the room to prevent blockage of the door)</p> <p><b>or</b></p> <p>___ sliding door other than pocket door</p> <p>___ toilet room opens onto public area or corridor</p> <p>___ <input type="checkbox"/> check if <u>not</u> included in project</p> <p>___ visual privacy is maintained</p> |
|---|---|---|

- 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
- (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
- 2.1-7.2.2.9 **GRAB BARS:**
- (1) \_\_\_\_\_ Grab bars anchored to sustain concentrated load 250 pounds
- (3) \_\_\_\_\_ Ends of grab bars constructed to prevent snagging clothes of patients staff & visitors
- 2.1-7.2.2.10 **HANDRAILS:**
- ☐ check if not included in project
- (2) \_\_\_\_\_ Rail ends return to wall or floor
- (3) \_\_\_\_\_ Handrail gripping surfaces & fasteners are smooth (free of sharp or abrasive elements) with 1/8-inch min radius
- (4) \_\_\_\_\_ Handrails have eased edges & corners
- (5) \_\_\_\_\_ Handrail finishes are cleanable
- 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

- 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
- (4) \_\_\_\_\_ Wall protection devices & corner guards durable & scrubbable
- 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
- 2.1-7.2.4.3 \_\_\_\_\_ Privacy curtains in patient care areas are washable
- 2.1-8.2 **HEATING VENTILATION & AIR-CONDITIONING (HVAC) SYSTEMS**
- 2.1-8.2.1.3/ Policy \_\_\_\_\_ Ventilation rates meet requirements of Table 8-1 in Part 3 ASHRAE Standard 170
- 2.2-8.3 **ELECTRICAL SYSTEMS**
- 2.2-8.3.4 **EMERGENCY EGRESS LIGHTING**
- \_\_\_\_\_ Automatic emergency lighting
- or**
- \_\_\_\_\_ Facility has total floor area of not more than 1,000 sf is located at grade level & has direct access to exits to grade