

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 2018 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. 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**

2.2-4.1

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
 ___ Negative pressure

Table 8.1/
Policy

2.1-4.1.2.2

___ laboratory workstations

(1)(a)

___ work counter

(1)(b)

___ laboratory sink

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
 ___ Negative pressure

Table 8.1/
Policy

2.1-4.1.2.5(1)

___ terminal sterilization provisions facilities & equipment (autoclave or electric oven) provided for terminal sterilization of bio-hazardous waste before transport

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

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

Ventilation:

___ Min. 10 air changes per hour
 ___ Exhaust
 ___ Negative pressure
 ___ No recirculating room units

Table 8.1

Architectural Requirements**Building Systems Requirements**

- (2) ☐ urine collection for drug screening
☐ check if not included in project
- ☐ handwashing station located directly outside toilet room & under staff control
- or**
- ☐ handwashing station located in toilet room
☐ water controlled by shutoff valves located outside room & directly accessible* to staff

- (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

- 2.1-4.1.8.3 Administrative Area:
☐ space for clerical work, filing & record maintenance/storage

Ventilation:

- ☐ Min. 10 air changes per hour Table 8.1/
☐ Exhaust Policy
☐ Negative pressure
☐ No recirculating room units

Architectural Requirements**Building Systems Requirements****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 8.1

___ Exhaust

___ Negative pressure

___ No recirculating room units

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 spaceAdjacent: Located next to but not necessarily connected to the identified area or roomImmediately accessible: Available either in or adjacent to the identified area or roomReadily 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****CORRIDOR WIDTH:**

2.1-7.2.2.1 ___ Min. 44"

IBC 1018.2

or

___ Detailed code review incorporated in Project Narrative

421 CMR 6.00 ___ Corridors include turning spaces for wheelchairs

2.1-7.2.2.2 CEILING HEIGHT:

(1) ___ Min ceiling height 7'-6" in corridors & in normally unoccupied spaces

(2) ___ Min. height 7'-6" above floor of suspended tracks, rails & pipes located in traffic path

___ Min. ceiling height 7'-10" in other areas

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)

(a)

Door Opening:

___ 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 services rooms & electrical closets) & doors with emergency breakaway hardware

(4)

___ Lever hardware or push/pull latch hardware

(5)

(a)

Doors for Patient Toilet Facilities:

___ door that swings outward

or

___ door equipped with emergency rescue hardware (permits quick access from outside the room to prevent blockage of the door)

or

___ sliding door other than pocket door

(b)

___ toilet room opens onto public area or corridor

☐ check if not included in project

___ visual privacy is maintained

- 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 (Policy based on input from Facility Guidelines Institute)
- 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