

COMPLIANCE CHECKLIST

IP26: Pharmacy Services

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 2014 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 (2000) and applicable related standards contained in the appendices of the Code
- State Building Code (780 CMR)
- Joint Commission on the Accreditation of Health Care Organizations
- CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities
- USP 797
- 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 Part II of the 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 symbols, unless otherwise directed in the checklist. If a functional space is not affected by a renovation project, the symbol "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).

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.

Facility Name:

DoN Project Number: (if applicable)

Facility Address:

Nursing Unit Bed Complements:

Current = Proposed =

Satellite Name: (if applicable)

Building/Floor Location:

Satellite Address: (if applicable)

Submission Dates:

Initial Date:

Revision Date:

Project Description:

Architectural Requirements

Building Systems Requirements

2.1-4.2

PHARMACY SERVICES

2.1-4.2.1.2

- Location:
- pharmacy room or suite located to be accessible to clinical areas of hospital & to facilitate staff control & security of pharmacy

2.1-4.2.2

PHARMACY AREAS

2.1-4.2.2.1

- Dispensing facilities
 - (1) room or area for receiving, breakout & inventory control of materials used in pharmacy
 - (2) work counters & space for automated & manual dispensing activities
 - (3) extemporaneous compounding area
 - sink
 - sufficient counter space for drug preparation
 - (4) area for reviewing & recording
 - (5) area for temporary storage, exchange & restocking of carts
 - (6) security provisions for drugs & personnel in dispensing counter area

Ventilation:

- Min. 4 air changes per hour Table 7.1
- Positive pressure

2.1-4.2.2.2

- Manufacturing facilities
 - check if not included in project

(1)

- bulk compounding area
- provisions for packaging & labeling
- quality control area

Ventilation:

- Min. 4 air changes per hour Table 7.1
- Positive pressure

2.1-4.2.2.3

- Storage (cabinets, shelves, and/or separate rooms or closets)
 - (1) bulk storage
 - (2) active storage
 - (3) refrigerated storage
 - (4) storage for volatile fluids & alcohol
 - (5) secured lockable storage for narcotics & controlled drugs
 - (6) equipment & supply storage for general supplies & equipment not in use

2.1-4.2.3

STERILE WORK AREAS

- check if not included in project

2.1-4.2.3.1(1)

- Layout:
- precludes unrelated traffic through sterile IV preparation rooms
 - precludes unrelated traffic through cytotoxic IV preparation rooms

2.1-4.2.3.1(2)

- robotic systems used in preparation of IV solutions (in either positive pressure sterile IV prep room or negative pressure cytotoxic IV prep room)
 - check if not included in project
 - separate robotics system in each room

Architectural Requirements

Building Systems Requirements

- 2.1-4.2.3.2 Sterile IV preparation room
 - check if not included in project
 - separate sterile work room with laminar-flow workstation designed for product protection
 - (1) laminar-flow workstation includes non hydroscopic HEPA filter
 - (2) laminar-flow workstation includes visible pressure gauge for detection of filter leaks or defects

DPH-BRP Policy ISO Class 7 clean room (as defined by USP 797)

- USP 797 Access to sterile IV preparation room through ISO Class 7 anteroom
- 2.1-4.2.6.5 handwashing station

Ventilation: USP 797
 Min. 30 air changes per hour
 Positive pressure
 HEPA filter

Ventilation: USP 797
 Min. 30 air changes per hour
 HEPA filter

- 2.1-4.2.3.3 Cytotoxic IV preparation room.
 - check if not included in project
 - separate room for preparation of cytotoxic IV admixtures under Class II (Type A2, BL, or B2) or Class III biological safety cabinet.

DPH-BRP Policy ISO Class 7 clean room (as defined by USP 797)

- USP 797 Access to sterile IV preparation room through ISO Class 7 anteroom
- 2.1-4.2.6.5 handwashing station

Ventilation: USP 797
 Min. 30 air changes per hour
 Negative pressure
 Contaminated exhaust

Ventilation: USP 797
 Min. 30 air changes per hour
 HEPA filter

SUPPORT AREAS FOR PHARMACY

- 2.1-4.2.6 **SUPPORT AREAS FOR PHARMACY**
- 2.1-4.2.6.2 Office
 - separate room or area for office functions
- 2.1-4.2.6.3 Room for patient counseling & instruction (location may be separate from pharmacy area)
- 2.1-4.2.6.4 Room for education & training (may be multipurpose room shared with other departments)
- 2.1-4.2.6.5 Handwashing station
 - located in an anteroom
 - or**
 - located immediately outside each room where open medications are prepared
- 2.1-4.2.6.6 Outpatient medication consultation area
 - check if not included in project (only if no medications dispensed to outpatients)

Architectural Requirements

- 2.1-4.2.6.11 Unit Dose Procedure:
 - check if not included in project
 - ___ additional space & equipment to accommodate supplies, packaging, labeling & storage, including space for carts

SUPPORT AREAS FOR STAFF

- 2.1-4.2.7 (may be shared with other departments)
- 2.1-4.2.7.2
- 2.1-4.2.7.1 ___ Lounge &, lockers
 - ___ readily accessible for pharmacy staff
- ___ Toilet facilities
 - ___ readily accessible for pharmacy staff

Building Systems Requirements

- Ventilation:
- ___ Min. 10 air changes per hour Table 7.1
 - ___ Exhaust

Architectural Details & MEP Requirements

2.1-7.2.2 ARCHITECTURAL DETAILS

- 2.1-7.2.2.1 CORRIDOR WIDTH:
 - ___ Aisles, corridors & ramps in adjunct areas not intended for the housing, treatment, or use of inpatients not less than 44" in clear width
- 2.1-7.2.2.2 CEILING HEIGHT:
 - ___ Min. ceiling height 7'-10"
- 2.1-7.2.2.3 DOORS & DOOR HARDWARE:
 - (1)
 - (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
 - ___ code review sheet attached
 - ___ no floor tracks
 - (3) ___ Min. clear width 34.5"
 - ___ Doors do not swing into corridors (except doors to non-occupiable spaces & doors with emergency breakaway hardware)
 - (4)
 - (b) ___ Lever hardware
- 2.1-7.2.2.7 GLAZING MATERIALS:
 - (4) ___ Glazing within 18" of floor
 - check if not included in project
 - ___ safety glass, wire glass or plastic break-resistant material

- 2.1-7.2.2.8 HANDWASHING STATIONS:
 - (1) ___ Handw. stations in patient care areas located to be visible & unobstructed
 - (3) ___ Anchoring suitable for vertical or horizontal force of 250 lbs
 - (4) Handwashing Station Countertops:
 - check if not included in project
 - ___ porcelain, stainless steel or solid surface materials
 - ___ plastic laminate countertops
 - check if not included in project
 - ___ substrate marine-grade plywood (or equivalent) with impervious seal
 - (5) ___ Designed to prevent storage beneath sink
 - (6) ___ Provisions for drying hands
 - (a) ___ Hand-drying device does not require hands to contact dispenser
 - (d) ___ Directly accessible* to sinks
 - (7) ___ Liquid or foam soap dispensers

2.1-7.2.3 SURFACES

- 2.1-7.2.3.1 FLOORING & WALL BASES:
 - (1) ___ Selected flooring surfaces cleanable & wear-resistant for location
 - (2) ___ Smooth transitions between different flooring materials
 - (3) ___ Flooring surfaces stable, firm & slip-resistant
- 2.1-7.2.3.2 WALLS & WALL PROTECTION:
 - (1)
 - (a) ___ Washable wall finishes
 - (b) ___ Wall finishes near plumbing fixtures smooth, scrubbable & water-resistant

- 2.1-7.2.3.3 CEILINGS:
 (1) ___ Ceilings in pharmacy areas cleanable with routine housekeeping equipment
 ___ acoustic & lay-in ceilings
 ___ check if not included in project
 ___ do not create ledges or crevices

2.1-8.2 **HEATING, VENTILATION, & AIR-CONDITIONING (HVAC) SYSTEMS**

- 4/6.3.1 Outdoor Air Intakes:
 4/6.3.1.1 ___ Located min. 25 feet from cooling towers & all exhaust & vent discharges
 ___ Bottom of air intake is at least 6'-0" above grade
 Roof Mounted Air Intakes:
 ___ check if not included in project
 ___ bottom min. 3'-0" above roof level

- 4/6.3.2 Exhaust discharges:
 ___ Ductwork under negative pressure for exhaust air from chemical fume hoods (except in mechanical room)
 ___ check if not included in project (only if no cytotoxic IV prep room)
 ___ discharge in vertical direction at least 10'-0" above roof level
 ___ located not less than 10'-0" horizontally from air intakes & operable windows/doors

- 4/6.4 Filtration:
 ___ Filter banks conform to Table 6.4
 4/6.4.1 ___ Filter Bank #1 placed upstream of heating & cooling coils
 4/6.4.2 ___ Filter Bank #2 installed downstream of cooling coils & supply fan

- 4/6.7 Air Distribution Systems
 4/6.7.1 ___ Ducted return or exhaust systems in spaces listed in Table 7.1 with required pressure relationships

- 4/6.7.3 Smoke & Fire barriers:
 ___ HVAC zones coordinated with compartmentation to minimize ductwork penetrations of fire & smoke barriers

- 4/6.8 Energy Recovery Systems:
 4/6.8.2 ___ Exhaust systems serving potentially contaminated rooms are not used for energy recovery

- 4/6.9 Duct Lining:
 ___ No duct lining in ductwork located downstream of Filter Bank #2

- 4/7. Space Ventilation:
 4/7.1 ___ Spaces ventilated per Table 7.1
 ___ Air movement from clean areas to less clean areas
 ___ Min. number of total air changes indicated either supplied for positive pressure rooms or exhausted for negative pressure rooms
 ___ Recirculating room HVAC units
 ___ check if not included in project
 ___ each unit serves only single space
 ___ min. MERV 6 filter for airflow downstream of cooling coils

- (5) Acoustic Considerations:
 ___ Equipment location or acoustic provisions limit noise associated with outdoor mechanical equipment to 65 dBA at building façade

- 2.1-8.2.1.2 Ventilation & Space-Conditioning:
 (2) ___ Mechanical ventilation provided for all rooms & areas in facility in accordance with Table 7.1 of Part 4

- 2.1-8.2.3.2 Ventilation Hoods:
 (1) Exhaust Hoods & Safety Cabinets:
 ___ check if not included in project
 (b) ___ makeup air provided around exhaust hoods to maintain required airflow direction & exhaust velocity
 (c) ___ makeup systems for hoods arranged to minimize "short circuiting" of air & to avoid reduction in air velocity at point of contaminant capture

- (2) Fume Hoods:
 (a) ___ average face velocity min. 75 ft/minute
 ___ connection to exhaust system to outside is separate from building exhaust system
 ___ exhaust fan located at discharge end of system
 ___ exhaust duct system of noncombustible corrosion-resistant material

2.1-8.3 **ELECTRICAL SYSTEMS**

2.1-8.3.3.1 **EMERGENCY ELECTRICAL SERVICE**

- (1) ___ Emergency power per NFPA 99, NFPA 101 & NFPA 110

2.1-8.3.5 **ELECTRICAL EQUIPMENT**

- 2.1-8.3.5.2 Required handwashing station tied to building electrical service
 - check if not included in project
 - connected to essential electrical system

2.1-8.4.2 **PLUMBING & OTHER PIPING SYSTEMS**

2.1-8.4.3 **PLUMBING FIXTURES**

- 2.1-8.4.3.1 (1) Materials material used for plumbing fixtures non-absorptive & acid resistant

2.1-8.4.3.2 Handwashing Station Sinks:

- (1) basins reduce risk of splashing to areas where direct patient care is provided, sterile procedures are performed & medications are prepared
- (2) basin min. 144 square inches
- min. dimension 9 inches
- (3) made of porcelain, stainless steel, or solid-surface materials
- (5) water discharge point of faucets at least 10 inches above bottom of basin
- (7) anchoring for sinks withstands min. vertical or horizontal force of 250 lbs
- (8) fittings operated without using hands for sinks used by medical staff
- (a) blade handles or single lever
 - min. 4 inches long
 - provide clearance required for operation
- or**
- (b) sensor-regulated water fixtures
 - meet user need for temperature & length of time water flows
 - designed to function at all times & during loss of normal power

2.1-8.6.2 **ELECTRONIC SURVEILLANCE SYSTEMS**

- check if not included in project
- 2.1-8.6.2.2 Monitoring devices not readily observable by general public or patients
- 2.1-8.6.2.3 Receive power from emergency electrical system