COMPLIANCE CHECKLIST

IP27_Pharmacy Services

The following checklist is intended to be used in plan review applications for health care facilities submitted to Massachusetts Department of Public Health This checklist summarizes & references applicable requirements from Licensure Regulations & 2022 Edition of FGI Guidelines for Design & Construction of Hospitals Applicants must verify compliance of plans submitted to Department with all referenced requirements from Licensure Regulations & FGI Guidelines when completing this Checklist separate Checklist must be completed for each nursing unit hospital or clinic department or clinical suite

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

- NFPA 101 Life Safety Code (2012) & applicable related standards contained in appendices of Code
- State Building Code (780 CMR)
- Accreditation requirements of Joint Commission
- CDC Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities
- USP 797 USP 800 & Regulations of Massachusetts Board of Registration in Pharmacy
- Occupational Safety & Health Standards (OSHA)
- Accessibility Guidelines of 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 following instructions & included in plan submissions for Self-Certification Process or Abbreviated Review Process
2. This checklist must be completed by project architect or engineer based on design actually reflected in plans at time of completion of checklist
3. Each requirement line (___) of this Checklist must be completed exclusively with one of following marks unless otherwise directed in checklist If functional space is not affected by renovation project mark “E” may be indicated on requirement line (___) before name of 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 given required function (e.g patient room or exam room) that clarification should be provided in Project Narrative & requirement lines are understood to only address functional spaces that are involved in project

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

E = Requirement relative to existing suite or area that has been *licensed* for its designated function is *not affected* by construction project & *does not pertain to required direct support space* for specific service affected by project “E” must not be used for existing required support space associated with new patient care room or area

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

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

4. All room functions marked with "X" must be shown on plans with same name labels as in this checklist
5. Mechanical electrical & plumbing requirements are only partially mentioned in this checklist relevant section of FGI Guidelines must be used for project compliance with all MEP requirements & for waiver references
6. Oxygen vacuum medical air waste anesthesia gas disposal & instrument air outlets (if required) are identified respectively by abbreviations "OX" "VAC" "MA" “WAGD” & “IA”
7. Requirements referenced with “FI” result from formal interpretations from FGI Interpretations Task Group
8. The location requirements including asterisks (*) refer to definitions of Glossary in beginning section of FGI Guidelines & 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	
2.1-4.2	**PHARMACY SERVICES**		
2.1-4.2.1.2	**LOCATION**		
(1)	___ Pharmacy room or suite accessible to clinical areas of hospital		
(2)	___ Controlled access to pharmacy room or suite		
2.1-4.2.2	**PHARMACY AREAS**		
2.1-4.2.2.1	___ Dispensing facilities		
(1)	___ room or area for receiving unpacking & inventory control of materials used in pharmacy	Ventilation: ___ Min 4 air changes per hour ___ Positive pressure	Table 7-1
(2)	___ work counters & space for automated & manual dispensing activities		
(3)	___ extemporaneous compounding area ___ sink & 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		
2.1-4.2.2.2	___ Manufacturing facilities		
(1)	___ bulk compounding area	Ventilation: ___ Min 4 air changes per hour ___ Positive pressure	Table 7-1
(2)	___ provisions for packaging & labeling		
(3)	___ quality control area		
2.1-4.2.2.3	___ Storage (storage cabinets shelves or separate rooms or closets)		
(1)	___ bulk storage	Ventilation: ___ Min 4 air changes per hour ___ Positive pressure	Table 7-1
(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 <u>not</u> included in project		
2.1-4.2.3.1			
(1)	___ Layout of pharmacy precludes unrelated traffic through non-hazardous drug IV preparation rooms & hazardous drug IV preparation rooms		
(2)	___ Positive pressure non-hazardous IV preparation room & negative pressure hazardous drug IV prep room do not share robotic systems		

	Architectural Requirements	Building Systems Requirements
(3)	___ Compounding area & equipment comply with requirements of USP & state board of pharmacy requirements	
	___ Project Narrative includes documentation on how these requirements are met	
2.1-4.2.3.2	___ Non-hazardous IV preparation area	
	☐ check if not included in project	
	___ laminar-flow workstation designed for product protection	
(1)	___ laminar-flow workstation includes non-hydroscopic filter rated at 99.97 percent (HEPA filter)	
(2)	___ laminar-flow workstation have visible pressure gauge for detection of filter leaks or defects	
	___ complies with regulations of Board of Registration in Pharmacy 247 CMR 17.00	
2.1-4.2.3.3	___ Hazardous drug IV preparation room	
	☐ check if not included in project	
	___ separate room provided for preparation of hazardous drug IV admixtures under class II (type A2 B1 or B2) or class III biological safety cabinet	
	___ complies with regulations of Board of Registration in Pharmacy 247 CMR 19.00	
2.1-4.2.8	**SUPPORT AREAS FOR PHARMACY**	
2.1-4.2.8.2	___ Separate room or area provided for office functions	
2.1-4.2.8.3	___ Room for education & training (may be multipurpose room shared w/ other departments)	
2.1-4.2.8.4	___ Outpatient medication consultation area	
	☐ check if not included in project (only if medications are not dispensed to outpatients from hospital pharmacy area)	
2.1-4.2.8.7	Handwashing station	
(1)	___ Handwashing station is provided in each room where open medication is prepared for administration except where prohibited by USP requirements	
(2)	Sterile compounding room	
	☐ check if not included in project	
	___ handwashing station be provided in anteroom	
2.1-4.2.8.13	___ Unit dose procedure used	
	☐ check if not included in project	
	___ additional equipment & supply storage	
	___ space for carts	

	Architectural Requirements	**Building Systems Requirements**
2.1-4.2.9	**SUPPORT AREAS FOR STAFF**	
2.1-4.2.9.2	(may be outside pharmacy area & shared with other departments) ___ Readily accessible* to pharmacy	
2.1-4.2.9.1	___ Lounge ___ Locker facilities ___ Staff toilet room	Ventilation: ___ Min 10 air changes per hour Table 7-1 ___ Exhaust ___ Negative pressure ___ No recirculating room units

*LOCATION TERMINOLOGY:

Directly accessible: Connected to 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 identified area or room

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

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

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 & unobstructed width

2.1-7.2.2.2 CEILING HEIGHT:
(1)
___ Min. ceiling height 7’-6” in corridors & in normally unoccupied spaces
___ 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

(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

2.1-7.2.2.7 GLAZING MATERIALS:
___ Glazing within 1 foot 6 inches of floor must be safety glass, wire glass or plastic break-resistant material

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 & to ensure single-unit dispensing
(6) ___ liquid or foam soap dispensers
(7) ___ no mirror at hand scrub stations or at handwashing stations in food preparation areas & clean & sterile supply areas

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

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

(5) ___ 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 not create ledges or crevices

2.1-8.2 **HEATING VENTILATION & AIR-CONDITIONING (HVAC) SYSTEMS**
Part 3/6.1.2 Heating & Cooling Sources:
Part 3/6.1.2.1 ___ provide heat sources & essential accessories in number & arrangement sufficient to accommodate facility needs (reserve capacity) even when any one of heat sources or essential accessories is not operating due to breakdown or routine maintenance
___ capacity of remaining source or sources is sufficient to provide for domestic hot water sterilization & dietary purposes; fuel sufficient to support owner's facility operation plan upon loss of fuel service is provided on site

Part 3/6.1.2.2 Central cooling systems greater than 400 tons (1407 kW) peak cooling load
☐ check if not included in project
___ number & arrangement of cooling sources & essential accessories is sufficient to support owner's facility operation plan upon breakdown or routine maintenance of any one of cooling sources.

Part 3/6.2 AIR-HANDLING UNIT (AHU) DESIGN:
Part 3/6.2.1 ___ AHU casing is designed to prevent water intrusion, resist corrosion & permit access for inspection & maintenance

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Part 3/6.3 OUTDOOR AIR INTAKES & EXHAUST DISCHARGES:
Part 3/6.3.1 Outdoor Air Intakes:
Part 3/6.3.1.1 ___ located such that shortest distance from intake to any specific potential outdoor contaminant source be equal to or greater than separation distance listed in Table 6-1
___ located min. of 25 ft from cooling towers & all exhaust & vent discharges
___ facilities with moderate-to-high risk of natural or man-made extraordinary incidents locate new air intakes away from public access
___ all intakes are designed to prevent entrainment of wind-driven rain
___ contain features for draining away precipitation
___ equipped with birdscreen of mesh no smaller than 0.5 in

Part 3/6.3.1.4 ___ intake in areaway
☐ check if not included in project
___ bottom of areaway air intake opening is at least 6 ft above grade
___ bottom of air intake opening from areaway into building is at least 3 ft above bottom of areaway

Part 3/6.3.2 Exhaust Discharges:
Part 3/6.3.2.1 ___ ductwork within building is under negative pressure for exhaust of contaminated air (i.e. air from AII rooms bronchoscopy & sputum collection exhaust, pharmacy hazardous-drug exhausted enclosures & laboratory work area chemical fume hoods)
___ exhaust discharge outlets with contaminated air located such that they reduce potential for recirculation of exhausted air back into building

Part 3/6.3.2.2 ___ exhaust discharge outlets with contaminated air additionally is arranged to discharge to atmosphere in vertical direction at least 10 ft above adjoining roof level

Part 3/6.4 FILTRATION:
a. ___ Particulate matter filters, minimum 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 7-1
c. ___ Air supplied from equipment serving multiple or different spaces is filtered in accordance with Table 7-1
d. ___ Air recirculated within room be filtered in accordance with Table 7-1 or Section 7.1(a)(5)
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 minimum filter efficiency of MERV-14, MERV-16 or HEPA in accordance with Table 7-1, the min. filter requirement listed in Table 7-1 is installed 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 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 6-2

Part 3/6.7.3 Smoke Barriers:
___ HVAC zones coordinated with compartmentation to minimize ductwork penetrations of fire & smoke barriers.

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 3/7 SPACE VENTILATION - HOSPITAL SPACES:
Part 3/7.1.a ___ Spaces ventilated according to Table 7-1
___ Air movement is from clean to less-
Part 3/7.1.a.1 clean areas
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 7-1 for each space meet filtration requirements of Section 6.4

Part 3/7.1a.5 ___ Air recirculation through room unit
☐ check if not included in project
___ complies with Table 7-1
___ room unit receive filtered & conditioned outdoor air
___ serve only a single space
___ provides min MERV 8 filter located upstream of any cold surface so that all of air passing over cold surface is filtered

2.1-8.3 **ELECTRICAL SYSTEMS**

2.1-8.3.2 **ELECTRICAL DISTRIBUTION & TRANSMISSION**

2.1-8.3.2.2 Panelboards:
(1) ___ panelboards serving life safety branch circuits serve floors on which they are located & floors immediately above & below
(2) ___ panelboard critical branch circuits serve floors on which they are located
(3) ___ panelboards not located in exit enclosures or exit passageways

2.1-8.3.3 **POWER-GENERATING & -STORING EQUIPMENT**

2.1-8.3.3.1 ___ Essential electrical system or emergency electrical power
(1) ___ essential electrical system complies with NFPA 99
(2) ___ emergency electrical power complies with NFPA 99

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
2.1-8.3.5.2 ___ Electronic health record system servers & centralized storage provided with uninterruptible power supply

2.1-8.3.6 **ELECTRICAL RECEPTACLES**

2.1-8.3.6.1 Receptacles In Corridors:

(1) ___ duplex-grounded receptacles for general use installed 50'-0" apart or less in all corridors

___ duplex-grounded receptacles for general use installed within 25'-0" of corridor ends

2.1-8.3.6.3 Essential Electrical System Receptacles:

(1) ___ cover plates for electrical receptacles supplied from essential electrical system are distinctively colored or marked for identification

(2) ___ same color is used throughout facility

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

___ no plumbing piping exposed overhead or on walls where leaks would create potential for food contamination

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 does not exceed 25'-0" in length

(3)(a) ___ no installation of dead-end piping (except for empty risers mains &

(3)(c) 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 temperatures & amounts indicated in Table 2.1-4

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 or oversized drip pans) to protect space below from leakage & condensation

- operating rooms
- delivery rooms
- procedure rooms
- trauma rooms
- nurseries
- central kitchens
- one-room sterile processing facilities
- clean workroom of two-room sterile processing facilities
- pharmacies
- Class 2 & 3 imaging rooms
- electronic mainframe rooms (EFs & TERs)
- main switchgear
- electrical rooms
- electronic data processing areas
- electric closets

(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 that is not open to restricted 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:

(1) ___ designed with basins & faucets that reduce risk of splashing to areas where direct patient care is provided, sterile procedures are performed, medications are prepared or food is prepared

(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 inches 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 medical & nursing staff, patients, public & food handlers 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

2.1-8.6.2 **ELECTRONIC SURVEILLANCE SYSTEMS**
☐ check if not included in project

2.1-8.6.2.1 ___ Display screens in patient areas are mounted in tamper-resistant enclosure that is unobtrusive

2.1-8.6.2.2 ___ Display screens are located so they are not readily observable by general public or patients

2.1-8.6.2.3 ___ Electronic surveillance systems receive power from essential electrical system