

Surveyor Guidance Checklist for On Site Activity:
Sterile Medication Compounding Assessment
Hospital Accreditation Program (HAP)

X	Assessment Item	Guidance	Joint Commission Standard	CMS CoP to crosswalk
Certification/Testing Report Evaluation				
	Primary Engineering Control ISO Level	<ul style="list-style-type: none"> Must be ISO 5 or less 	MM.05.01.07 EP 4	482.23(c)
	Primary Engineering Control Viable Particle Testing <i>Surface</i>	<ul style="list-style-type: none"> Value must be at or less than 3 CFU/cubic meter 	IC.02.01.01 EP 1	482.42
	Primary Engineering Control Viable Particle Testing <i>Air</i>	<ul style="list-style-type: none"> Value must be at or less than 1 CFU/cubic meter 	IC.02.01.01 EP 1	482.42
	Primary Engineering Control HEPA filter leak test	<ul style="list-style-type: none"> Must show passed or evidence that holes were patched. 	IC.02.01.01 EP 1	482.42
	Secondary Engineering Control Air Exchanges per Hour	<ul style="list-style-type: none"> Must have 30/hour. Compounding hood can contribute up to 15 to complete the 30. 	EC.02.05.01 EP 15	482.42
	Secondary Engineering Control Air Pressure Differential	<ul style="list-style-type: none"> Buffer area= <ul style="list-style-type: none"> Non-hazardous = + 0.02-0.05" H₂O to unclassified space Hazardous = - 0.01" H₂O Ante area = positive to unclassified space 	EC.02.05.01 EP 15	482.42
	Secondary Engineering Control ISO Level	<ul style="list-style-type: none"> Buffer area must ISO 7 or less Ante area must be ISO 8 or less 	EC.02.06.01 EP 1	482.41(a)
	Secondary Engineering Control Viable Particle Testing <i>Surface</i>	<ul style="list-style-type: none"> Buffer area value must be at or less than 5 CFU/cubic meter Ante area value must be at or less than 100 CFU/cubic meter 	IC.02.01.01 EP 1	482.42
	Secondary Engineering Control Viable particle testing <i>Air</i>	<ul style="list-style-type: none"> Buffer area value must be at or less than 10 CFU/cubic meter Ante area value must be at or less than 100 CFU/cubic meter 	IC.02.01.01 EP 1	482.42
	Secondary Engineering Control HEPA filter leak test	<ul style="list-style-type: none"> Must show passed or evidence that holes were patched. 	IC.02.01.01 EP 1	482.42
	Evidence of action taken by organization when any item is out of range	<ul style="list-style-type: none"> There must be evidence of remediation actions taken when items do not pass and subsequent testing to ensure compliance. If this is not present then must be scored. 	LD.04.01.01 EP 3	N/A
	Primary Engineering Control certification / testing frequency	<ul style="list-style-type: none"> Each component listed above must be tested and certified every 6 months. Lack of 6 month interval must be scored Also any time PEC is moved or relocated 	EC.02.04.01 EP 4	483.41(d)(2)
	Secondary Engineering Control certification / testing frequency	<ul style="list-style-type: none"> Each component listed above must be tested and certified every 6 months. Lack of 6 month interval must be scored 	EC.02.06.01 ep 1	482.41(a)
	Air flow monitoring	<ul style="list-style-type: none"> must have continuous monitoring 	EC.02.05.01 EP 15	482.42
Compounding Evaluation				
Room Structure				
	Floors	<ul style="list-style-type: none"> Must be solid and coved on corners to prevent 90 degree angles where floor meets wall No rips/tears ; check corners for dust 	EC.02.06.01 EP 1	482.41(a)
	Ceiling	<ul style="list-style-type: none"> Must be solid material or with sealed down in ceiling tiles (tiles must be caulked into place) 	EC.02.06.01 EP 1	482.41(a)

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		<ul style="list-style-type: none"> Sprinkler heads should be inset with pop outs, if not check for dust 		
	Walls	<ul style="list-style-type: none"> Must be smooth with no cracks Where flooring meets walls must not have a ledge 	EC.02.06.01 EP 1	482.41(a)
	Primary Engineering Control placement	<ul style="list-style-type: none"> Must be placed in an area with ISO 7 or less (if not then can only use a 12 hour BUD) 	MM.05.01.07 EP 2	482.23 (c)
Staff Handwashing/PPE Garbing				
		<ul style="list-style-type: none"> Handwashing must occur to elbows minimum 30 seconds Staff wear no make-up, jewelry, or outer garments(sweaters, hoodies, etc) 	IC.02.01.01 EP 1	482.42
		<ul style="list-style-type: none"> Observe order of donning of PPE which must be from dirtiest to cleanest 	IC.02.01.01 EP 2	482.42
Primary Engineering Control Cleaning				
		<ul style="list-style-type: none"> Sterile alcohol must be utilized to clean the hoods 	IC.02.01.01 EP 2	482.42
		<ul style="list-style-type: none"> Direction of cleaning depends on airflow direction of hood 	MM.05.01.07 EP 2	482.23 (c)
		<ul style="list-style-type: none"> Cleaning must be done with lint free cloths (not gauze) 	MM.05.01.07 EP 2	482.23 (c)
Sterile Compounding Observation				
	Item placement	<ul style="list-style-type: none"> Items are wiped down with sterile alcohol as they enter the compounding hood 	MM.05.01.07 EP 2	482.23 (c)
		<ul style="list-style-type: none"> Items must be placed 6 inches from all sides of the hood including the front 	MM.05.01.07 EP 2	482.23 (c)
	Protecting critical sites	<ul style="list-style-type: none"> The following sites can never be touch: <ul style="list-style-type: none"> Any part of the needle; septum of the vial; the sides of the plunger of syringe Placement of hands must never block first air to critical points 	MM.05.01.07 EP 2	482.23 (c)
	Single Dose Vial Use	<ul style="list-style-type: none"> Single dose vials can be used for up to 6 hours if they are kept within the ISO 5 environment. If they are removed from the environment then they may be used for 1 hour from initial puncture 	MM.05.01.07 EP1	N/A
	Large Volume Bags	<ul style="list-style-type: none"> 1 liter bags of sterile water for injection are usable for up to 6 hours if kept in the hood 2 liter bags and larger follow manufacture IFU 	If not labeled: MM.03.01.01 EP 7 If used beyond MIFU: MM.03.01.01 EP 2	N/A N/A
	Limited storage in buffer area	<ul style="list-style-type: none"> Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area 	MM.05.01.07 EP 2	482.23 (c)
	Compounder Glove cleaning	<ul style="list-style-type: none"> Should be conducted any time hands leave ISO 5 Use sterile alcohol 	MM.05.01.07 EP 2	482.23 (c)
	CAI/CACI glove exchange	<ul style="list-style-type: none"> This should occur based on manufacturer IFU. 	EC.02.04.01 EP 4	483.41(d)(2)
	Product labeling	<ul style="list-style-type: none"> If BUD is based on refrigeration then must have a store in refrigerator (or similar sticker) label 	MM.05.01.09 EP 12	N/A
PEC/SEC Cleaning				
	Cleaning frequency for SEC	<ul style="list-style-type: none"> Daily – floors and easily cleanable work surfaces Monthly – walls, ceiling, storage shelves 	IC.02.01.01 EP 1	482.42
	Cleaning frequency for PEC	<ul style="list-style-type: none"> At the beginning of each work shift Before each batch preparation is started Every 30 minutes during continuous compounding periods of individual CSPs When there are spills 	MM.05.01.07 EP 2	482.23(c)

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		<ul style="list-style-type: none"> When surface contamination is known or suspected from procedural breaches 		
	Cleaning products	<ul style="list-style-type: none"> ORG selects agent – ensure proper dilution 	IC.02.01.01 EP 1	482.42
	Cleaning order not correct for PEC	<ul style="list-style-type: none"> Based on direction of airflow of hood Always cleanest to dirtiest 	MM.05.01.07 EP 2	482.23 (c)
	Cleaning order not correct for SEC	<ul style="list-style-type: none"> Always cleanest to dirtiest 	IC.02.01.01 EP 1	482.42
High Risk Compounding Additions				
	Sterilization Process Performed (if not done: Call SIG)	<ul style="list-style-type: none"> Any product which is classified as High Risk Compounding MUST go through a sterilization process 	MM.05.01.07 EP 1	482.25(b)(1)
	Sterilization Record Keeping	<ul style="list-style-type: none"> Records must have at minimum: <ul style="list-style-type: none"> Compounder Name Date of Products sterilization Identifier of products in this batch (Lot) Results of indicators (for biological must have evidence of control and tested BI) description of sterilization conditions and duration (if not by filtration) 	MM.05.01.11 EP 2	482.25(b)(1)
	Sterilization QA Process completed (if not done: Call SIG)	<ul style="list-style-type: none"> If sterilization by filtration <ul style="list-style-type: none"> Must have test of filter after sterilization completed based on IFU If sterilization by all other methods QA Testing required includes biological indicator in every load and temperature sensing device (can be part of hardware of sterilizer) 	MM.05.01.07 EP 1	482.25(b)(1)
	Bacterial Endotoxin (Pyrogen) Testing	<ul style="list-style-type: none"> Required when High Risk Compounds are: <ul style="list-style-type: none"> Prepared in groups of more than 25 identical individual single-dose packages multiple-dose vials (MDVs) for administration to multiple patients Exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized before they are dispensed or administered. If required and not completed, call SIG 	MM.05.01.07 EP 1	482.25(b)(1)
	Sterility Testing	<ul style="list-style-type: none"> Required when High Risk Compounds are: <ul style="list-style-type: none"> Prepared in groups of more than 25 identical individual single-dose packages multiple-dose vials (MDVs) for administration to multiple patients Exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized before they are dispensed or administered. If required and not completed, call SIG 	MM.05.01.07 EP 1	482.25(b)(1)
Hazardous Compounding Additions				
	PEC type utilized	<ul style="list-style-type: none"> Must utilize either a biological safety cabinet or a CACI 	If in policy MM.01.01.03 EP 3 If not in policy MM.01.01.03 EP 2	N/A N/A

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	PPE utilization	<ul style="list-style-type: none"> Must wear 2 pairs of chemotherapy gloves (sterile) 	If in policy MM.01.01.03 EP 3 If not in policy MM.01.01.03 EP 2	N/A N/A
	SEC Design – physical location	<ul style="list-style-type: none"> Must have limited access to only those who need to access area 	EC.02.02.01 EP 5	482.41(a)
Beyond Use Dating (unless sterility testing has been done to extend the dating listed below)				
	Immediate Use	<ul style="list-style-type: none"> 1 hour from start of compounding 	MM.05.01.07 EP 5	482.23(c)
	Low Risk Compounding	<ul style="list-style-type: none"> Room Temperature: 48 hours Refrigerator: 14 days Freezer: 45 days 	MM.05.01.07 EP 5	482.23(c)
	Medium Risk Compounding	<ul style="list-style-type: none"> Room Temperature: 30 hours Refrigerator: 9 days Freezer: 45 days 	MM.05.01.07 EP 5	482.23(c)
	High Risk Compounding	<ul style="list-style-type: none"> Room Temperature: 24 hours Refrigerator: 3 days Freezer: 45 days 	MM.05.01.07 EP 5	482.23(c)
Compounding Staff Competency Evaluation				
	Required competencies	<ul style="list-style-type: none"> For compounding pharmacy staff members Minimum required competencies: <ul style="list-style-type: none"> Didactic Testing (Organization must define “pass” score) Visual observation of hand washing, donning PPE Media Fill Test Gloved Finger Tip Testing (x3 for initial) 	HR.01.06.01 EP 1	N/A
	Media-Fill Test	<ul style="list-style-type: none"> The test complexity must match the complexity level of compounding. Low/Medium Risk versus High Risk 	Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	N/A
	Gloved Fingertip Testing <i>Initial</i>	<ul style="list-style-type: none"> 3 separate test required To pass test cannot exceed “0” CFU 	HR.01.06.01 EP 5	N/A
	Gloved Fingertip Testing <i>Ongoing</i>	<ul style="list-style-type: none"> Ongoing test requires one sample only To pass test cannot exceed 3 CFU 	HR.01.06.01 EP 6	N/A
	Observation Competency	<ul style="list-style-type: none"> Includes following items <ul style="list-style-type: none"> Garbing of PPE Aseptic Technique 	Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	N/A
	Didactic Written testing	<ul style="list-style-type: none"> Hazardous compounding must be incorporated if applicable to compounder reviewed 	Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	N/A