Version 2020.3

Surveyor Guidance Checklist for On Site Activity: Sterile Compounding Assessment

Hospital Accreditation Program (HAP)

Surveyors should utilize the appropriate column for hazardous medications based on determine organization hazardous medication preparation chapter utilization

X	Assessment Item	2008 USP 797 for Non-Hazardous Medication Compounding	2008 USP 797 for Hazardous Medication Compounding	USP 800 for Hazardous Medication Compounding	Joint Commission Standard	CMS CoP
	Primary Engineering Control ISO Level	• Must be ISO 5 or less	• Must be ISO 5 or less	• Must be ISO 5 or less	MM.05.01.07 EP2	482.25(b)(1)
	Primary Engineering Control Viable Particle Testing *Surface**	• Value must be at or less than 3 CFU/plate or swab • Must be completed at least every 6 months	• Value must be at or less than 3 CFU/plate or swab • Must be completed at least every 6 months	• Value must be at or less than 3 CFU/plate or swab • Must be completed at least every 6 months	IC.02.01.01 EP1	482.25(b)(1)
	Primary Engineering Control Viable Particle Testing *Air**	• Value must be at or less than 1 CFU/cubic meter • Must be completed at least every 6 months	• Value must be at or less than 1 CFU/cubic meter • Must be completed at least every 6 months	• Value must be at or less than 1 CFU/cubic meter • Must be completed at least every 6 months	IC.02.01.01 EP1	482.25(b)(1)
	Primary Engineering Control HEPA filter leak test	• If testing method listed is CETA-CAG then leak testing must be done every certification. • Must show passed or evidence that holes were patched.	• If testing method listed is CETA-CAG then leak testing must be done every certification. • Must show passed or evidence that holes were patched.	• If testing method listed is CETA-CAG then leak testing must be done every certification. • Must show passed or evidence that holes were patched.	IC.02.01.01 EP1	482.25(b)(1)
	Secondary Engineering Control Air Exchanges per Hour	• Must have 30/hour. Compounding hood can contribute up to 15 to complete the 30.	• Must have at least 30/hour. Compounding hood can contribute up to 15 to complete the 30.	• Must have at least 30/hour.	EC.02.05.01 EP15	482.25(b)(1)
	Secondary Engineering Control Air Pressure Differential	• Buffer area= must be at least + 0.02" H_20 to unclassified space • Ante area = positive to pharmacy area	• Buffer area= at least - 0.01" H_20 to adjacent space • Ante area = positive to unclassified space (pharmacy)	• Buffer area= - 0.01 to -0.03" H_20 to adjacent space • Ante area = positive to unclassified space	EC.02.05.01 EP15	482.25(b)(1)
	Secondary Engineering Control ISO Level	• Buffer area must ISO 7 or less • Ante area must be ISO 8 or less;	• Buffer area must ISO 7 or less • Ante area must be ISO 7 or less	• Buffer area must ISO 7 or less • Ante area must be ISO 7 or less	EC.02.06.01 EP1	482.25(b)(1)
	Secondary Engineering Control Viable Particle Testing *Surface**	• Buffer area: at or less than 5 CFU/plate or swab • Ante area: at or less than 100 CFU/ plate or swab	• Buffer area: at or less than 5 CFU/ plate or swab • Ante area: at or less than 100 CFU/ plate or swab	• Buffer area: at or less than 5 CFU/ plate or swab • Ante area: at or less than 100 CFU/ plate or swab	IC.02.01.01 EP1	482.25(b)(1)

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		• Must be completed at least every 6 months	• Must be completed at least every 6 months	• Must be completed at least every 6 months		
	Secondary Engineering Control Viable particle testing *Air**	• Buffer area at or less than 10 CFU/cubic meter • Ante area at or less than 100 CFU/cubic meter • Must be completed at least every 6 months	• Buffer area at or less than 10 CFU/cubic meter • Ante area at or less than 100 CFU/cubic meter • Must be completed at least every 6 months	• Buffer area at or less than 10 CFU/cubic meter • Ante area at or less than 100 CFU/cubic meter • Must be completed at least every 6 months	IC.02.01.01 EP1	482.25(b)(1)
	Secondary Engineering Control HEPA filter	• Must show passed or evidence that holes were patched. • If testing reference is CETA-CAG for SEC then HEPA filter must be checked every certification • If testing reference is USP 797, for SEC then HEPA filter testing required upon installation only	• Must show passed or evidence that holes were patched. • If testing reference is CETA-CAG for SEC then HEPA filter must be checked every certification • If testing reference is USP 797, for SEC then HEPA filter testing required upon installation only	• Must show passed or evidence that holes were patched. • If testing reference is CETA-CAG for SEC then HEPA filter must be checked every certification • If testing reference is USP 797, for SEC then HEPA filter testing required upon installation only	IC.02.01.01 EP1	482.25(b)(1)
	Evidence of action taken by organization when any item is out of range	• 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.	• 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.	• 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 EP3	482.25(b)(1)
	Primary Engineering Control certification / testing frequency	• 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	• 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	• 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 EP4	482.25(b)(1)
	Secondary Engineering Control certification / testing frequency	• Each component listed above must be tested and certified every 6 months.	• Each component listed above must be tested and certified every 6 months.	• Each component listed above must be tested and certified every 6 months.	EC.02.06.01 EP1	482.25(b)(1)

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	Cleanroom Temperature	• No temperature/humidity level requirement. • Required to monitor and document a daily value of temperature.	• No temperature/humidity level requirement. • Required to monitor and document a daily value of temperature.	• No temperature/humidity level requirement. • Required to monitor and document a daily value of temperature.	Not monitoring: EC.02.05.01 EP 15	482.25(b)(1)
	Segregated Compounding Area (SCA)	• Location should be segregated from normal operations •	• Hazardous preparation is prohibited in SCA	**Containment SCA (C-SCA)** • Negative pressure between 0.01 and 0.03inches of water to adjacent spaces • Minimum 12 ACPH HEPA filtered supply air • Hand washing sink must be placed at least 1 meter from C-PEC • Only low /medium risk HD CSP • Must be externally vented • Must have fixed walls and door	EC.02.06.01 EP1	482.25(b)(1)
Compounding Evaluation						
Room Structure (Hazardous and Non-Hazardous Sterile Compounding in Classified Locations)						
	Floors	• Must be solid and coved on corners • No rips/tears; check corners for dust	• Must be solid and covered on corners • No rips/tears; check corners for dust	• Must be solid and covered on corners • No rips/tears; check corners for dust	EC.02.06.01 EP1	482.25(b)(1)
	Ceiling	• Must be solid material or with sealed drop in ceiling tiles (tiles must be caulked into place) • Sprinkler heads preferred to be inset with pop outs, if not check for dust	• Must be solid material or with sealed drop in ceiling tiles (tiles must be caulked into place) • Sprinkler heads preferred to be inset with pop outs, if not check for dust	• Must be solid material or with sealed drop in ceiling tiles (tiles must be caulked into place) • Sprinkler heads preferred to be inset with pop outs, if not check for dust	EC.02.06.01 EP1	482.25(b)(1)
	Walls	• Must be smooth with no cracks • Must withstand cleaning activity • Where flooring meets walls if ledge exists, check for dust.	• Must be smooth with no cracks • Must withstand cleaning activity • Where flooring meets walls if ledge exists, check for dust.	• Must be smooth with no cracks • Where flooring meets walls if ledge exists, check for dust. • Must withstand cleaning activity	EC.02.06.01 EP1	482.25(b)(1)

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	Primary Engineering Control placement	• Must be placed in an area with ISO 7 or less (if not then can only use a 12- hour BUD)	• Must be placed in an area with ISO 7 or less with an attached buffer space • May utilize CSTD for low volume in a non-negative space	• Must be placed in an area with ISO 7 or less • May utilize a C-SCA. See C-SCA for requirements	MM.05.01.07 EP 2	482.25(b)(1)
	Additional structural requirements			• Must have signage posted for hazardous medication handling areas	EC.02.06.01 EP1	482.25(b)(1)
Staff Handwashing/PPE Garbing (Hazardous and Non-Hazardous Sterile Compounding)						
	Hand Hygiene	• Handwashing must occur up to elbows minimum 30 seconds	• Handwashing must occur up to elbows minimum 30 seconds	• Handwashing must occur up to elbows minimum 30 seconds	IC.02.01.01 EP2	482.25(b)(1)
	Restricted items	• Staff wear no make-up, jewelry, or outer garments (sweaters, hoodies, etc)	• Staff wear no make-up, jewelry, or outer garments (sweaters, hoodies, etc)	• Staff wear no make-up, jewelry, or outer garments (sweaters, hoodies, etc)	IC.02.01.01 EP1	482.25(b)(1)
	Order of PPE donning	• Observe order of donning of PPE which must be from dirtiest to cleanest	• Observe order of donning of PPE which must be from dirtiest to cleanest and per organization policy	• Observe order of donning of PPE which must be from dirtiest to cleanest	IC.02.01.01 EP1	482.25(b)(1)
	PPE Utilization (gloves)	• Must utilize sterile gloves	• Must wear 2 pairs of chemotherapy gloves (sterile)	• Must be double gloved. • Only outer glove must be sterile • Gloves must be ASTM D6978 or equivalent • Must be changed when torn, punctured or contaminated • Must be powder-free • If worn during compounding, must be carefully removed and discarded immediately in an approved HD waste container inside C-PEC or contained in a sealable bag for discarding outside C-PEC.	IC.02.01.01 EP 2	482.25(b)(1)
	Use of non-sterile products in	• Call central office for guidance. Prior to calling find out how they	• Call central office for guidance. Prior to calling find	• Call central office for guidance. Prior to calling find out how they		

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	preparing sterile compounded preparations	quality assure the sterilization process of the final product.	out how they quality assure the sterilization process of the final product.	quality assure the sterilization process of the final product.		
Sterile Compounding Observation (Hazardous and Non-Hazardous Sterile Compounding)						
	Primary Engineering Control Parameters	• May utilize any type of PEC for these preparations	• Must utilize one of the following types of PEC: • BSC or CACI	• Must utilize either • BSC or CACI • Must be externally vented	EC.02.05.01 EP15	482.25(b)(1)
	Item placement in PEC	• Item placement should be based on IFU of PEC and smoke studies • Items are wiped down with sterile alcohol as they enter the compounding hood	• Item placement should be based on IFU of PEC and smoke studies • Items are wiped down with sterile alcohol as they enter the compounding hood	• Item placement should be based on IFU of PEC and smoke studies • Items are wiped down with sterile alcohol as they enter the compounding hood	MM.05.01.07 EP2	482.25(b)(1)
	Protecting critical sites	• The following sites can never be touched: o 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	• The following sites can never be touched: o 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	• The following sites can never be touched: o 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 EP2	482.25(b)(1)
	Single Dose Vial Use	• 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 must be used for 1 hour from initial puncture	• 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 must be used for 1 hour from initial puncture	• 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 must be used for 1 hour from initial puncture	If wrong BUD: MM.03.01.01 EP2 No label with BUD: MM.03.01.01 EP 7 If not wiped down: IC.02.01.01 EP 2	482.25(a) 482.25(a) 482.25(b)(1)
	Large Volume Bags	• 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 manufacturer IFU	• 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 manufacturer IFU	• 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 manufacturer IFU	If not labeled: MM.03.01.01 EP 7 If used beyond MIFU: MM.03.01.01 EP 2	482.25(a) 482.25(a)

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	Limited storage in classified area	• Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area	• Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area	• 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 EP2	482.25(b)(1)
	Compounder Glove disinfecting	• Should be conducted any time hands leave ISO 5 • Use sterile alcohol	• Should be conducted any time hands leave ISO 5 • Use sterile alcohol	• Should be conducted any time hands leave ISO 5 • Use sterile alcohol	MM.05.01.07 EP2	482.25(b)(1)
	CAI/CACI glove exchange	• This should occur based on manufacturer IFU.	• This should occur based on manufacturer IFU.	• This should occur based on manufacturer IFU.	EC.02.04.01 EP4	482.25(b)(1)
	Product labeling	• If BUD is based on refrigeration, then must have a store in refrigerator (or similar sticker) label	• If BUD is based on refrigeration, then must have a store in refrigerator (or similar sticker) label	• If BUD is based on refrigeration, then must have a store in refrigerator (or similar sticker) label	If wrong BUD: MM.03.01.01 EP2 No label with BUD: MM.03.01.01 EP 7	482.25(a) 482.25(a)
	Immediate Use CSP	• Must have clean uncluttered area • Must use aseptic technique • Organization defines competency requirements, if any • Labeling must follow Joint Commission requirements. • Compliance with MM.05.01.07 EP 1 must be evaluated.	• Not allowed	• Not allowed	MM.05.01.07 EP5	482.23(c)
PEC/SEC Cleaning/Disinfecting/Decontamination/Sporicidal Application						
	Primary Engineering Control *Decontamination*	• Not specifically required in USP 797 Chapter	• Not specifically required in USP 797 Chapter	**Frequency** • At least daily (when used) • Any time a spill occurs • Before and after certification • Any time voluntary interruption occurs • When the C-PEC is tested/certified • Area under work tray is Monthly **Decontamination order** • Based on direction of airflow of hood	**Frequency** MM.05.01.07 EP 2 **Cleaning order** MM.05.01.07 EP 2	482.25(b)(1)

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				• Always cleanest to dirtiest **Product Selection** • Completed by organization • Ensure proper dilution of products utilized	**Product Selection** IC.02.01.01 EP 1	482.25(b)(1)
	Primary Engineering Control *Cleaning/Disinfection*	**Frequency** • 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 • When surface contamination is known or suspected from procedural breaches **Cleaning order** • Based on direction of airflow of hood • Always cleanest to dirtiest **Product Selection** • Completed by organization • If mixing required, ensure proper dilution of products utilized	**Frequency** • 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 • When surface contamination is known or suspected from procedural breaches **Cleaning order** • Based on direction of airflow of hood • Always cleanest to dirtiest **Product Selection** • Completed by organization • Ensure proper dilution of products utilized	**Frequency** • 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 • When surface contamination is known or suspected from procedural breaches **Cleaning order** • Based on direction of airflow of hood • Always cleanest to dirtiest **Product Selection** • Completed by organization • Ensure proper dilution of products utilized	**Frequency** MM.05.01.07 EP 2 **Cleaning order** MM.05.01.07 EP 2 **Product Selection** IC.02.01.01 EP 1	482.25(b)(1) 482.25(b)(1) 482.25(b)(1)
	Secondary Engineering Control *Decontamination / Cleaning*	**Frequency** • Daily – floors and easily cleanable work surfaces • Monthly – walls, ceiling, storage shelves	**Frequency** • Daily – floors and easily cleanable work surfaces • Monthly – walls, ceiling, storage shelves	**Frequency** • Daily – floors and easily cleanable work surfaces • Monthly – walls, ceiling, storage shelves	IC.02.01.01 EP 1	482.25(b)(1)
Beyond Use Dating (unless sterility testing has been done to extend the dating listed below)						
	Immediate Use	• 1 hour from start of compounding	• Not permitted for hazardous medication	• Not permitted for hazardous medication	MM.05.01.07 EP5	482.25(b)(1)

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	Beyond Use Dating	**Low Risk Compounding:** • Room Temperature: 48 hours • Refrigerator: 14 days • Freezer: 45 days **Medium Risk Compounding:** • Room Temperature: 30 Hours • Refrigerator: 9 days • Freezer: 45 days **High Risk Compounding:** • Room Temperature: 24 Hours • Refrigerator: 3 days • Freezer: 45 days	**Low Risk Compounding:** • Room Temperature: 48 hours • Refrigerator: 14 days • Freezer: 45 days **Medium Risk Compounding:** • Room Temperature: 30 Hours • Refrigerator: 9 days • Freezer: 45 days **High Risk Compounding:** • Room Temperature: 24 Hours • Refrigerator: 3 days • Freezer: 45 days	**Low Risk Compounding:** • Room Temperature: 48 hours • Refrigerator: 14 days • Freezer: 45 days **Medium Risk Compounding:** • Room Temperature: 30 Hours • Refrigerator: 9 days • Freezer: 45 days **High Risk Compounding:** • Room Temperature: 30 Hours • Refrigerator: 3 days • Freezer: 45 days	MM.05.01.07 EP5	482.25(b)(1)
Compounding Staff Competency Evaluation						
	Defining required ***competencies*** *For compounding pharmacy staff members OR anyone utilizing a PEC*	Minimum required competencies: • Didactic Testing • Visual observation of hand washing, donning PPE, ascetic technique • Media Fill Test • Gloved Finger Tip Testing (x3 for initial)	Minimum required competencies: • Didactic Testing • Visual observation of hand washing, donning PPE, ascetic technique • Media Fill Test • Gloved Finger Tip Testing (x3 for initial)	Minimum required competencies: • Didactic Testing • Visual observation of hand washing, donning PPE, ascetic technique • Media Fill Test • Gloved Finger Tip Testing (x3 for initial)	HR.01.06.01 EP1	
	Didactic Written Testing Low/Med Risk every 12 months High Risk every 6 months	• Must establish a pass/fail score • Must be evidence of scoring and remediation if failed	• Must establish a pass/fail score • Must be evidence of scoring and remediation if failed • Hazardous compounding must be incorporated if applicable to compounder reviewed	• Must establish a pass/fail score • Must be evidence of scoring and remediation if failed •	Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	482.25(b)(1) 482.25(b)(1)
	Media-Fill Test Low/Med Risk every 12 months	• The test complexity must match the complexity level of compounding. • Low/Medium Risk versus High	• May use results from non-hazardous compounding • The test complexity must match the complexity level of	• May use results from non-hazardous compounding • The test complexity must match the complexity level of compounding.	Initial HR.01.06.01 EP 5 Ongoing	482.25(b)(1)

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	High Risk every 6 months	Risk	compounding. • Low/Medium Risk versus High Risk	• Low/Medium Risk versus High Risk	HR.01.06.01 EP 6	482.25(b)(1)
	Gloved Fingertip Testing ***Initial AND Ongoing*** Low/Med Risk every 12 months High Risk every 6 months	**Initial** • 3 separate tests required • Cannot exceed "0" CFU **Ongoing** • Ongoing test requires one sample only • Cannot exceed 3 CFU	**Initial** • 3 separate tests required • Cannot exceed "0" CFU **Ongoing** • Ongoing test requires one sample only • Cannot exceed 3 CFU	**Initial** • 3 separate tests required • Cannot exceed "0" CFU **Ongoing** • Ongoing test requires one sample only • Cannot exceed 3 CFU	Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	482.25(b)(1)
	Observation Competency Low/Med Risk every 12 months High Risk every 6 months	• Includes following items o Garbing of PPE o Aseptic Technique	• Includes following items o Garbing of PPE o Aseptic Technique	• Includes following items o Garbing of PPE o Aseptic Technique	Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	482.25(b)(1)
	Additional hazardous medication training required	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*		• **Competence** must be reassessed: o Prior to independently handling HDs o At least every 12 months and when a new HD or new equipment is used, or o A new or significant change in process or SOP occurs. • **Training** must include: o Overview of organization's list of HDs and their risks o Review of SOPs related to handling HDs o Proper use of PPE o Proper use of equipment and devices o Spill management	**Competency:** Lack of defining: HR.01.06.01 EP 1 Initial HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP6 **Training:** HR.01.05.03 EP 1	 N/A 482.25(b)(1) 482.25(b)(1) N/A

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				o Response to known or suspected HD exposure		
Hazardous Specific Compounding Additional Items USP 800						
	Annual evaluation of hazardous medication	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*		Org must maintain a list of HDs: • Must include items on current NIOSH list in addition to other agents not on list • May risk assess out for all NIOSH Table 2 and 3 medications and Table 1 medications that do not require further manipulation (e.g. tablets) (risk assessment must be completed every 12 months) • Assessment of risk must minimally include: o Type of HD o Dosage form o Risk of exposure o Packaging o Manipulation Org must review list at least annually and whenever a new agent or dosage form is used.	MM.01.01.03 EP1	N/A
	HD Receipt	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*		SOPs for receiving HDs must include: • HDs must be delivered to the HD storage area immediately upon arrival • PPE, including chemo gloves must be worn when unpacking HDs	MM.01.01.03 EP2	N/A

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				• A spill kit must be accessible in receiving area • Must have policies for steps for receiving and handling of damaged shipping containers		
	HD storage *Applies only to items used for hazardous drug compounding*	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*		• Must be stored separately from non-HD products • Storage area must be o Negative pressure o Externally vented o At least 12 ACPH • If refrigerated, must be dedicated refrigerator located in room with minimum 12 ACPH (could be storage room, buffer room C-SCA)	MM.01.01.03 EP2	N/A
	HD-PPE	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*		Organization must develop SOPs for PPE based on risk of exposure and activities performed when handling HD including during: o Receipt o Storage o Transport o Compounding o Administration o Deactivation/decontamination, cleaning and disinfecting o Spill control Potentially contaminated clothing must not be taken home.	MM.01.01.03 EP2	N/A

**Note: For viable testing of Primary and Secondary Engineering Controls. Fungal testing is only required for those organizations that conduct High Risk (non-sterile to sterile compounding). However, if an organization chooses to test for fungal growth, remediation must be completed, or non-compliance shall be scored based on this tool.*