

657—13.25(155A) Media-fill testing by personnel. The pharmacy shall develop, maintain, and implement written procedures that include appropriate media-fill testing by personnel authorized to compound preparations. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required. Tests shall be performed without interruption in an ISO Class 5 environment under conditions that closely simulate the stressful conditions encountered during compounding of the specific risk level preparations for which the test is intended. The pharmacy shall maintain records of media-fill testing performed, and results of testing procedures shall be available to the board or agents of the board. Compounding personnel whose media-fill test vials result in gross microbial colonization shall be immediately instructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

13.25(1) Low-risk MFT procedure. Each person authorized to compound low-risk preparations shall annually perform an appropriate successful MFT procedure. The following is an example of a low-risk MFT procedure:

1. Using the same sterile 10-ml syringe and vented needle combination, aseptically transferring three sets of four 5-ml aliquots of sterile soybean-casein digest medium into separate sealed, empty, sterile 30-ml clear vials (i.e., four 5-ml aliquots into each of three 30-ml vials);
2. Affixing sterile adhesive seal closures onto the three filled vials;
3. Incubating the vials at temperatures between 25 and 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before the passage of 14 days.

13.25(2) Medium-risk MFT procedure. Each person authorized to compound medium-risk preparations shall annually perform an appropriate successful MFT procedure. The following is an example of a medium-risk MFT procedure:

1. Aseptically transferring six 100-ml aliquots of sterile soybean-casein digest medium by gravity through separate tubing sets into separate evacuated sterile containers;
2. Arranging the six containers as three pairs and using a sterile 10-ml syringe and 18-gauge needle combination to exchange two 5-ml aliquots of medium from one container to the other container in the pair (for example, adding 5-ml aliquot from the first container to the second container in the pair, agitating the second container for 10 seconds, and transferring 5-ml aliquot from the second container back to the first container in the pair; then agitating the first container for 10 seconds and transferring the next 5-ml aliquot from the first container back to the second container in the pair; and repeating the procedure for each pair of containers);
3. Aseptically injecting a 5-ml aliquot of medium from each container into a sealed, empty, sterile 10-ml clear vial using a sterile 10-ml syringe and vented needle. Affixing sterile adhesive seals to the rubber closures on the three filled vials and incubating the vials at temperatures within a range of 20 to 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before the passage of 14 days.

13.25(3) High-risk MFT procedure. Each person authorized to compound high-risk preparations shall semiannually perform an appropriate successful MFT procedure. The following is an example of a high-risk MFT procedure:

1. Dissolving 3 gm of nonsterile commercially available soybean-casein digest medium in 100 ml of nonbacteriostatic water to make a 3 percent solution;
2. Drawing 25 ml of the medium into each of three 30-ml sterile syringes. Transferring 5 ml from each syringe into separate sterile 10-ml vials (these vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation);
3. Under aseptic conditions and using aseptic techniques, affixing a sterile 0.2 micron porosity filter unit and a 20-gauge needle to each syringe. Injecting the next 10 ml from each syringe into three separate 10-ml sterile vials. Repeating the process into three more vials. Labeling all vials, affixing sterile adhesive seals to the closure of the nine vials, and incubating them at temperatures between 25 and 35 degrees Celsius. Inspecting for microbial growth over 14 days. Failure is indicated by visible turbidity in the medium on or before the passage of 14 days.