

## Viable Air Sampling

Every pharmacy must develop an environmental sampling plan to check for microbial contamination in the compounding area. The plan will include sampling for airborne viable particles and conducting surface sampling. The sampling plan will detail where samples are taken, how samples are taken, when samples are taken and under what conditions. This article details the requirements of viable air sampling; a later article will address surface sampling.

Viable air sampling must occur in all ISO classified areas (PEC, ante area, and buffer area) and in the segregated compounding area. The areas sampled must be those areas at greatest risk for microbial contamination such as areas near the hoods, pass-throughs or doors. Viable air sampling shall be performed at a minimum every 6 months in conjunction with hood and room certification. Viable air sampling may be performed by trained facility personnel or most outside certifiers will perform viable air sampling as part of the hood or room certification.

Viable air sampling shall be performed via impaction. Properly calibrated electronic air sampling equipment shall be used to test 400 to 1000 liters of air at every sample location. The growth medium used in the test shall be able to support the growth of bacteria (i.e., TSA). In facilities that perform high risk compounding a growth medium that supports the growth of fungi shall also be used (i.e., MEA). After sampling the media plates will be incubated for an adequate time and at an appropriate temperature to promote multiplication of microorganisms. TSA should be incubated at 30 to 35 degrees for 48 to 72 hours. MEA should be incubated at 26 to 30 degrees for 5 to 7 days. After incubation, the number of microorganism colonies are counted on each plate and reported as a number of cfu per cubic meter of air.

All cfu shall be analyzed down to the genus because highly pathogenic microorganisms require immediate remedy. Any growth of the following microorganisms: gram-negative rods, coagulase positive staphylococcus, mold and yeast requires action. The action limits for other microorganisms are below:

| ISO Classification | CFU per cubic meter<br>1000 liters sampled | CFU per cubic meter<br>400 liters sampled |
|--------------------|--|---|
| ISO Class 5        | >1   | >1  |
| ISO Class 7        | >10  | >4  |
| ISO Class 8        | >100                                       | >40                                       |

Facilities must track and trend the data collected in the environmental sampling plan to evaluate the overall control of the compounding environment. If a sampled area consistently shows growth the facility shall also take action and consult with competent microbiology personnel.

When responding to microbial growth the facility should re-evaluate procedures and shall investigate into the source of the contamination. Procedures such as personnel work practices, cleaning procedures, and operational procedures should be evaluated. Possible sources of contamination include HVAC systems, HEPA filters, and personnel. After identifying and correcting potential sources of contamination and correcting procedural concerns the facility shall clean the area and resample.