9 **Compare certification reports over time:** Review test results and reporting for trends over time. Each report is a snapshot in time, so changes that occur from report to report can be an early indicator of a drop in performance. Confirm leak tests on every HEPA filter and evaluate any reduced air velocities, declining pressure differentials, or losses in air changes per hour.

10 **Keep copies of maintenance records:** Copy and file all records of pre-filter changes and HVAC maintenance. Use other test results to evaluate whether pre-filters are being changed with adequate frequency.

If the proposed <797> revisions are approved, the type of microorganism will no longer trigger an action limit. Instead, viable limits will only be based on the number of colony forming units (CFUs) recovered. In addition, the proposed revision will no longer require routine genus identification of CFUs. Only exceeded action limits will require identification. It is still too early to know the full impact of these changes, but they do pose some questions.

Will states change regulations to respond to the new requirements? Will third-party microbiology labs adjust their services? With less sample identification, will pharmacies only have limited knowledge of what's a typical growth in their cleanroom? We are interested in your comments. Please write us at Eric.Bauer@capsharmacy.com

In this issue, we have emphasized the importance of having a dedicated HVAC system for your cleanroom. This is even more critical for buffer rooms that are negative pressure. Primary engineering controls that are ventilated will remove a lot of air from the room, but the pressure differential cannot be greater than negative 0.03.

To avoid having too much negative pressure, a large amount of clean air must be put back into the room. If not provided exclusively from the HEPA filters, the buffer room will take air from any path of least resistance (e.g., gaps, leaks, and any other openings). Not only are these a source of unfiltered air, they can also be a route used by spores and other viable contamination to gain access into your cleanroom.

Success Requires Creative Solutions

CAPS Consulting℠ is a team of pharmacy experts who are proficient in sterile compounding. We perform USP <797>, USP <800>, and 503B outsourcing compliance tests each and every day, year round, at 22 regional 503A pharmacies and 3 503B outsourcing facilities across the United States. Our consulting team is ready to share this expertise with you.

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