

CriticalPoint Pearls of Knowledge — December 2025

Before the New Year: Three Essential Moves to Strengthen Your Environmental Monitoring Program

Introduction

As the year winds down, most pharmacy teams are busy closing out projects, finalizing inventory, and preparing for the next cycle of operational demands. However, a critical task may remain overlooked until surveyors arrive—reviewing and recalibrating the Environmental Monitoring Program (EMP). A well-designed EMP is the backbone of your sterile compounding quality system, and the end of the year is the perfect time for a quality reset, a deep dive into program performance, and strategic planning for the year ahead.

Whether you are a designated person (DP) refining your oversight responsibilities or a pharmacy leader striving to elevate quality standards, these year-end actions will improve state of control, strengthen compliance, and ensure the sterile compounding environment stays robust going into next year. Here are the three essential steps that every hospital or compounding pharmacy should complete before ringing in the new year.

1. Reassess and optimize your sampling plan

Your sampling plan can't be a static document. Like the cleanroom itself, it must evolve alongside the facility, personnel activities, workflows, and equipment changes that shape daily operations. A year-end sampling plan review ensures the program remains risk-based, rational, and aligned with current compounding realities.

Keep in mind that a successful outcome of the assessment may be that no changes to the current sampling plan are required. This typically occurs when there have been minimal changes to current operations, workflow activity, or equipment usage.

Evaluate whether sampling sites still reflect real risk

Avoid randomly sampling locations or moving sample locations around each month. Location selection must reflect workflow operations that have high potential for contamination risk to the compounded sterile preparation (CSP). Remember that it's okay to have the same boring locations each sample session. This is because consistency in sample locations supports reliable trending data.



Consider that throughout the year, PECs are relocated, workflows shift, and staff movement patterns evolve. Therefore, areas for higher contamination risks may change. If your sampling plan looks identical to what you created three years ago, it may no longer reflect your actual contamination pathways. Reassess each location:

- When observing personnel workflow behaviors, does the current sample location still represent a high-traffic or high-touch area?
- Does this surface interact directly or indirectly with sterile compounding?
- Have new risks emerged (e.g., new HD workflow, increased volumes, PEC aging)?



Review sampling frequency

Sampling frequency should be justified by risk—not tradition. Year-end data may reveal that your facility requires:

- more frequent sampling in ISO Class 7 areas due to having marginal trends
- additional sampling after construction and renovations, new hires, or equipment failure
- adjustments to match increased production or higher personnel traffic
- more personnel sampling monitoring (post-compounding gloved fingertip and thumb sampling and surface sampling at the DCA)

Reassess alert and action levels

Alert and action levels are often set once and forgotten. However, based on annual trending, you may find they need recalibration.

- **If levels are too high:** issues go undetected until contamination events occur.
- **If levels are too sensitive:** your EMP team is swamped with unnecessary investigations and corrective and preventive actions (CAPAs).

Right-sizing these thresholds directly impacts efficiency and effectiveness of the microbial state of control. USP <797> action levels are the baseline of the minimum standard. For example, you may find that your typical ISO Class 8 environment recoveries are far below the minimum requirements of >50 colony forming units (CFUs) for surface sampling.



If your facility typically recovers well below 20 CFUs—for example, a routine range of 5–15 CFUs—then setting your action level at USP’s default >50 CFUs is neither meaningful nor protective. In reality, contamination levels of 30–40 CFUs would represent a significant loss of control that your current limits would fail to detect.

In this scenario, facility-specific alert levels set below 20 CFUs for ISO 8 surface samples provide a more accurate reflection of your historical trends. These tailored alert and action limits offer an earlier warning when conditions begin to drift and allow you to respond to excursions long before they reach the USP minimum threshold.

When adjusting alert and action levels, it’s CriticalPoint’s best practice recommendation to create a transcript to describe the changes made.

This formally documents the justification and rationale when making the necessary changes to the program. Remember to document the evidence that supports the “why” behind your decision to change the monitoring levels.

Validate media, vendors, and equipment

A sampling plan is only as reliable as the supplies and partners supporting it. Use this time to evaluate:

- media certificates of analysis (COAs) and consistency across lots
- recovery performance and laboratory identification accuracy
- turnaround times from your contract lab
- calibration and maintenance records for sampling equipment

II. Perform annual data trending and create a summary report

Trending is where your EMP truly comes to life. Data without interpretation does not demonstrate control. Surveyors, accreditors, and your own leadership expect to see evidence that you understand your environment and can identify changes early. A robust annual summary is the ultimate demonstration of oversight.



Gather all environmental data

This includes:

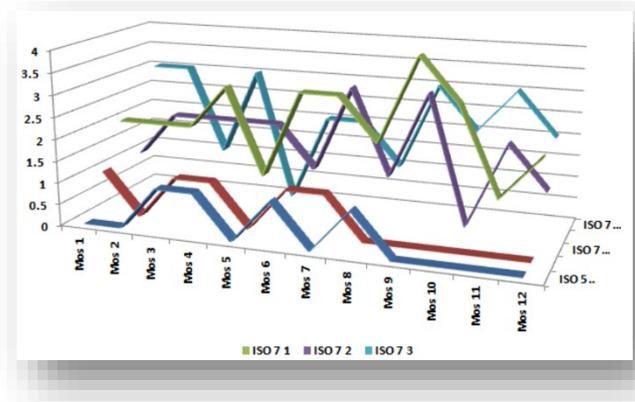
- frequency of sampling
- viable air and surface samples
- nonviable airborne particle monitoring (from certification reports)
- differential pressure logs
- humidity and temperature data
- incubator performance logs (if performing in-house incubation)
- organism identification reports
- CAPA documentation

An annual review totals these individual data points into a meaningful narrative.

Identify patterns and trends

Look for:

- sites with recurring borderline results
- slow upward drifts in recoveries
- seasonal fluctuations (common in many regions)
- correlations with staffing levels or shifts
- primary and secondary engineering controls (PECs and SECs) that may be declining in performance
- cleaning or disinfection inconsistencies
- personnel performance quality monitoring



Visual trend charts make problem areas stand out and help justify future changes to sampling frequency or cleaning routines.

Review CAPAs for effectiveness

Did CAPAs resolve the root cause? Did the problem reoccur weeks or months later? Assess whether the CAPA truly addressed:

- personnel performance
- environmental control
- cleaning approaches
- equipment performance
- facility integrity

This step helps identify whether policies, training, or procedures need updates. In addition, inspectors tend to spend time on CAPAs during their visits. It's beneficial beforehand to review and ensure documentation is appropriate, clear, and descriptive.

Create an annual EMP summary

A strong summary includes:

- executive overview of environmental control health
- trend analysis results and graphs
- major events and contamination findings
- CAPAs and outcomes
- identified risks and recommended mitigation steps
- goals for next year



This document becomes your best defense and your best leadership tool. Sharing the summary report with staff and leadership can aid cultural buy-in for improved performance and environmental quality.

CriticalPoint recommends creating a formal, inspection-ready annual EMP summary that clearly demonstrates your microbial state of control. The easier it is for inspectors to understand what occurred over the past 12 months, the fewer questions they’ll ask—and the less likely they are to dig deeper into the details of the entire EMP program.

III. Conduct a documentation & inspection-readiness audit

Even the best EMP does poorly during inspection if documentation is incomplete. Year end is the ideal time to clean up gaps, reconcile discrepancies, and ensure every activity is defensible.

Audit-required documentation

Review all EMP materials, including:

- daily/weekly/monthly sampling forms
- incubation logs if applicable
- media receipt and COA documentation
- external laboratory results
- corrective actions and investigations
- equipment calibration and maintenance records
- training documentation for sampling personnel
- SOPs for EMP processes
- DP-oversight records

Sample Pharmacy
Facility and Personnel Sampling Action Report

Section 1: Initial Investigation Actions Taken
Action began at: Interim read: _____ day or Final read

Type of environmental sample: Viable air sampling (VAS) * Single sample or Multiple samples
Check all that apply: ISO 5 ISO 7 ISO 8 Non-ISO classified Negative space Positive space
Performed under which conditions: Static Dynamic
Describe specific location(s) from ESP: _____ Date sampled: _____

Surface sampling (SS) * Single sample or Multiple samples
Check all that apply: ISO 5 ISO 7 ISO 8 Non-ISO classified Negative space Positive space
Performed under which conditions: Static Dynamic
Describe unit(s) location based on ESP: _____ Date sampled: _____

Type of personnel sample: sampled randomly or during predetermined testing occurrence

Initial GFT * # CFU L hand: _____ R hand: _____ Date sampled: _____
 Ongoing GFT * # CFU L hand: _____ R hand: _____ Date sampled: _____
 Surface sample (during compounding) * # CFU L hand: _____ R hand: _____ Date sampled: _____
 Post media-fill GFT (during compounding) * # CFU L hand: _____ R hand: _____ Date sampled: _____
 Media-fill unit (MFU) * # units made: _____ # units positive: _____ Date units prepared: _____

Type of excursion:
 Below action level AND organism of concern (see SOP-205)
 Alert level exceeded: If alert level is exceeded but the action level is not, then perform an evaluation of appropriate facility engineering controls, personnel, work practice changes, and environmental factors that could be causing this increase in personnel or environmental findings in an effort to regain microbial control. Document review, conclusions, and actions taken.
 Action level exceeded: Complete all sections of this form

Be prepared for any inquiry or deep dive during an inspection. Ensure all documentation and supporting materials are readily accessible, complete, legible, and accurate.

Review CAPAs from the last 12 months

Verify:

- CAPAs were closed appropriately
- root causes were clearly defined when possible
- effectiveness checks were documented
- no recurring issues exist

CAPA mismanagement is one of the top red flags during inspections.

Review/Update SOPs and training materials

Make sure procedures match real practice. Outdated SOPs can instantly lead to inspection findings.

Ensure:

- references to old equipment are removed
- current workflows are accurately described (and are followed in practice)
- program management and participant roles and responsibilities are clearly defined
- DP and supporting staff duties are up to date

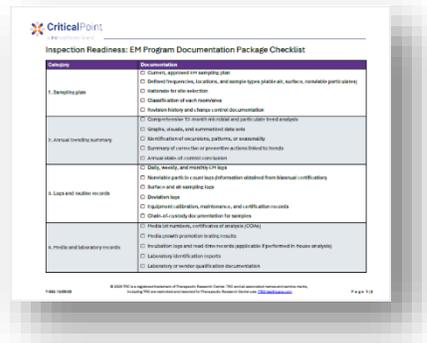


Prepare an inspection-ready EMP folder

Organized, indexed documents ensure efficient navigation during regulatory visits. Include:

- sampling plan
- annual trending summary
- all logs
- media records
- CAPAs
- training documents

Download CriticalPoint's
EM Program
Documentation
Package Checklist



Summary

Strengthening your Environmental Monitoring Program (EMP) is the most impactful year-end action for pharmacy leaders. Proactive EMP management is foundational to patient safety and sterile compounding excellence, going beyond simple regulatory compliance. Start the new year inspection-ready by focusing on three essential steps: refining your sampling plan, analyzing your historical trends, and completing a comprehensive documentation audit. Invest in this reset now for a safer, more controlled, and compliant environment.