

What to Do When Your Cleanroom Fails an EM Test

Investigation, root cause analysis, corrective action, and documentation—at a glance.

ALERT vs. ACTION LIMITS

Alert Limit

~90th percentile. Signals drift. Document and trend.

Action Limit

~95th percentile. Requires investigation and CAPA every time.

THE FIRST 24 HOURS

- 1 **Document the excursion**—value, location, date, time, personnel, conditions
- 2 **Notify QA immediately**—formal notification for every action-limit breach
- 3 **Assess product exposure**—identify production activity during the excursion window
- 4 **Quarantine affected batches**—hold product pending investigation
- 5 **Increase monitoring**—affected area and adjacent zones
- 6 **Review HVAC and pressure logs**—differential pressure, particulates, HVAC records

ROOT CAUSE CATEGORIES



Personnel — Gowning breaches, aseptic technique, behavioral drift



HVAC / Airflow — Filter degradation, pressure losses, ductwork contamination



Equipment / Surfaces — Hidden contamination, degraded finishes



Process / Material Flow — Transfer breaches, concurrent ops, chemical changes



Sampling Method — Expired media, incubation errors, technique issues

WHEN TO CONSIDER WHOLE-ROOM BIODECONTAMINATION

- ✓ Repeat excursions at the same location despite cleaning and CAPA
- ✓ Recovery of spore-forming organisms resistant to liquid disinfectants
- ✓ Post-construction or post-maintenance remediation
- ✓ Facility-wide contamination events—water system, mold, Gram-negative recovery
- ✓ Return-to-service qualification after shutdown, renovation, or equipment install

WHAT INSPECTORS LOOK FOR

- 1 Clear timeline linking excursion to preceding events
- 2 Organism ID connected to probable root cause
- 3 Documented root cause determination or rationale
- 4 CAPA records with effectiveness verification plan
- 5 Post-CAPA monitoring data showing return to normal



Do not re-clean and re-test without documenting the initial finding. A passing result after re-cleaning only proves cleaning works.

Tip: Organism ID narrows root cause—skin flora points to personnel, spore-formers to surfaces, Gram-negatives to water systems.