Standard Operating Procedure Update

Document ID: SOP-MFG-014 Rev. 6
Title: Cleanroom Environmental Monitoring and Response
Owner: Manufacturing Quality Assurance
Effective Date: Draft (Pending Approval)

1. Purpose

This revision defines updated monitoring frequencies, alert/action levels, and corrective action expectations for Grade B cleanrooms supporting aseptic filling operations.

2. Scope

Applies to all operators, supervisors, and QA personnel performing routine viable and non-viable environmental monitoring (EM) in Fill Suite B-2 and B-3. Related documents include WI-MFG-014a (Settle Plate Placement) and CAPA-552 action plan.

Review Point 1: Section 5.2 introduces revised alert levels for airborne particulates but references ISO Class 7 whereas historical qualification is ISO Class 6. Confirm alignment with facility qualification report FQR-2024-18.

3. Definitions

- **Alert Level:** Measurement requiring investigation but not necessarily batch impact.
- **Action Level:** Measurement necessitating documented deviation and product impact assessment.
- **CFU:** Colony forming unit.

4. Responsibilities

- **Operators:** Perform sampling as scheduled, document results in EM Tracker, and notify QA of excursions within 30 minutes.
- **QA Reviewer:** Evaluate excursions, assign corrective actions, and determine product disposition.
- **Facilities:** Maintain HVAC differential pressure logs and service cleanroom equipment.

5. Procedure Overview

5.1 Sampling Frequencies

Area	Sample Type	Frequency
Grade B room air	Viable (active)	Per fill shift
Grade B room air	Non-viable	Continuous
Grade A critical zone	Viable (surface)	Pre- and post-fill
Grade B personnel	Glove prints	Pre-shift and post-shift

5.2 Alert and Action Levels (Excerpts)

- **Non-viable particles (0.5 microm):** Alert 3,500/m^3; Action 7,000/m^3.
- **Viable air (Grade B):** Alert 5 CFU/m^3; Action 10 CFU/m^3.
- **Surface (Grade A):** Alert 1 CFU/plate; Action 3 CFU/plate.

Review Point 2: Cross-check revised alert/action table with Validation Summary VS-777 to ensure CAPA-552 commitments (action level reduction by 20%) are fully reflected.

5.3 Response to Excursions

1. Quarantine impacted batches pending QA assessment.
2. Perform immediate cleaning using approved sporicidal agents.
3. Initiate deviation (QMS-F-004) and document root cause analysis.
4. Conduct resampling within 4 hours; if results exceed action level, escalate to Site Quality Head.

5.4 Documentation

- Record data in EM Tracker with user ID and timestamp.
- Attach calibration records for sampling equipment in deviation packages.
- Archive reports per Record Retention Policy QP-001.

6. Training and Change Control

All impacted personnel must complete training module LMS-014 within 10 business days of SOP approval. Change control CC-893 documents impacted systems and validation requirements.

7. References

- ISO 14644-1:2015 Cleanrooms and associated controlled environments.
- VS-777 Validation Summary, Annex C.
- CAPA-552 action plan documentation.

8. Document History

Revision	Date	Description
5	Mar 2024	Added glove print frequency clarification
6	Draft	Updated alert/action levels, CAPA-552 linkage

9. Approvals (Pending)

- Manufacturing QA Manager: _____
- Production Director: _____
- Site Quality Head: _____