

Annex 1 2022 Comparison Factsheet: Grade B Sample Frequency

The 2022 revision of Annex 1 expresses that Grade B monitoring frequency should be similar to Grade A.

Wording in 2022 Annex 1

9.24 Continuous viable air monitoring in grade A (e.g. air sampling or settle plates) should be undertaken for the full duration of critical processing, including equipment (aseptic set-up) assembly and critical processing. A similar approach should be considered for grade B cleanrooms based on the risk of impact on the aseptic processing. The monitoring should be performed in such a way that all interventions, transient events and any system deterioration would be captured and any risk caused by interventions of the monitoring operations is avoided.