

Annex 1 2022 Comparison Factsheet: Grade Level Detail

The 2022 revision of Annex 1 includes a greater level of detail describing requirements and guidance on operations in Grade A - D facilities.

Grade	Wording in 2022 Annex 1	Line
Grade A	Grade A zone: The critical zone for high risk operations or for making aseptic connections by ensuring protection by first air (e.g. aseptic processing line, filling zone, stopper bowl, open ampoules and vials). Normally, such conditions are provided by a localised airflow protection, such as unidirectional airflow work stations, RABS or isolators. The maintenance of unidirectional airflow should be demonstrated and qualified across the whole of the Grade A zone. Direct intervention (e.g. without the protection of barrier and glove port technology) into the Grade A zone by operators should be minimized by premises, equipment, process and procedural design.	188 - 195
Grade B	Grade B area: For aseptic preparation and filling, this is the background cleanroom for the Grade A zone (where it is not an isolator). When transfer holes are used to transfer filled, closed products to an adjacent cleanrooms of a lower grade, airflow visualization studies should demonstrate that air does not ingress from the lower grade cleanrooms to the Grade B. Pressure differentials should be continuously monitored. Cleanrooms of lower grade than Grade B can be considered where isolator technology is used (refer to paragraph 4.22).	197 - 202
Grade C + D	Grade C and D area: These are cleanrooms used for carrying out less critical stages in the manufacture of aseptically filled sterile products but can be used for the preparation /filling of terminally sterilized products. (See section 8 for the specific details on terminal sterilization activities).	204 - 207



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