

Documents or Standards Applicable to Cleanrooms

Standard or Document	Title	Notes
ISO 14644-1	Classification of air cleanliness by particle concentration	ISO 14644-1 and 2 provide guidance for performing particle counts
ISO 14644-2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	
Fed Standard 209E		Cancelled/outdated Standard but has useful information
CETA CAG 003-2006		This has information for how cleanrooms are certified
ASHRAE Design Guide for Cleanrooms		Good overall guide for the design and operation of cleanrooms
USP <1116> Microbial Control and Monitoring of Aseptic Processing Environments		Part of the USP Compounding Compendium
FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice		General guidance from the FDA on performing sterile compounding/aseptic processing

