

USP Secondary Engineering Controls Requirements

Category	USP 797 (2022)			USP 800 (2022)			
	SCA	Ante-Room	Buffer Room	C-SCA	HD Storage Room	Ante-Room	Buffer Room
ISO Classification	Unclassified	ISO 8	ISO 7	Unclassified	Unclassified	ISO 7	ISO 7
HEPA Air Supply	Not Required	Required at Ceiling	Required at Ceiling	Not Required	Not Required	Required at Ceiling	Required at Ceiling
ACPHour	0	20	30	12	12	30	30
ACPMInute	0.000	0.333	0.500	0.2	0.2	0.5	0.5
Differential Pressure	0 inWC	>0.02 inWC	>0.02 inWC	-0.01 to -0.03 inWC	<0 in WC	>0.02 inWC	-0.01 to -0.03 inWC
Differential Pressure	0 Pa	>5 Pa	>5 Pa	-2.5 to -7.5 Pa	-2.5 to -7.5 Pa	>5 Pa	-2.5 to -7.5 Pa
Relative Humidity	<60%	<60%	<60%	See USP 797	Refers to USP 797	See USP 797	See USP 797
Temperature (C)	<20° C	<20° C	<20° C	See USP 797	Refers to USP 797	See USP 797	See USP 797
Temperature (F)	<68° F	<68° F	<68° F	See USP 797	Refers to USP 797	See USP 797	See USP 797
External Ventilation	Not Required	Not Required	Not Required	Required	Required	Not Required	Required

ISO 14644-1 Cleanroom Standards							
Classification	Maximum Particles/m3						FED STD 209E Equivalent
	≥0.1µm	≥0.2µm	≥0.3µm	≥0.5µm	≥1µm	≥5µm	
ISO 1	10	2	1	0	0	0	
ISO 2	100	24	10	4	1	0	
ISO 3	1000	237	102	35	8	0	Class 1
ISO 4	10000	2370	1020	352	83	3	Class 10
ISO 5	100000	23700	10200	3520	832	29	Class 100
ISO 6	1000000	237000	102000	35200	8320	293	Class 1,000
ISO 7	10000000	1000000	1020000	352000	83200	2930	Class 10,000
ISO 8	100000000	10000000	10000000	3520000	832000	29300	Class 100,000
ISO 9	1000000000	100000000	100000000	35200000	8320000	293000	Room Air