

Clean rooms are classified according to the level of purity of the air contained in a controlled environment. Classes designate the level of cleanliness that the clean room complies with which is detailed by the number and magnitude of the particles per cubic meters of air. The ISO classification across the United State and Canada is called the ISO classification system ISO 14644-1.

This ISO standard includes these clean room classes : ISO 1, ISO 2, ISO 3, ISO 4, ISO 5, ISO 6, ISO 7, ISO 8 and ISO 9. While ISO 1 is the purist class and ISO 9 is the least pure class. Even if it's classified as the "least pure" class, the ISO 9 clean room environment is cleaner than a regular room.

The most common ISO clean room classes are ISO 7 and ISO 8. The Federal Standard 209 ( FS 209E ) equivalent for these ISO classes are Class 10,000 and Class 100 000.

The old Federal Standard 209E ( FS 209E ) includes these clean room classes : Class 100,000; Class 10,000; Class 1,000; Class 100; Class 10; Class 1. This standard was replaced in 1999 by ISO-14644-1. It was withdrawn in 2001, however the standard is still widely used.

Clean rooms are obligated also follow industry-specific and international standards. For example, EU GMP (A-B-C-D), applies to pharmaceutical products and [USP \(795, 797 and 800\) to compounding pharmacies](#).

US FED STD 209E Cleanroom Standards   Cleanroom Classifications Class						
Class	Maximum Particles/ft <sup>3</sup>					ISO equivalent
	>0.1 um	>0.2 um	>0.3 um	>0.5 um	>5 um	
1	35	7	3	1		ISO3
10	350	75	30	10		ISO4
100				100		ISO5
1,000				1,000	7	ISO6
10,000				10,000	70	ISO7
100,000				100,000	700	ISO8
ISO 14644-1 Cleanroom Standards   Cleanroom Classifications						
Class	Maximum Particles/ft <sup>3</sup>					FED STD 209E equivalent
	>0.1 um	>0.2 um	>0.3 um	>0.5 um	>5 um	
ISO1	10	2				
ISO2	100	24	10	4		
ISO3	1,000	237	102	35	8	Class 1
ISO4	10,000	2,370	1,020	352	83	Class 10
ISO5	100,000	23,700	100,200	3,520	832	Class 100
ISO6	1,000,000	237,000	102,000	35,200	8,320	Class 1,000
ISO7				352,000	83,200	Class 10,000
ISO8				3,520,000	832,000	Class 100,000
ISO9				35,200,000	8,320,000	Room Air