

# Heating, Ventilation and Air- Conditioning (HVAC)

Classification of cleanrooms as  
per

ISO 14644-1:2015

INTERNATIONAL  
STANDARD

ISO  
14644-1

Second edition  
2015-12-15

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**Cleanrooms and associated controlled  
environments —**

**Part 1:  
Classification of air cleanliness by  
particle concentration**

*Salles propres et environnements maîtrisés apparentés —  
Partie 1: Classification de la propreté particulaire de l'air*

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Reference number  
ISO 14644-1:2015(E)

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# Air Grade Classification as per ISO 14644

## Criteria used for sample volume

- No change. Remember ISO requirement of sample time of not less than 1 minute

## ISO 14644-1:1999, ISO 5 class, 0.5 micron size:

- Minimum volume for each sample point is:

$$V = (20/3520) \times 1000 \text{ (lt)} = 5.7 \text{ litres}$$

- If a 1 cfm counter is used: volume of each sample = 28.3 litres
- If a 50 lpm, 50 litres.
- If a hand held counter of 0.1 cfm: need at least 2 minutes to sample 5.7 litres.

# Air Grade Classification as per ISO 14644

For ISO 14644-1:1999, ISO 5 class, considering 0.5 and 5 microns:

- Minimum volume for each sample point is:  
 $(20/29) \times 1000 = 690$  litres

(limit conc. for 5 microns = 29 part/m<sup>3</sup>).

- Required sample time for each sample point:

1 cfm counter = 25 min

50 lpm counter = 20 min

# Air Grade Classification as per ISO 14644

- For ISO 14644:2015 there is NO limit for 5 microns in class ISO 5, therefore, only possible classification is using 0.5 microns
- For GMP, need to follow existing table: limit for particles  $\geq 5$  microns = 20 for Grade A at rest and in-operation; and 29 for Grade B at rest, and 2,900 in operation.
- The volumen criteria has not changed between both versions of ISO 14644 (1999 and 2015):

Grade A:  $V_{min} = (20/20) \times 1000 = 1000$  litros

Grado B at rest:  $V_{min} = (20/29) \times 1000 = 690$  litros

- Need to clearly state the approach. Adaptation period between ISO and GMP norms.

# Air Grade Classification as per ISO 14644

Table 1 Selected airborne particulate cleanliness classes						
ISO 14644-1:2015 Classification Number (N)	Maximum concentration limits (particles/m <sup>3</sup> )					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
ISO Class 1	10					
ISO Class 2	100	24	10			
ISO Class 3	1 000	237	102	35		
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	298
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

Table 1: ISO 14644-1:2015 – New Maximum Concentration Limits

Difference with GMP requirement: No 5 µm defined for ISO 5 !!

# Combined GMP / ISO Table

Classify in accordance to ISO 14644-1

	Maximum permitted number of particles per m <sup>3</sup> ≥ the tabulated size			
	At Rest		In Operation	
Grade	0.5 μm	5.0 μm	0.5 μm	5.0 μm
A	3,520 ISO 5	20	3,520 ISO 5	20
B	3,520 ISO 5	29	352,000 ISO 7	2,900
C	352,000 ISO 7	2,900	3,520,000 ISO 8	29,000
D	3,520,000 ISO 8	29,000	Not defined	Not defined

## Air Grade Classification as per ISO 14644

- New ISO version 2015: Cleanrooms & associated environments. Part 1: Classification of air cleanliness by particle concentration.
- Occupancy states; instrumentation; ISO class numbers
- Demonstration of compliance: principles, testing, test report  
Annex A: (Normative) Method of classification
- Changes between 1999 and 2015 versions: more consistent statistical approach to selection and number of sample locations, and evaluation fo data.



# Air Grade Classification as per ISO 14644

## ISO 14644 family:

- 1: Classification
- 2: Monitoring of particles
- 3: Test methods
- 4: Design, construction & start-up
- 5: Operations
- 7: Separative devices (hoods)
  
- ISO 14698 Cleanrooms and associated controlled environments – Biocontamination Control

## Air Grade Classification as per ISO 14644

- Instrument used for classification: Light scattering airborne particle counter (LSAPC)
- Cleanroom: “room within which the concentration of airborne particles is controlled & classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room”
- Unidirectional Air flow (UDAF): “Controlled airflow with a steady velocity and airstreams (parallel)”

# Air Grade Classification as per ISO 14644

- Classification frequency: based on R.A. (annually)
- Test report:
  - Testing data: date
  - ISO version used
  - Diagram showing locations
  - ISO class; occupancy state; particle size
  - Instrument ID; calibration report (as per ISO 21501)
  - Test results, including data from each location.
- Preparation for particle count testing (ie, pre-requisites). See ISO 14644-3.

# Air Grade Classification as per ISO 14644

## Sample Locations

- Table A1: Minimum number of locations related to the area
- Divide area into equal sections
- Determine representative point in each section (working level or another point) – “worst case”.

# Air Grade Classification as per ISO 14644

## EXERCISES