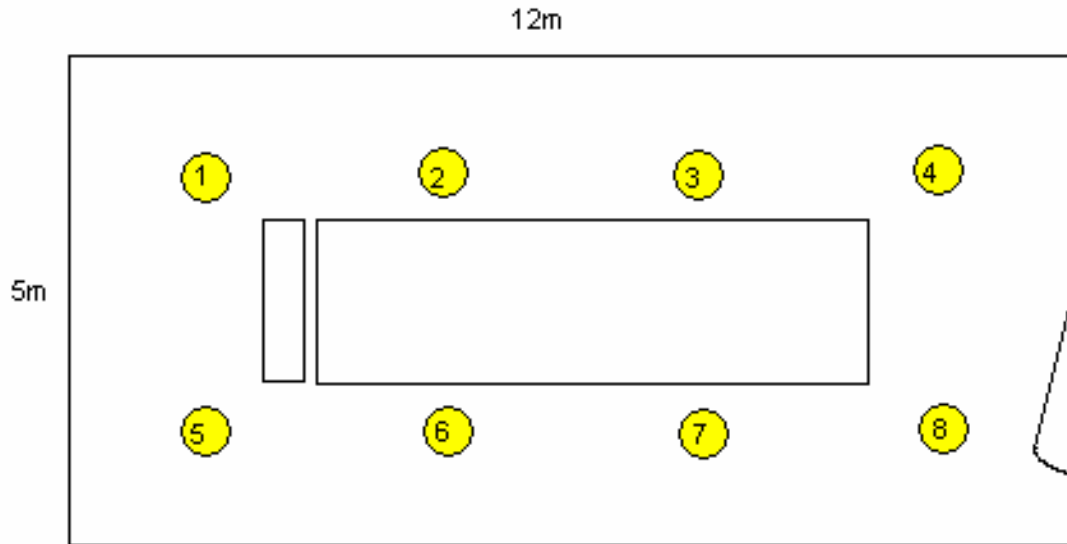


EXAMPLE: Certifying a Cleanroom to ISO 14644-1, Class 5

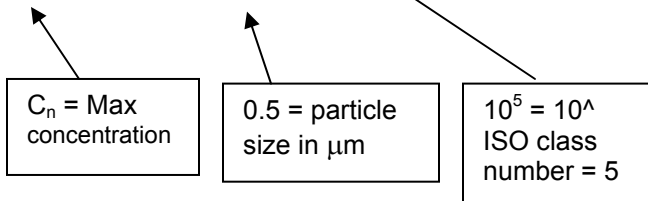
Assume we have a clean room that we want to use as an aseptic preparation area. This room needs to meet ISO Class 5 at 0.5 μm (i.e., FS209 Class100) when it is in the operational state. This example shows how we go about demonstrating whether this room meets the desired cleanliness classification.

The room is 12m by 5 m and has a worktable in the center of the room. For ISO certification, we do not look at different functional areas, but consider the cleanliness of the room as a whole.



**Step 1. Calculate the maximum permitted particle concentration**

$$C_n = (0.1/0.5)^{2.08} \times 10^5 = 3,517, \text{ which rounds to } \mathbf{3,520 \text{ counts/m}^3}$$



**Step 2. Calculate the number of sample locations**

$$N_L = \sqrt{A} = \sqrt{12 \times 5} = \sqrt{60} = 7.74 = \mathbf{8 \text{ locations to sample}}$$

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Sqr.Rt. of floor  
area in m<sup>2</sup>

NOTE: In contrast to FS209, for ISO the number of sample locations is independent of classification and particle size.

## Step 3. Calculate the sample volume

$$\begin{aligned} V_s &= \frac{20}{C_{n,m}} \times 1,000 \\ &= \frac{20}{3,517} \times 1,000 = 5.69 \text{ liters} \quad \text{minimum sample volume} \end{aligned}$$

From ISO14644-1 Section B.4.2.2, Minimum Sample Volume = 2 liters, and Minimum Sample Period = 1 minute. So, since standard particle counters run @28.3 l/min, the minimum sample volume is met (and exceeded) by taking a 1-minute sample with a 28.3 LPM (i.e., 1.0 CFM) particle counter.

Thus, to meet specification we must take a 1-minute sample at each of the 8 locations. ISO calls for the sample locations to be spread evenly across the room, with the samples taken at work height.

## Step 4. Take sample measurements at each location and record results

Location	Number /Cu. ft.	Number /m <sup>3</sup>
1	20	708
2	25	885
3	43	1,522
4	66	2,336
5	95	3,363
6	73	2,584
7	65	2,301
8	59	2,089

## Step 5. Perform statistical analysis on the results

### Step 5.1 Average

$$\begin{aligned} \bar{x} &= \frac{(708 + 885 + 1522 + 2336 + 3363 + 2584 + 2301 + 2089)}{8} \\ &= \frac{15,788}{8} = 1,974 \text{ particles/m}^3 \end{aligned}$$

### Step 5.2 Standard Deviation

$$S^2 = \frac{1}{7} \{ (708-1974)^2 + (885-1974)^2 + (1522-1974)^2 + (2336-1974)^2 + (3363-1974)^2 + (2584-1974)^2 + (2301-1974)^2 + (2089-1974)^2 \}$$

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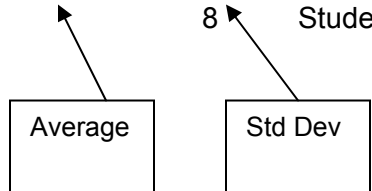
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$$= 5,545,600$$

$$S = \sqrt{5,545,600} = 2,355 \text{ n/m}^3$$

**Step 5.3 95% Upper Confidence Limit (UCL)**

95% UCL =  $1,974 + 1.9 \frac{(2,355)}{8}$ , where 8 = number of samples, and 1.9 is Student's t value from Table C1, ISO16644-1.



$$= 2,533 \text{ n/m}^3$$

**Step 6. Define report**

Max. value from all 8 locations = 3,363 n/m<sup>3</sup> < 3,520 class limit = PASS

95%UCL = 2,533 n/m<sup>3</sup> < 3,520 class limit = PASS

***Conclusion: This room meets the specification for an ISO class 5 cleanroom at 0.5µm and now can be used for appropriate manufacturing purposes.***

**Periodic Certification Required**

Room certification must periodically be repeated on a frequency defined by ISO14644-2.

Class	Maximum Time Interval	Test Method
=< ISO 5	6 months	ISO 14644-1 Annex B
> ISO 5	12 months	ISO 14644-1 Annex B

For a class 5 or cleaner environment this is defined as every 6 months, for a class 6 or greater cleanroom the interval is every 12 months. This interval can be extended to the maximum permitted interval providing that one can show that 'no significant change' has occurred in the control of this cleanroom, by evidence of continued compliance. Therefore, this Class 5 cleanrooms may not need to be re-validated on a 6 month basis, but can extend the period between re-classifications if compliance is demonstrated.