



# PROCLEANROOM

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## ISO14644 GUIDE - INTRODUCTION AND CHANGES OF THE CLEANROOM STANDARD WHAT DOES THIS MEAN TO ME?

A cleanroom, or clean zone, is an environment with low particle concentration and is intended to minimise contamination of your product or process. Pollution comes in various forms: airborne particles and fibres, microorganisms and vapours. The amount of contamination in a cleanroom is expressed in the amount of airborne particles within a defined volume of air (m<sup>3</sup>). Cleanrooms and clean zones have to meet international cleanroom standards. The ISO 14644. According to this standard, the definition of a cleanroom is:

“Cleanroom – room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room.”

There have been recent revisions to the ISO14644 part 1 and 2, the ISO14644-1:2015 and ISO14644-2:2015.

### HISTORY

Up until 2001, the American FED-STD-209E was the only accepted standard for cleanrooms and clean zones. The ISO14644 norms were based on the 'US Federal Standard 209E for Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones'. The need for a single, universally accepted norm for the classification and testing of cleanrooms had long since been present. After the ANSI and IEST had advocated a new ISO14644 norm, the first document of this norm was published in 1999. In the year 2000, the ISO 14644-2 followed, after which the process was initiated to phase out the FED-STD-209E. On November 29 of 2001, the document was officially declared expired and replaced by the ISO14644-1:1999 and ISO14644-2:2000.



Over the past 5 years, the technical committee has been working on a revision of the base documents 14644-1 and -2. The update was set up specifically to improve the cleanroom standard, with the following points of departure:

- Simplify the classification process and if possible remove the '95% upper confidence limit' (UCL) for a low number of sample locations.
- Review the classification procedure and focus more on cleanrooms in practice.
- Generally adjust the standard to current ways of thinking and sector requirements.
- Prevent large adjustments to the principles of the current ISO classes 1-9.
- Simplify and clarify the requirements and guidelines related to testing frequency and monitoring clean zones and cleanrooms.
- See how testing intervals can be extended, if automatic monitoring systems are in place to show it is under control.

After feedback from users and experts, the newest revisions of 14644-1 and -2 were accepted by the majority of the ISO committee. Since 2016, the new revisions are increasingly being adopted by the industry.

## DEFINITIONS

*ISO14644-1:2015 – Cleanrooms and associated controlled environments*

*Part 1. 'Classification of air cleanliness by particle concentration'*

This part, with an altered title compared to the ISO14644-1:1999, specifies the cleanliness classes for cleanrooms and monitored environments worldwide, based on the number of particles as concentration in air volume. It also specifies the standard testing methods to determine classes, including the selection of sample locations and the use of 'light scattering airborne particle counters'.

It is the first chapter in a series of documents that describe the testing methods and limits. The standard is used in various market sectors, including micro-electronics, pharmaceuticals, aerospace industry, medical devices, healthcare and the food industry.



*ISO14644-2:2015 – Cleanrooms and associated controlled environments*

*Part 2. 'Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration'*

Describes the specifications for a monitoring plan based on a risk analysis focussing on planned usage. This part has also had a change in title compared to the old ISO14644-2:1999. Collected data offers proof for performance of the cleanrooms or clean zone performance, related to air cleanliness based on the number of particles as concentration in air volume.

For the complete overview of all parts of the ISO14644, see Annex 1, table 1.

## MOST IMPORTANT CHANGES IN ISO14644-1:2015

The most important change is in the field of sampling methods. Previous methods were to a certain extent dependent on personal interpretations in order to determine the number of samples and especially sample locations. The improved sampling method in the updated ISO14644-1:2015 combined with an improved guideline regarding the calibration of particle counters increases confidence in the performance of tested cleanrooms.

The statistical accuracy has been increased by increasing the number of sample locations and the evaluation of collected data. This has eliminated the need for the '95% Upper Confidence Limit' (UCL). The UCL calculation was previously necessary for cleanrooms with 2 to 9 sample locations. The number of sample locations is now determined by a table (see Annex 2, table 1) instead of a formula.

The cleanroom or clean zone should also henceforth be divided into a grid with a number of sections equal to the required number of locations in table 1 (Annex 2). The sample locations are to be located within the individual sections. The layout of the cleanroom or clean zone, the presence of machinery and air flow systems is to be considered when determining sample locations. Additional sample locations may be added to the required minimum number.

The limits for particles with a size of  $\geq 5.0$  micron have been taken out for ISO class 5, in the guiding table (see table 1) for limits on particle size specified per ISO class. The reason for this is the statistical and sample limitations for particles in low concentrations. This can make measurements unreliable. For the complete overview with a cross table to the FED 209E and the EU GMP, see table 2 and 3 in Annex 1.

**Table 1: Maximum concentration limits** (particles/m<sup>3</sup> of air)

| ISO Classification number | $\geq 0,1 \mu\text{m}$ | $\geq 0,2 \mu\text{m}$ | $\geq 0,3 \mu\text{m}$ | $\geq 0,5 \mu\text{m}$ | $\geq 1,0 \mu\text{m}$ | $\geq 5,0 \mu\text{m}$ |
|---------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| ISO Class 1               | 10                     | <del>2</del>           | -                      | -                      | -                      | -                      |
| ISO Class 2               | 100                    | 24                     | 10                     | <del>4</del>           | -                      | -                      |
| ISO Class 3               | 1.000                  | 237                    | 102                    | 35                     | <del>8</del>           | -                      |
| ISO Class 4               | 10.000                 | 2.370                  | 1.020                  | 352                    | 83                     | -                      |
| ISO Class 5               | 100.000                | 23.700                 | 10.200                 | 3.520                  | 832                    | <del>29</del>          |
| ISO Class 6               | 1.000.000              | 237.000                | 102.000                | 35.200                 | 8.320                  | 293                    |
| 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                |

Source: NEN-EN-ISO 14644-1

**Note:** The current EU GMP norms still require measurements for particles of  $\geq 5.0$  micron in size in Grade A and B environments for both classifications and reclassifications and monitoring. In order to determine  $\geq 5.0$  micron particle size for ISO class 5, the 'M descriptor' may be used.

The ISO14644-1:2015 describes the considerations for classifications related to particle sizes of 0.1 to 5 microns diameter. Smaller particles (nanoparticles) are now separately described in part 12 (14644-12).

Decimal classes are no longer determined by a formula in the ISO14644-1:2015. The formula has been taken out and replaced by a table (see Annex 3, table 1).

### **MOST IMPORTANT CHANGES IN ISO14644-2:2015**

The 'At rest' and 'In Operation' classification is to be regularly executed with the purpose of a risk analysis and a resulting monitoring strategy/plan of the cleanroom or clean zone, focussed on the specific process of the user. If the cleanroom or clean zone is equipped with machinery for continuous monitoring for contamination by airborne particles (as a result of the risk analysis), the validation interval of the classification can be longer, if desired. Naturally, this is only the case if the results of continuous monitoring remain within specifications. In the pharmaceutical and related industries, the interval should be no longer than a year.

### *Particle counters*

The requirements for particle counters have been described in the ISO14644-3 since its publication in 2005 and is in line with the ISO21501-4.

ISO21501-4 'Determination of particle size distribution - Single particle light interaction methods - Part 4: light scattering airborne particle counter for clean spaces'

In order to increase confidence in the performance of tested cleanrooms and clean zones, the revised ISO14644-1 contains criteria for particle counters as specified in ISO 14644-3. It offers consistent testing methods for the calibration of particle counters. Although many particle counters on the market have been designed for use in spaces with low particle concentrations, certain devices provide inaccurate results. This means some devices will not meet the requirements set by the ISO21501-4 and ISO14644-4. Calibration of particle counters should now meet the requirements set by ISO21501-4.

### **SUMMARISING THE MOST IMPORTANT CHANGES**

The non-extreme changes influence all users of cleanrooms and clean zones to a greater or lesser extent. Substantial changes have been implemented which influence the way cleanrooms and clean zones are classified, as well as particle counter requirements.

- The number of sample locations is no longer determined by a formula  $\sqrt{\text{total room m}^2}$ , but is now directly dictated by a table (see Annex 2, table 1).
- Sample locations are to be spaced out in a grid.
- Particles of  $\geq 5$  micron in ISO class 5 environments have been removed from the table for concentration limits.
- The UCL calculation is no longer necessary (class 2 through 9). Each sample is considered individually and is to meet the limit for the class in question.
- Particle counters are to be calibrated and verified according to ISO21501-4 (following from ISO14644-3).
- Classification interval should follow from a risk analysis and a resulting monitoring plan. Applying continuous monitoring systems can offer a longer interval.

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## ANNEX 1

Table 1, overview of all parts of the ISO14644

| The standard currently contains: |   |
|----------------------------------|---|
| ISO14644-1                       | Classification of air cleanliness by particle concentration   |
| ISO14644-2                       | Specifications for testing and monitoring to prove continued compliance with ISO14644                           |
| ISO14644-3                       | Test Methods  |
| ISO14644-4                       | Design, construction and Start-up   |
| ISO14644-5                       | Operations  |
| ISO14644-6                       | Vocabulary  |
| ISO14644-7                       | Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)                               |
| ISO14644-8                       | Classification of air cleanliness by chemical concentration (ACC)   |
| ISO14644-9                       | Classification of surface cleanliness by particle concentration   |
| ISO14644-10                      | Classification of surface cleanliness by chemical concentration   |
| ISO14644-11                      | DRAFT   |
| ISO14644-12                      | DRAFT - Classification of air cleanliness by nanoscale particle concentration                                   |
| ISO14644-13                      | Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications |
| ISO14644-14                      | Assessment of suitability for use of equipment by airborne particle concentration                               |

Source: NEN-EN-ISO 14644-1

Table 2, maximum concentration limits (particles/m<sup>3</sup> of air)

| ISO Classification number | ≥ 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     | 293      |
| 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  |

Source: NEN-EN-ISO 14644-1

Table 3, cross reference to FED209E and the EU GGMP

| Cleanroom Standard    | Cleanroom Classification |         |         |         |         |         |
|-----------------------|--------------------------|---------|---------|---------|---------|---------|
| ISO 14644-1           | Class 3                  | Class 4 | Class 5 | Class 6 | Class 7 | Class 8 |
| Federal Standard 209E | 1                        | 10      | 100     | 1.000   | 10.000  | 100.000 |
| EU GGMP               | -                        | -       | A/B     | -       | C       | D       |
| Air changes per hour  | 360-540                  | 300-540 | 240-480 | 150-240 | 60-90   | 5-48    |

Source: Modular cleanrooms brochure, ProCleanroom

## ANNEX 2

Table 1, number of sampling locations

| Area of cleanroom (m <sup>2</sup> ) less than or equal to | Minimum number of sampling locations to be tested ( $N_L$ ) |
|---|---|
| 2   | 1   |
| 4   | 2   |
| 6   | 3   |
| 8   | 4   |
| 10  | 5   |
| 24  | 6   |
| 28  | 7   |
| 32  | 8   |
| 36  | 9   |
| 52  | 10  |
| 56  | 11  |
| 64  | 12  |
| 68  | 13  |
| 72  | 14  |
| 76  | 15  |
| 104   | 16  |
| 108   | 17  |
| 116   | 18  |
| 148   | 19  |
| 156   | 20  |
| 192   | 21  |
| 232   | 22  |
| 276   | 23  |
| 352   | 24  |
| 436   | 25  |
| 636   | 26  |
| 1.000   | 27  |
| >1.000  | See Formula (A.1 ISO14644-1)                                |

Source: NEN-EN-ISO 14644-1

## ANNEX 3

Table 1, intermediate decimal air cleanliness classes by particle concentration, maximum concentration limits (particles/m<sup>3</sup> of air)

| ISO Class number (N) | ≥ 0,1 µm  | ≥ 0,2 µm | ≥ 0,3 µm | ≥ 0,5 µm   | ≥ 1,0 µm  | ≥ 5,0 µm |
|----------------------|-----------|----------|----------|------------|-----------|----------|
| ISO Class 1,5        | 32        | -        | -        | -          | -         | -        |
| ISO Class 2,5        | 316       | 75       | 32       | -          | -         | -        |
| ISO Class 3,5        | 3.160     | 748      | 322      | 111        | -         | -        |
| ISO Class 4,5        | 31.600    | 7.480    | 3.220    | 1.110      | 263       | -        |
| ISO Class 5,5        | 316.000   | 74.800   | 32.200   | 11.100     | 2.630     | -        |
| ISO Class 6,5        | 3.160.000 | 748.000  | 322.000  | 111.000    | 26.300    | 925      |
| ISO Class 7,5        | -         | -        | -        | 1.110.000  | 263.000   | 9.250    |
| ISO Class 8,5        | -         | -        | -        | 11.100.000 | 2.630.000 | 92.500   |

Source: NEN-EN-ISO 14644-1

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