New standard on macro-particles and visible particles in cleanrooms

ISO 14644-17 Particle deposition rate applications

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Summary

The ISO TC209 developed a series of standards on cleanrooms and associated controlled environments. 14 parts of ISO 14644 have been published. With respect to particles the focus has been on airborne particles up to 5 micrometers. In many applications larger particles, even visible particles need to be controlled. ISO 14644-17 'Particle deposition rate applications' provides guidance on the control of macroparticles. Background information with a personal view is given. The new standard offers control tools for many industries.

Introduction

A cleanroom or an associated controlled clean environment is used to limit contamination of vulnerable surfaces by particles or microbe carrying particles. Classified cleanrooms do not predict the expected surface contamination by particles although the likelihood of surface contamination reduces in case the cleanroom class in operation is better. In ISO 14644-3:2019 Annex B10 the measurement of a particle deposition rate is described. However, no information is given on the application of particle deposition rate.

Particle deposition rate is determined by air cleanliness during operation. The air cleanliness is determined by the cleanroom installation AND by the way the cleanroom is used. The particle deposition rate provides information on the quality of the operations programs in a cleanroom. The new standard can be used to set requirements, to establish control and to demonstrate control by monitoring the particle deposition rate. In case particle deposition rate is higher than expected by the established cleanroom class is most cases the cleanroom operation needs to be improved.

Particle deposition rate

A particle deposition rate determines the change of surface cleanliness with respect to particles during exposure. Since particles deposit from the air onto a surface the particle deposition rate depends on the air cleanliness. The deposition of particles depends on their concentration in the air and their deposition velocity. The deposition velocity is the combination of the sedimentation velocity and the local air movement. Turbulent air flows can increase the deposition velocity. The sedimentation velocity depends on the size of the particle and the specific density. In cleanrooms the majority of the particles are emitted by personnel. In most cases the average density is about 1,200 kg/m^3. The deposition velocity depends on particle size and increases with the square of the particle size. One can calculate the sedimentation velocity using Stokes' law, but in a cleanroom it is useful to determine the cumulative sedimentation velocity which depends on the particle size distribution [1]. In general the number of particles is reciprocal proportional to the particle size. In table 1 the deposition velocity for some particle sizes and measured cumulative deposition velocities in an ISO 8 cleanroom are given.

Table 1: Deposition velocities of particles

Equivalent aerodynamic particle diameter (µm)	Deposition velocity (cm/s) of particles with discrete diameters	Deposition velocity (cm/s) of particles with cumulative diameters
5	0.09	0.29
10	0.36	0.91
25	2.3	4.2
40	5.8	9.1
50	9.0	13
100	29	41

One can observe a particle in an air pocket. If this pocket leaves the cleanroom before a particle can leave the air pocket by deposition it will be removed from the cleanroom. This means that particle deposition is influenced by the residence time of an air pocket in the cleanroom. This residence time is influenced by the local air change rate which depends on the air supply per m^2, the cleanroom height and the ventilation effectiveness [2].

The particle deposition rate of macroparticles depends on the removal efficiency of the cleanroom installation and the way the cleanroom is used. The most important operational aspects are garment use, entry procedures, cleaning program and working methods.

The particle deposition rate R_D is expressed as the number of particles ≥D µm per square meter per hour. In general the number of particles is reciprocal proportional to the particle size. The particle deposition rate level L gives the deposition rate of the equivalent number of particles ≥10 µm per $m^2 \cdot h$. The particle deposition rate levels are given in order of magnitudes from L = 1 to L = 1,000,000.

Need for new standard

Particle deposition is especially observed during operation in cleanrooms where people are working. Personnel generates, carries and distributes particles of all sizes. Most particles up to about 25 micrometer can be removed by air flow. The air cleanliness with respect to particles ≥25 µm is difficult to determine directly.

An air cleanliness level does not give direct information on the likelihood of product contamination. A particle deposition rate gives a relation between airborne particle concentration and likelihood of product surface contamination. The expected number of critical particles is the particle deposition rate for these critical particles times the product area times the time of exposure.

Both aspects were the reason to write a standard on particle deposition rate. Since the measurement method is already described in ISO 14644-3:2019 the title of ISO 14644-17:2021 is 'Particle deposition rate applications'. In contamination control cleanliness requirements can be derived from an impact assessment. Required product cleanliness levels are input for the particle deposition rate control to be established. In operation the effectiveness of the control can be demonstrated by monitoring the particle deposition rate.

In some applications, like optical systems not the number of particles is important, but the obscuration or area coverage. The area coverage is the sum of the cross section areas of the deposited particles relative to the observed area. The obscuration rate is the change of the particle area coverage during exposure and can be applied in a similar way as the particle deposition rate to determine the expected surface contamination [3].

Measurement of particle deposition rate

Particle deposition rate can also be expressed as the change of surface cleanliness in number of particles larger than or equal to the smallest measured particle size per surface area during exposure. The surface concentration can be recalculated to the particle size of interest by multiplying the concentration with the observed particle size and dividing by the particle size of interest.

Particle deposition rates can be measured using witness plates and measuring the surface cleanliness before and after exposure and determining the time of exposure in the associated state of occupancy. Instruments to measure a particle deposition rate using dedicated witness plates are available. Instruments with a built-in test surface can measure the change of surface cleanliness with short intervals and can be used as real time particle deposition monitors [4].

Particle deposition rate limit

The maximum acceptable contamination in number of particles larger than or equal to a critical particle size on a critical surface is determined by the particle deposition rate during exposure. So by determining the vulnerable area, the time of exposure and the maximum number of critical particles the limit for the particle deposition rate can be determined. For particles up to almost 40 micrometer an empirical relation is given with the air cleanliness for particles ≥5 µm per m^3 during operation. In combination with the intended use, this can be used as requirement for the cleanroom installation.

Particle deposition causes an increase of the concentration of particles on surfaces. Surface particles can be transferred onto other surfaces during contact and after some time to resuspension of particles. The deposition of larger particles can be limited by proper operational programs. The entry program should limit the introduction of particles and the cleaning program should remove surface particles frequently to keep the surface cleanliness within a given limit. Guidance is given in ISO 14644-5.

Establish control for a particle deposition rate limit

To establish air cleanliness control ISO 14644-4:2022 "Design, construction and startup" can be used for design, construction and startup. To manage energy consumption ISO 14644-16:2019 "Energy efficiency in cleanrooms and clean air devices" can be applied. In the design, the intended operation should be considered to include the facilities to implement the operations programs. After verification of the construction of the cleanroom installation and training of personnel, the operation can start.

Demonstrate control by monitoring particle deposition rate

By monitoring the particle deposition rate the control can be demonstrated. In case the particle deposition rate is too high, the particle size distribution provides information on the type of improvements that can be made. An example in an ISO 6 cleanroom is given in figure 1.

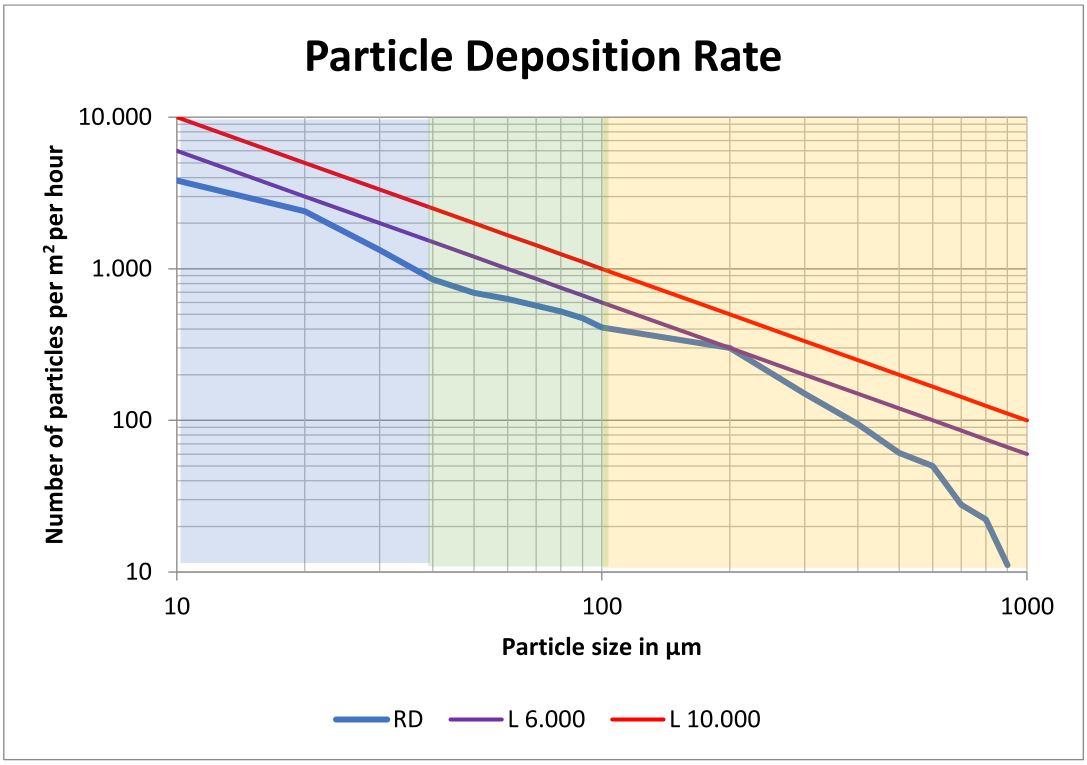

Figure 1. Cumulative particle deposition rate R_D distribution with PDR Level lines

If the particle deposition rate of particles > 100 um is too high, the cleaning program and its execution should be improved.
In case the particle deposition rate for particles ≥ 40 µm to ≥100 µm is too high, the personnel discipline should be improved by for example more occlusive and cleaner cleanroom clothing, better changing procedure and work processes.
In case the particle deposition rate for particles ≥5 µm to ≥30 µm is too high, it can be reduced by increasing the air supply and/or improving the ventilation efficiency.

Real time particle deposition monitoring data can be used to find potential sources.

Conclusion

The new standard is especially useful for products that are sensitive to macro particles, microbe carrying particles and/or visible particles in cleanrooms with personnel. Especially when critical area's are large and/or exposure times are long.

Industries that use particle deposition rates are aerospace, automotive, batteries, medical devices, optical system, displays and electronics. Microbial deposition rate is proportional to the particle deposition rate and therefore can be applied in the control microbiological contamination in life sciences and hospitals.

References

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[2] Whyte W, Agricola K and Derks M. *Airborne particle deposition in cleanrooms: relationship between deposition rate and airborne concentration.* Clean Air and Containment Review 2016; Issue **25**: 4-10. http://eprints.gla.ac.uk/119091/1/119091.pdf

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