INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY

## Contamination Control Division Technical Guide 1004

# IEST-G-CC1004

# Sequential-Sampling Plan for Use in Classification of the Particulate Cleanliness of Air in Cleanrooms and Clean Zones

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**SECTION**



**APPENDIX**



**FIGURE**

# Sequential-Sampling Plan for Use in Classification of the Particulate Cleanliness of Air in Cleanrooms and Clean Zones IEST-G-CC1004

*[This guide is based on a paper by Cooper and Milholland (reference 7a).]*

## 1 Application

This guide provides background and support for the use of sequential-sampling plans for the classification of air cleanliness in cleanrooms and clean zones. Such plans are generally most appropriate for environments where air cleanliness is expected to qualify as ISO Class 4 or cleaner.

The sequential-sampling plan described herein has been developed to match the operating characteristic (OC) curve of the traditional single-stage-sampling plan. As a result, the probability of passing or failing a given classification is about the same for both plans.

When compared to sampling times required by traditional single-stage-sampling methods, however, sequential sampling is found to be capable of saving about 80 percent of the sampling time when the air sampled is very clean, 35 percent when the air just meets the class limit, and more than 80 percent when the concentration of particles in the air exceeds 2.5 times the class limit.

Sequential sampling is especially applicable as an alternative to a single-stage-sampling scheme in cases where the upper confidence limit (UCL) on the grand mean of the particle concentration is not required or when, with some further development, it can be used to provide an equivalent estimate of the UCL.

***NOTE: The statistical validity of data from long-term sampling of very clean air at a given location is based upon the assumption that the particle concentration will remain relatively constant or will vary only in a random manner during the sampling period. Statistical validity may be degraded, however, if unique phenomena are present that can cause significant variations in concentration.***

  

# 2 Definitions

## 2.1 classification

a) A relative measure of air cleanliness, expressed in terms of a standard system of class limits such as that defined by ISO 14644-1.

b) The process of determining the class limit concentration of particles.

## 2.2 class limit

The maximum allowable concentration of particles (in particles per cubic meter of air), of a specified particle size and larger, as determined by the equation upon which the classification system is based.

## 2.3 pass/fail decision

The result of the analysis of sampling data and comparison with specified class limits, whereby the determination of class verification is made.

## 2.4 sequential-sampling plan

An alternative method of gathering particle concentration data by multistage sampling which, under appropriate circumstances, can enable more efficient and cost-effective determination of pass / fail decisions regarding classification.

## 2.5 single-stage-sampling plan

The sampling protocol that involves collecting samples of air whose volume is at least equivalent to the volume that would be required if the particle concentration were at the class limit being verified. This sampling protocol is also known as the *fixed-sampling plan*.

# 3 Background

Standard practice for the classification of air in cleanrooms, such as the procedure described in ISO 14644-1 (reference 7b), calls for the acquisition of one or more samples of air at each of a specified number of locations throughout the space being classified. The minimum volume of each of these samples of air is defined as the volume that would theoretically contain 20 particles, if the particle concentration in the air being sampled were at the designated class limit.

In order to meet the specified classification, the average particle concentration at each sampling location must not exceed the specified class-limit concentration. In addition, an upper confidence limit (UCL) calculated from all of the location averages must not exceed the specified class-limit concentration. If both of these requirements are met, the air cleanliness in the space being sampled is said to meet a certain class limit, as defined and determined in accordance with ISO 14644-1. Typically, environments used for microelectronics manufacture are cleaner than ISO Class 5, for example.

The advantages of sequential sampling can be shown by comparing it with the more customary procedure of single-stage sampling. The protocol for single-stage sampling involves the collection of complete, discrete samples of fixed extent. Sequential sampling, as introduced by Wald (reference 7c), is based on the comparison of the running (cumulative) count total against a limit that is a function of the amount (extent) of sampling completed. Wald noted that sequential sampling generally entails less sampling (and, consequently, less time) than any single-stage-sampling plan having the same probabilities of false acceptance and false rejection.

In classification testing of a cleanroom that is expected to meet ISO Class 5 (per ISO 14644-1), reduced sampling time may not be significant, as a particle counter operating at a volume flow rate of 28.3 L / min (1 $ft^3$ / min) would register 20 particles in the size range 0.5 µm and larger in only 0.2 min, if the air being sampled were at the class limit.

Sampling in a much cleaner environment, however, can extend the time required to register the necessary 20 counts to impractical extremes. This extension of time is the result of the combined effects of fewer available particles present in the air of lower particle concentration, and the lower sample flow rate that is typical of particle counters or condensation nucleus counters that are capable of detecting particles small enough to be (statistically) present in sufficient quantity. For example, classification of the air in a cleanroom that is expected to meet ISO Class 1, using a particle counting system capable of counting particles 0.1 µm and larger at a volume flow rate of 2.83 L / min (0.1 $ft^3$ / min) would require a sampling time of 706 min at each location.

# 4 Operating characteristic curve

Figure 1 shows the operating characteristic (OC) curve, the curve that results from counting particles in air according to the single-stage-sampling technique at a single location in accordance with