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FEDERAL STANDARD

AIRBORNE PARTICULATE CLEANLINESS CLASSES IN CLEANROOMS AND CLEAN ZONES

This Standard is approved by the Commissioner, Federal Supply Service, General Services Administration, for the use of all Federal agencies.

FSC 3694

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1. Scope and limitations.

1.1 Scope. This document establishes standard classes, and provides for alternative classes, of air cleanliness for cleanrooms and clean zones based on specified concentrations of airborne particles. It prescribes methods for verifying air cleanliness and requires that a plan be established for monitoring air cleanliness. It also provides a method for determining and describing concentrations (U descriptors) of ultrafine particles.

1.2 Limitations. The requirements of this document do not apply to equipment or supplies for use within cleanrooms or clean zones. Except for size classification and population, this document is not intended to characterize the physical, chemical, radiological, or viable nature of airborne particles. No universal relationship has been established between the concentration of airborne particles and the concentration of viable airborne particles. In addition to the need for a clean air supply that is monitored for total particulate contamination and that meets established limits, special requirements are necessary for monitoring and controlling other forms of contamination.

2. Referenced documents.

2.1 Box, George E. P., Hunter, William G., and Hunter, J. Stuart, Statistics for Experimenters, John Wiley & Sons, New York, 1978.

2.2 Hinds, W. C., Aerosol Technology: Properties, Behavior, and Measurement of Airborne Particles, John Wiley & Sons, New York (1982).

2.3 FED-STD-376, Preferred Metric Units for General Use by the Federal Government.

The International System of units (SI) is preferred. In the event of a conflict between SI and U. S. customary units, SI units shall take precedence.

3. Definitions.

3.1 Airborne particulate cleanliness class. The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air (per cubic foot of air), shown for the class in Table I, as determined by the statistical methods of 5.4. The name of the class in SI units is taken from the logarithm (base 10) of the maximum allowable number of particles, 0.5 μm and larger, per cubic meter. The name of the class in English (U.S. customary) units is taken from the maximum allowable number of particles, 0.5 μm and larger, per cubic foot.

3.2 Anisokinetic sampling. The condition of sampling in which the mean velocity of the flowing air stream differs from the mean velocity of the air entering the inlet of the sampling probe. Because of particle inertia, anisokinetic sampling can cause the concentration of particles in the sample to differ from the concentration of particles in the air being sampled.

3.3 Calibration. Comparison of a measurement standard or instrument of unknown accuracy with another standard or instrument of known accuracy to detect, correlate, report, or eliminate by adjustment any variation in the accuracy of the unknown standard or instrument.

3.4 Clean zone. A defined space in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class.

3.5 Cleanroom. A room in which the concentration of airborne particles is controlled and which contains one or more clean zones.

3.5.1 As-built cleanroom (facility). A cleanroom (facility) that is complete and ready for operation, with all services connected and functional, but without equipment or operating personnel in the facility.

3.5.2 At-rest cleanroom (facility). A cleanroom (facility) that is complete, with all services functioning and with equipment installed and operable or operating, as specified,[1] but without operating personnel in the facility.

3.5.3 Operational cleanroom (facility). A cleanroom (facility) in normal operation, with all services functioning and with equipment and personnel, if applicable, present and performing their normal work functions in the facility.

3.6 Condensation nucleus counter (CNC). An instrument for counting small airborne particles, approximately 0.01 μm and larger, by optically detecting droplets formed by condensation of a vapor upon the particles.

3.7 Discrete-particle counter (DPC). An instrument, such as an optical particle counter or a condensation nucleus counter, capable of resolving responses from individual particles.

3.8 Entrance plane. A plane perpendicular to the unidirectional airflow located immediately upstream of the region of interest (typically the work area unless otherwise specified[1]) and having the same dimensions as the cross section of the clean zone perpendicular to the direction of the airflow.

3.9 Isoaxial. A condition of sampling in which the direction of the airflow into the sampling probe inlet is the same as that of the unidirectional airflow being sampled.

3.10 Isokinetic sampling. The condition of isoaxial sampling in which the mean velocity of the air entering the probe inlet is the same as the mean velocity of the unidirectional airflow at that location.

3.11 Monitoring. The routine determination of airborne particle concentrations, as well as other relevant conditions, in cleanrooms and clean zones.

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

3.12 Nonunidirectional airflow. Airflow which does not meet the definition of unidirectional airflow; previously referred to as "turbulent" or "non-laminar" airflow.

3.13 Particle. An object of solid or liquid composition, or both, and generally between 0.001 and 1000 μm in size.

3.14 Particle concentration. The number of individual particles per unit volume of air.

3.15 Particle size. The apparent maximum linear dimension of a particle in the plane of observation as seen with a microscope, or the equivalent diameter of a particle detected by automatic instrumentation. The equivalent diameter is the diameter of a reference sphere having known properties and producing the same response in the sensing instrument as the particle being measured.

3.16 Student's t statistic. The distribution:

t = [(sample mean) - (population mean)]/[standard error of the sample mean]

obtained from sampling a normal (Gaussian) distribution. Tables of critical values are available in statistics texts (see 2.1).

3.17 U descriptor. The maximum allowable concentration (particles per cubic meter of air) of ultrafine particles. The U descriptor serves as an upper confidence limit or as the upper limit for the location averages, or both, as appropriate. U descriptors are independent of airborne particulate cleanliness classes, and may be specified alone or in conjunction with one or more airborne particulate cleanliness classes.

3.18 Ultrafine particles. Particles in the size range from approximately 0.02 μm to the upper limit of detectability of the DPC described in Appendix D. Ultrafine particles are operationally defined by the relationship for counting efficiency vs. particle size of Appendix D.

3.19 Unidirectional airflow. Airflow having generally parallel streamlines, operating in a single direction, and with uniform velocity over its cross section; previously referred to as "laminar" airflow.

3.20 Upper confidence limit (UCL). An upper limit of the estimated mean which has been calculated so that, in a specified percentage of cases, its value exceeds the true population mean, both means having been sampled from a normal (Gaussian) distribution. In this Standard, a 95% UCL is used.

3.21 Verification. The procedure for determining the compliance of air in a cleanroom or clean zone to an airborne particulate cleanliness class limit or a U descriptor, or both, as specified.[1]

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

4. Airborne particulate cleanliness classes and U descriptors. Verification of air cleanliness, in accordance with section 5 of this Standard, utilizes a system of classification based upon specified limits.

This section defines standard classes of air cleanliness, each having specific concentrations of airborne particles in specific particle size ranges (see Table I). Provisions are also made for defining standard classes based upon alternative particle sizes, and for defining alternative (nonstandard) classes. In addition, a basis is provided for describing air cleanliness in terms of concentrations (U descriptors) of ultrafine particles.

A system of nomenclature suitable for describing all classes and U descriptors is given.

4.1 Classes listed in Table I. For the airborne particulate cleanliness classes listed in Table I, verification of air cleanliness shall be performed by measurement at one or more of the particle sizes listed in Table I or at other specified particle sizes, as follows:

4.1.1 Measurement at particle sizes listed in Table I. Verification shall be performed by measurement at one or more of the particle sizes listed for the class in Table I, as specified,[1] and shall be reported using the format described in 4.4.1. The airborne particulate cleanliness class is considered met if the particle concentration measurements for the specified size or sizes are within the limits given in Table I, as determined by the statistical analysis of 5.4.

4.1.2 Measurement at alternative particle sizes. Verification may be performed by measurement at particle sizes other than those listed in Table I, with the following limitation: The alternative particle size or sizes selected must be within the range of sizes listed for the indicated class in Table I. The airborne particulate cleanliness class is considered met if the particle concentration measurements for each selected alternative size do not exceed the limit given in Table I for the next larger particle size, as determined by the statistical analysis of 5.4. Verification shall be reported using the format described in 4.4.1.

4.2 Provision for defining alternative airborne particulate cleanliness classes. Classes other than those shown in Table I (for example, Classes M 2.2, M 4.3, and M 6.4 (Classes 5, 600, and 70 000)) may be defined when special conditions dictate their use. The name for an alternative class shall be based on the concentration limit specified for particles 0.5 μm and larger, in the same manner as the classes listed in Table I. Concentration limits for other particle sizes shall be in the same proportions as those of the next cleaner class in Table I; these limits can be calculated by using the appropriate equation in the footnote under Table I. Similarly, for classes cleaner than Class M 1 or Class 1, the concentration limits at particle sizes other than 0.5 μm shall be in the same proportions as those of Class M 1 or Class 1.

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

TABLE I

AIRBORNE PARTICULATE CLEANLINESS CLASSES

Class limits are given for each class name. The limits designate specific concentrations (particles per unit volume) of airborne particles with sizes equal to and larger than the particle sizes shown*

Class Name**		Class limits									
		0.1 μm		0.2 μm		0.3 μm		0.5 μm		5 μm	
		Volume units		Volume units		Volume units		Volume units		Volume units	
SI	English***	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)
M 1		350	9.91	75.7	2.14	30.9	0.875	10.0	0.283	–	–
M 1.5	1	1 240	35.0	265	7.50	106	3.00	35.3	1.00	–	–
M 2		3 500	99.1	757	21.4	309	8.75	100	2.83	–	–
M 2.5	10	12 400	350	2 650	75.0	1 060	30.0	353	10.0	–	–
M 3		35 000	991	7 570	214	3 090	87.5	1 000	28.3	–	–
M 3.5	100	–	–	26 500	750	10 600	300	3 530	100	–	–
M 4		–	–	75 700	2140	30 900	875	10 000	283	–	–
M 4.5	1 000	–	–	–	–	–	–	35 300	1 000	247	7.00
M 5		–	–	–	–	–	–	100 000	2 830	618	17.5
M 5.5	10 000	–	–	–	–	–	–	353 000	10 000	2 470	70.0
M 6		–	–	–	–	–	–	1 000 000	28 300	6 180	175
M6.5	100 000	–	–	–	–	–	–	3 530 000	100 000	24 700	700
M 7		–	–	–	–	–	–	10 000 000	283 000	61 800	1 750

*The class limits shown in Table I are defined for classification purposes only and do not necessarily represent the size distribution to be found in any particular situation.

**Concentration limits for intermediate classes can be calculated, approximately, from the following equations:

$$\text{particles}/m^3 = 10^M(0.5/d)^{2.2}$$

where M is the numerical designation of the class based on SI units, and d is the particle size in micrometers, or

$$\text{particles}/ft^3 = N_C(0.5/d)^{2.2}$$

where N_C is the numerical designation of the class based on English (U. S. customary) units, and d is the particle size in micrometers.

***For naming and describing the classes, SI names and units are preferred; however, English (U.S. customary) units may be used.

When expressed in SI units, the numerical designation of the class is derived from the logarithm (base 10, with the mantissa truncated to a single decimal place) of the maximum allowable number of particles, 0.5 µm and larger, per cubic meter of air. When expressed in English (U. S. customary) units, the numerical designation of the class is derived from the maximum allowable number of particles, 0.5 µm and larger, per cubic foot of air.

(a) For alternative classes less clean than Class M 4.5 (Class 1000), verification shall be performed by measurement either in the particle size range 0.5 µm and larger or in the particle size range 5 µm and larger, or both, as specified.[1]

(b) For alternative classes cleaner than Class M 4.5 (Class 1000) but less clean than Class M 3.5 (Class 100), verification shall be performed by measurement in one or more of the particle size ranges: 0.2 µm and larger, 0.3 µm and larger, and 0.5 µm and larger, as specified.[1]

(c) For alternative classes cleaner than Class M 3.5 (Class 100), verification shall be performed by measurement in one or more of the particle size ranges: 0.1 µm and larger, 0.2 µm and larger, 0.3 µm and larger, and 0.5 µm and larger, as specified.[1]

4.3 Provision for describing ultrafine particle concentrations (U descriptors). A U descriptor, if specified,[1] shall be used to express the concentration of ultrafine particles as defined in 3.17. The U descriptor may supplement the class definition or may be used alone. The format for U descriptors is described in 4.4.2.

4.4 Nomenclature for airborne particle concentrations.

4.4.1 Format for airborne particulate cleanliness classes. Classes shall be expressed by using the format "Class X (at Y µm)," where:

X represents the numerical designation of the airborne particulate cleanliness class; and

Y represents the particle size or sizes for which the corresponding particle concentration (class) limits are specified.

For example:

"Class M 2.5 (at 0.3 µm and 0.5 µm)" describes air with not more than 1060 particles/m^3 of a size 0.3 µm and larger, nor more than 353 particles/m^3 of a size 0.5 µm and larger.

"Class 100 (at 0.5 µm)" describes air with not more than 100 particles/ft^3 of a size 0.5 µm and larger.

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

4.4.2 Format for U descriptors. A U descriptor may be used alone or as a supplement to the specification of an airborne particulate cleanliness class. Specifying a particle size for U descriptors is unnecessary, since the lower cutoff for ultrafine particles is determined by the equipment used (see 3.18 and Appendix D).

U descriptors shall be expressed by using the format "U(x)," where:

x is the maximum allowable concentration (particles per cubic meter of air) of ultrafine particles.

For example:

"U(20)" describes air with not more than 20 ultrafine particles/m^3.

"Class M 1.5 (at 0.3 μm), U(2000)" describes air with not more than 106 particles/m^3 of a size 0.3 μm and larger, and not more than 2000 ultrafine particles/m^3.

5. Verification and monitoring of airborne particulate cleanliness.

5.1 Verification of airborne particulate cleanliness. Verification, the procedure for determining the compliance of air in a cleanroom or clean zone to an airborne particulate cleanliness class limit or a U descriptor, or both, as defined in section 4, shall be performed by measuring the concentrations of airborne particles under the conditions set forth in 5.1.1 through 5.1.4. The particle size or sizes at which the measurements are to be made for verification shall be specified, using the appropriate format as described in 4.4.

5.1.1 Frequency. After initial verification, tests shall be performed at periodic intervals, or as otherwise specified.[1]

5.1.2 Environmental test conditions. Verification of air cleanliness shall be accomplished by measuring particle concentrations under specified[1] operating conditions, including the following.

5.1.2.1 Status of cleanroom or clean zone during verification. The status of the cleanroom or clean zone during verification shall be reported as "as-built," "at-rest," "operational," or as otherwise specified.[1]

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

5.1.2.2 Environmental factors. Measurements and observations of applicable environmental factors related to the cleanroom or clean zone during verification shall be recorded. Such factors may include, but are not limited to, air velocity, air volume change rate, room pressurization, makeup air volume, unidirectional airflow parallelism, air turbulence, air temperature, humidity or dew point, and room vibration. The presence of equipment and personnel activity should also be noted.

5.1.3 Particle counting. Verification of air cleanliness in cleanrooms and clean zones shall be performed in accordance with the appropriate particle counting method or methods in 5.3, as specified.[1] Appropriate sampling locations and sampling plan shall be selected from the following subparagraphs.

5.1.3.1 Sample locations and number: unidirectional airflow. For unidirectional airflow, the sample locations shall be uniformly spaced throughout the clean zone at the entrance plane, unless otherwise specified,[1] except as limited by equipment in the clean zone.

The minimum number of sample locations required for verification in a clean zone with unidirectional airflow shall be the lesser of (a) or (b):

(a) SI units: $\mathbf{A/2.32}$

where $\mathbf{A}$ is the area of the entrance plane in $\mathbf{m^2}$

English (U. S. customary) units: $\mathbf{A/25}$

where $\mathbf{A}$ is the area of the entrance plane in $\mathbf{ft^2}$

(b) SI units: $\mathbf{A \times 64/(10^M)^{0.5}}$

where $\mathbf{A}$ is the area of the entrance plane in $\mathbf{m^2}$, and $\mathbf{M}$ is the SI numerical designation of the class listed in Table I

English (U. S. customary) units: $\mathbf{A/(N_C)^{0.5}}$

where $\mathbf{A}$ is the area of the entrance plane in $\mathbf{ft^2}$, and $\mathbf{N_C}$ is the numerical designation of the class, in English (U. S. customary) units, listed in Table I

The number of locations shall always be rounded to the next higher integer.

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

5.1.3.2 Sample locations and number: nonunidirectional airflow. For nonunidirectional airflow, the sample locations shall be uniformly spaced horizontally, and as specified[1] vertically, throughout the clean zone, except as limited by equipment within the clean zone.

The minimum number of sample locations required for verification in a clean zone with nonunidirectional airflow shall be equal to:

SI units: $A \times 64/(10^M)^{0.5}$

where A is the floor area of the clean zone in m^2, and M is the SI numerical designation of the class listed in Table I

English (U. S. customary) units: $A/(N_C)^{0.5}$

where A is the floor area of the clean zone in ft^2, and N_C is the numerical designation of the class in English (U. S. customary) units listed in Table I

The number of locations shall always be rounded to the next higher integer.

5.1.3.3 Restrictions on sample locations. No fewer than two locations shall be sampled for any clean zone. The sample locations shall be uniformly spaced throughout the clean zone except as limited by equipment within the clean zone. At least one sample shall be taken at each of the sample locations selected (see 5.1.3.1 or 5.1.3.2). More than one sample may be taken at each location, and different numbers of samples may be taken at different locations, but a total of at least five samples shall be taken in each zone. Sampling at more locations than the required minimum will result in greater precision in the mean of the location averages and, when applicable, its upper confidence limit.

5.1.3.4 Sample volume and sampling time. The volume of air sampled and time of sampling shall be determined in accordance with the applicable paragraph below.

5.1.3.4.1 Single sampling plan for classes in Table I. Each sample of air tested at each location shall be of sufficient volume such that at least 20 particles would be detected, if the particle concentration were at the class limit, for each specified particle size. The following formula provides a means of calculating the minimum volume of air to be sampled as a function of the

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

number of particles per unit volume listed in the appropriate cell of Table I:

Volume = 20 particles/[class limit (particles/volume) from Table I]

The volume of air sampled shall be no less than 0.00283 m^3 (0.1 ft^3), and the results of the calculation of the sample volume shall not be rounded down.[2]

A larger sample volume will decrease the variation between samples, but the volume should not be so large as to render the sampling time impractical. Sample volumes need not be identical at all locations; however, the particle concentration shall be reported in terms of particles per cubic meter (per cubic foot) of air regardless of the sample volume. The volume of air sampled shall also be reported. Sampling larger volumes than the required minimum will result in greater precision in the mean of the location averages and its upper confidence limit.

The sampling time is calculated by dividing the sample volume by the sample flow rate.

5.1.3.4.2 Single sampling plan for alternative classes or particle sizes. The minimum sample volume required for verifying the compliance of air to other class limits, as defined in 4.2, shall be the volume determined for the next cleaner class listed in Table I, in accordance with the procedure described in 5.1.3.4.1.

The minimum sample volume for verification by measurement at alternative particle sizes, as described in 4.1.2, shall be the volume determined for the next larger particle size shown in Table I, in accordance with the procedure described in 5.1.3.4.1.

The sampling time is calculated by dividing the sample volume by the sample flow rate.

Other considerations concerning sample volume, as detailed in 5.1.3.4.1, also apply in these situations.

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[2] Example:

The minimum sample volume for Class M 2.5 (at 0.5 μm) [Class 10 (at 0.5 μm)]:

volume = 20 particles/(353 particles/m^3)

= 0.0567 m^3 or

volume = 20 particles/(10 particles/ft^3)

= 2.00 ft^3

5.1.3.4.3 Single sampling plan for U descriptors. The sample volume required for verifying the concentration of ultrafine particles shall be the volume of air sufficient to permit at least 20 particles to be detected at the specified U descriptor. The minimum volume, in cubic meters, shall be calculated by dividing 20 by the U descriptor. The results of this calculation shall not be rounded down, and in no case shall the volume be less than 0.00283 m^3.

The sampling time is calculated by dividing the sample volume by the sample flow rate.

5.1.3.4.4 Sequential sampling plan. As an alternative method for verifying the compliance of air to the limits of airborne particulate cleanliness Classes M 2.5 and cleaner (Classes 10 and cleaner), the sequential sampling plan described in Appendix F may be used (Sequential Sampling: An Optional Method for Verifying the Compliance of Air to the Limits of Airborne Particulate Cleanliness Classes M 2.5 and Cleaner). The advantage of sequential sampling is the potential to reduce significantly the sample volume at each location and, consequently, to reduce sampling times.

5.1.4 Interpretation of the data. Statistical evaluation of particle concentration measurement data shall be performed, in accordance with 5.4, to verify compliance of air to airborne particulate cleanliness class limits or U descriptors, or both. If a sequential sampling plan is used, the data analysis described in Appendix F shall be used.

5.2 Monitoring of airborne particulate cleanliness. After verification, airborne particulate cleanliness shall be monitored while the cleanroom or clean zone is operational, or as otherwise specified.[1,3] Other environmental factors, such as those listed in 5.1.2.2, may also be monitored as specified[1] to indicate trends in variables that may be related to airborne particulate cleanliness.

5.2.1 Monitoring plan. A monitoring plan shall be established based on the airborne particulate cleanliness and the degree to which contamination must be controlled for protection of process and product, as specified.[1]

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[1] When terms such as "shall be specified," "as specified," etc. are used without further reference, the degree of control needed to meet requirements will be specified by the user or contracting agency.

[3] For monitoring purposes only, determining the extent to which particles are contaminating surfaces may be accomplished by allowing airborne particles to deposit on test surfaces and then counting them by appropriate methods. The relationship between airborne and deposited particles, however, is complex. Although the concentration of airborne particles in ambient air is an important variable influencing the deposition of these particles, it is not the only variable; unfortunately, the magnitudes of many of the other variables may either be unknown or not easily measured. Therefore, while the rate of particle deposition on surfaces can be a suitable monitor for airborne particulate cleanliness, an unambiguous relationship cannot be given.

The plan shall specify the frequency of monitoring, the operating conditions, and the method of counting particles. The number of locations and the number and volume of samples, as well as the method used for interpreting the data, shall also be specified.

5.2.2 Particle counting for monitoring. Particle counting for the monitoring plan shall be performed using one of the methods in 5.3, as specified.[1] Particle concentration measurements shall be made at selected locations throughout the clean zone, or where cleanliness levels are especially critical, or where higher particle concentrations have been found during verification.

5.3 Methods and equipment for measuring airborne particle concentrations. The method and equipment to be used for measuring airborne particle concentrations shall be selected on the basis of the particle size or sizes specified. The methods in the following paragraphs are suitable for verifying the compliance of air to airborne particulate cleanliness class limits or U descriptors, as appropriate, and may also be used for monitoring air cleanliness. Other particle counting methods or equipment, or combinations of other methods and equipment, may be used if demonstrated to have accuracy and repeatability equal to or better than these methods and equipment.

Equipment used to determine the concentration of airborne particles shall be properly maintained in accordance with the manufacturer's instructions and periodically calibrated, as specified.[1]

5.3.1 Counting particles 5 micrometers and larger. The concentrations of particles in the range 5 μm and larger shall be determined by using the procedures in Appendix A (Counting and Sizing Airborne Particles Using Optical Microscopy).

Alternatively, a discrete-particle counter (DPC) may be used if the procedures described below for sample acquisition, handling, and measurement are satisfied. The counting efficiency of the DPC for particles larger than 5 μm shall be stated in accordance with the procedures of Appendix B (Operation of a Discrete-particle Counter). The DPC shall be operated to count only those particles 5 μm and larger.

Whichever method is used, the probe inlet dimensions, sample flow rates, and probe orientations should be selected to permit isokinetic sample acquisition. Isokinetic sampling is preferred, but if it cannot be achieved, an estimate of sampling bias shall be obtained by using the procedures of Appendix C (Isokinetic and Anisokinetic Sampling). Even when the probe inlet faces directly into the airflow (isoaxial sampling), artificial enrichment or depletion of the ambient particle concentration can occur at the inlet if the velocity of the airflow into the inlet differs from the velocity of the airflow in the immediate vicinity of the probe. Formulas are available for calculating the effects of such

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anisokinetic sampling upon observed measurements of particle concentrations (see, for example, 2.2 and Appendix C). For particles 0.5 μm and smaller, these artificial enrichments and depletions in concentration can be shown to be less than 5% and can be ignored. For particles 5 μm and larger, however, when the predicted artificial change in concentration exceeds 5%, the projected increase or decrease should be reported and the correction applied to the data before comparison with airborne particulate cleanliness class limits.

5.3.2 Counting particles smaller than 5 micrometers. The concentrations of particles smaller than 5 μm shall be determined by using a DPC in accordance with the procedures of Appendix B. Particle size data shall be reported in terms of equivalent diameter as calibrated against reference standard particles.

As mentioned (see 5.3.1), the bias resulting from anisokinetic sampling is less than 5% for particles 0.5 μm and smaller, but can be substantial for particles 5 μm and larger. However, if verification is to be performed at one or more particle sizes in the range **between** 0.5 μm and 5 μm (that is, intermediate sizes not listed in Table I), the likelihood of bias from anisokinetic sampling increases with increasing particle size, and a correction for anisokinetic sampling may be necessary.

5.3.3 Counting ultrafine particles. The concentrations of ultrafine particles shall be determined by using the procedures of Appendix D (Method for Measuring the Concentration of Ultrafine Particles).

5.3.4 Limitations of particle counting methods. Discrete-particle counters with unlike designs or operating principles may yield different data when used to sample air at the same location. Even recently calibrated instruments of like design may show significant differences. Caution should be used when comparing measurements from different instruments.

DPC's shall not be used to measure particle concentrations or particle sizes exceeding the upper limits specified by their manufacturers.

Since the sizing and counting of particles by optical microscopy defines size on the basis of a "longest dimension," while DPC's define size on the basis of "equivalent diameter," particle concentration data obtained from the two methods may not be equivalent and therefore shall not be combined.

5.3.5 Calibration of particle counting instrumentation. All instruments shall be calibrated against known reference standards at regular intervals using accepted procedures, as specified.[1] Calibration may include, but is not limited to, airflow rate and particle size. Calibration with respect to particle size shall be carried out for each size measured in verification.

5.4 Statistical analysis. Collection and statistical analysis of airborne particle concentration data to verify the compliance of air to specified airborne particulate cleanliness class limits or U descriptors shall be performed in accordance with the following subparagraphs. This statistical analysis deals only with random errors (lack of precision), not errors of a nonrandom nature (bias) such as erroneous calibration.

If a sequential sampling plan is used, the data shall be treated in accordance with the analysis described in Appendix F.

A rationale for the statistical methods used in this Standard is given in Appendix E.

5.4.1 Acceptance criteria for verification. The air in a cleanroom or clean zone shall have met the acceptance criteria for an airborne particulate cleanliness class (see Table I for standard limits) or U descriptor when the averages of the particle concentrations measured at each of the locations fall at or below the class limit or U descriptor. Additionally, if the total number of locations sampled is less than ten, the mean of these averages must fall at or below the class limit or U descriptor with a 95% UCL.

5.4.2 Calculations to determine acceptance.

5.4.2.1 Average particle concentration at a location. The average particle concentration, **A**, at a location is the sum of the individual sample particle concentrations, **C_i**, divided by the number of samples taken at the location, **N**, as shown in equation 5-1. If only one sample is taken, it is the average particle concentration.

$$A = (C_1 + C_2 + \ldots + C_N)/N \qquad \text{(Equation 5-1)}$$

5.4.2.2 Mean of the averages. The mean of the averages, **M**, is the sum of the individual averages, **A_i**, divided by the number of locations, **L**, as shown in equation 5-2. All locations are weighted equally, regardless of the number of samples taken.

$$M = (A_1 + A_2 + \ldots + A_L)/L \qquad \text{(Equation 5-2)}$$

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5.4.2.3 Standard deviation of the averages. The standard deviation of the averages, **SD**, is the square root of the sum of the squares of differences between each of the individual averages and the mean of the averages, $(A_i - M)^2$, divided by the number of locations, **L**, minus one, as shown in equation 5-3.

$$SD=\sqrt{\frac{(A_1-M)^2+(A_2-M)^2+\ldots+(A_L-M)^2}{L-1}}$$ (Equation 5-3)

5.4.2.4 Standard error of the mean of the averages. The standard error, **SE**, of the mean of the averages, **M**, is determined by dividing the standard deviation, **SD**, by the square root of the number of locations, as shown in equation 5-4.

$$SE=\frac{SD}{\sqrt{L}}$$ (Equation 5-4)

5.4.2.5 Upper confidence limit (UCL). The 95% UCL of the mean of averages, **M**, is determined by adding to the mean the product of the appropriate **UCL** factor (see Table II) and the standard error, **SE**, as shown in equation 5-5.

$$UCL = M + (UCL\ Factor \times SE)$$ (Equation 5-5)

TABLE II

UCL FACTOR FOR 95% UPPER CONFIDENCE LIMIT

No. of locations, L	2	3	4	5	6	7	8	9	>9*
95% UCL factor	6.31	2.92	2.35	2.13	2.02	1.94	1.90	1.86	NA.

*When the number of locations is greater than 9, the calculation of a **UCL** is not required (see 5.4.1).

5.4.2.6 Sample calculation. A sample calculation is given in Appendix E.

6. Recommendation for changes. When a Federal agency considers that this Standard does not provide for its essential needs, written request for changing this Standard, supported by adequate justification, shall be sent to the General Services Administration (GSA). This justification shall explain wherein the Standard does not provide for essential needs. The request shall be sent to the General Services Administration, General Products Commodity Center, Federal Supply Service, Engineering Division (7FXE), 819 Taylor Street, Fort Worth, TX 76102. The GSA will determine the appropriate action to be taken and will notify the requesting agency.

7. Conflict with referenced documents. Where the requirements stated in this Standard conflict with any document referenced herein, the requirements of this Standard shall take precedence. The nature of such conflicts shall be submitted in duplicate to the General Services Administration, General Products Commodity Center, Federal Supply Service, Engineering Division (7FXE), 819 Taylor Street, Fort Worth, TX 76102.

8. Federal agency interests.

Department of Commerce
Department of Defense, Office of the Assistant Secretary of Defense
    (Installations and Logistics)
    Army
    Navy
    Air Force - Custodian - 99
        - Reviewer - 84
Department of Energy
Department of Health and Human Services
Department of Transportation
General Services Administration
National Aeronautics and Space Administration
Nuclear Regulatory Commission

APPENDIX A

COUNTING AND SIZING AIRBORNE PARTICLES USING OPTICAL MICROSCOPY

A10. Scope. This appendix describes methods for determining the concentration of particles 5 µm and larger in cleanrooms and clean zones. By collecting the particles on a membrane filter and counting them using optical microscopy, their concentration in the air which is sampled can be determined.

A20. Summary of the method.

A20.1 Description. Using vacuum, a sample of air is drawn through a membrane filter. The rate of flow is controlled by a limiting orifice or by a flowmeter; thus, the total volume of air sampled is determined by the sampling time. The membrane filter is subsequently examined microscopically to determine the number of particles 5 µm and larger collected from the sample of air.

A20.2 Alternatives to optical microscopy. Image analysis or projection microscopy may replace direct optical microscopy for the sizing and counting of particles, provided the accuracy and reproducibility equal or exceed that of direct optical microscopy.

A20.3 Acceptable sampling procedures. Two acceptable procedures for sampling air for particles are described in this Appendix: (a) the Aerosol Monitor Method, and (b) the Open Filter Holder Method.

A30. Equipment.

A30.1 Equipment common to both methods.

A30.1.1 Microscope. Binocular microscope with ocular-objective combinations capable of 100- to 250-fold magnifications. A combination should be chosen so that the smallest division of the ocular reticle, at the highest magnification, is less than or equal to 5 µm. The objective used at the highest magnification should have a numerical aperture of at least 0.25.

A30.1.2 Ocular reticle. A 5- or 10-mm scale with 100 divisions or a micrometer eyepiece with a movable scale.

A30.1.3 Stage micrometer. A conventional stage micrometer with scale gradations of 0.01 to 0.1 mm per division.

A30.1.4 External illuminator.

A30.1.5 Vacuum source. Capable of maintaining a vacuum of 67 kPa (9.7 lb/inch^2) while pumping at a rate of at least 0.00047 m^3/s (1 ft^3/min).

A30.1.6 Timer, 60-minute range.

A30.1.7 Flowmeter or limiting orifice. Calibrated in line with the vacuum train.

A30.1.8 Manual counter.

A30.1.9 Filter storage holders. Petri slides with covers for the storage of membrane filters after use and during counting.

A30.1.10 Rinse fluid. Distilled or deionized water subsequently filtered through a membrane having pores 0.45 µm or smaller.

A30.1.11 Forceps. Flat, with unserrated tips.

A30.2 Equipment specific to Aerosol Monitor Method.

A30.2.1 Aerosol monitors. Dark, pore size 0.8 µm or smaller, with imprinted grid, and white (for contrast when counting dark particles), pore size 0.8 µm or smaller, with imprinted grid.

A30.2.2 Aerosol adapter and tubing.

A30.3 Equipment specific to Open Filter Holder Method.

A30.3.1 Filter holder.

A30.3.2 Membrane filters. Dark, pore size 0.8 µm or smaller, with imprinted grid, and white (for contrast when counting dark particles), pore size 0.8 µm or smaller, with imprinted grid.

A30.4 Optional equipment.

A30.4.1 Image analyzer.

A30.4.2 Projection microscope and screen.

A40. Preparation of equipment.

A40.1 For both methods. Equipment should be readied and stored (using protective covers or other suitable enclosures) in a cleanroom or clean zone having an airborne particulate cleanliness equal to or cleaner than that of the cleanroom or clean zone to be tested. Personnel performing sampling, sizing, and counting operations should wear garments consistent with the airborne particulate cleanliness class of the cleanroom or clean zone to be tested.

Using rinse fluid, wash the internal surfaces of all Petri slides that will be used to hold and transport membrane filters after the sampling and during counting. Allow the Petri slides to dry in a clean unidirectional airflow.

A40.2 Preparation for the Aerosol Monitor Method.

A40.2.1 Determining background count. If an average background count for a package of monitors (in the particle size range of interest) is provided by the manufacturer, examine 5% of the monitors in the package and determine the average background count on the membranes by using the method in A70. If the count so obtained equals or is less than the manufacturer's value, use the latter as the background count for all monitors in the package. If the count so obtained is higher than the manufacturer's value, or if no value was provided, determine a background count for each monitor used.

A40.2.2 Packaging and handling of aerosol monitors. After a background count has been determined, place the aerosol monitors in clean containers and transport them to the sampling location. Aerosol monitors should be opened only at the sample location or to remove a membrane filter.

A40.3 Preparation for the Open Filter Holder Method.

A40.3.1 Determining background count. Determine a representative background count for the membrane filters from each box of filters to be used. Examine two or more filter membranes per box, at 40-fold or higher magnification, using the procedure described in A70, and record the average count.

A40.3.2 Cleaning the membrane filter holder and mounting the filter. Disassemble and wash the membrane filter holder. After rinsing it with rinse fluid, allow the holder to dry in a clean, unidirectional airflow; do not wipe dry. With the holder still in the unidirectional airflow, use forceps to mount a membrane filter (grid side up) in the holder.

A40.3.3 Packaging and transport. Place the loaded filter holder into a clean container and transport it to the sampling location. The holder should be exposed only when sampling is about to take place or when removing or replacing a membrane filter.

A50. Sampling the air.

A50.1 Orientation and flow. When sampling air in cleanrooms and clean zones with unidirectional airflow, orient the aerosol monitor or filter holder to face into the airflow and adjust the rate of sampling to achieve isokinetic conditions (see Appendix C).

When sampling air in cleanrooms and clean zones with nonunidirectional airflow, orient the aerosol monitor or filter holder so that the opening faces upward, unless otherwise specified; the airflow into the filter should be adjusted to 0.00012 m^3/s (0.25 ft^3/min) for a 25-mm filter or 0.00047 m^3/s (1 ft^3/min) for a 47-mm filter.

For Class M 4.5 (Class 1000) the volume of air sampled should not be less than 0.28 m^3 (10 ft^3); for Class M 5.5 (Class 10 000) and classes less clean, no less than 0.028 m^3 (1 ft^3) of air should be sampled.

A50.2 Using the Aerosol Monitor Method.

A50.2.1 Setup. At the location to be sampled, remove the bottom plug from an aerosol monitor. Connect the monitor in series with the aerosol adapter, the limiting orifice or flowmeter (or orifice-flowmeter combination), and the vacuum source. Position the aerosol monitor as required.

If a pump is used, it should either be exhausted outside the area being sampled, or else appropriately filtered, to avoid contaminating the clean environment. If a flowmeter is used, adjust the flow to obtain the specified sampling flow rate.

A50.2.2 Sampling. Remove the top portion of the aerosol monitor and store it in a clean location. Activate the vacuum source, start the timer, and sample the air for a time sufficient to provide the required volume of air at the selected flow rate. When that time has elapsed, remove the aerosol monitor from the vacuum train and replace the top portion of the monitor. The bottom plug need not be replaced. Identify the aerosol monitor with a sample identification tag. Transport the aerosol monitor to a clean zone for counting; the clean zone should have an airborne particulate cleanliness equal to or cleaner than that of the clean zone sampled.

A50.3 Using the Open Filter Holder Method.

A50.3.1 Setup. At the location to be sampled, connect the filter holder in series with the limiting orifice or flowmeter (or orifice-flowmeter combination), and the vacuum source. Position the filter holder as required.

If a pump is used, it should either be exhausted outside the area being sampled, or else appropriately filtered, to avoid contaminating the clean environment. If a flowmeter is used, adjust the flow to obtain the specified sampling flow rate.

A50.3.2 Sampling. Remove the cover from the membrane filter holder and store it in a clean location. Activate the vacuum source, start the timer, and sample the air for a time sufficient to provide the required volume of air at the selected flow rate. When that time has elapsed, remove the filter holder from the vacuum train and replace the cover. Identify the filter holder with a sample identification tag. Transport the filter holder to a clean zone for counting; the clean zone should have an airborne particulate cleanliness equal to or cleaner than that of the clean zone sampled.

A60. Calibration of the microscope.

A60.1 Setup. Verify that the microscope has eyepiece-objective combinations capable of 100- to 250-fold magnification. Adjust the lamp and focus the microscope to illuminate evenly the entire field of view. Place the stage micrometer on the mechanical stage. Adjust and focus each eyepiece independently to give a sharp image of the gradations on the stage micrometer.

If an image analyzer or projection microscope is used, perform a similar calibration.

A60.2 Procedure. The following steps are used to calibrate a specific ocular reticle paired with a specific stage micrometer for the measurement of particles at any selected level of magnification.

(a) Determine and record the number of stage micrometer divisions, S, of size M (micrometers), corresponding to the number of divisions, R, in the full scale of the ocular reticle for each magnification of interest.

(b) Calibrate the scale of the ocular reticle for a given magnification using the formula:

$$S \times M/R = \text{Micrometers per scale division of the ocular reticle} \qquad \text{(Equation A60-1)}$$

Example:

For a given ocular reticle and stage micrometer at 100-fold magnification, let 150 divisions of the reticle correspond to 100 divisions, each 5.0 μm in length, of the stage micrometer. Using equation A60-1,

$$\begin{aligned} S \times M/R &= (100 \text{ divisions}) \times (5.0\ \mu\text{m/division})/(150 \text{ divisions}) \\ &= 3.33\ \mu\text{m per scale division of the ocular reticle} \end{aligned}$$

(c) Calculate the number of divisions of the ocular reticle corresponding to each specific particle size of interest.

Example:

Using the same data as in (b), calculate the number of divisions of the ocular reticle required to size particles in the range of 10 to 20 μm.

Since, at 100-fold magnification, each division of the ocular scale equals 3.33 μm, counting particles whose longest dimensions span 3 to 6 divisions will size particles in the range of 10 to 20 μm.

If the microscope has a zoom mechanism, appropriate intermediate magnifications may be selected in order to calibrate the ocular scale to integral values only. A change in interpupillary distance between operators changes focal length and, therefore, calibration.

A70. Counting and sizing particles by optical microscopy.

A70.1 Setup. In a cleanroom or clean zone suitable for the counting and sizing of particles, remove the membrane filter from the aerosol monitor or open filter holder using forceps. Insert the membrane, grid side up, in a clean Petri slide and cover it with the lid. Place the Petri slide on the microscope stage. Adjust the angle and focus of the illuminator to provide optimum particle definition at the magnification used for counting. Use an oblique lighting angle of 10 to 20 degrees so that the particle casts a shadow, thus enhancing definition.

A70.2 Selecting a field size. Select a field size which contains fewer than approximately 50 particles, 5 μm and larger. Possible choices are: a single grid square, a rectangle defined by one side of a grid square and the entire calibrated scale in the ocular reticle, or a rectangle defined by one side of a grid square and a portion of the calibrated scale of the ocular reticle.

A70.3 Counting particles. Estimate the total number of particles, 5 μm and larger, present on the membrane filter by examining one or two of the selected fields. If this estimate is greater than 500, use the procedure for counting particles described in A70.4.

If the estimate is less than 500, count all of the particles on the entire effective filtering area of the membrane. Scan the membrane by manipulating the stage so that the particles pass under the calibrated ocular scale. The size of a particle is determined by its longest dimension. The eyepiece with its calibrated ocular scale may be rotated if necessary. Using a manual counter, tally all particles with sizes in the range of interest. Record the number of particles counted in each field.

A70.4 Statistical particle counting. When the estimate of the number of particles, 5 μm and larger, on the membrane filter exceeds 500, a statistical counting method should be used. After a unit field size has been selected, particles are counted in a number of fields of that size until the following statistical requirement is met:

$$F \times N > 500 \qquad \text{(Equation A70-1)}$$

where:

F = number of unit fields counted, and

N = total number of particles counted in F unit fields.

The total number of particles on the membrane is then calculated from the following equation:

$$P = N \times A/(F \times a) \qquad \text{(Equation A70-2)}$$

where:

P = total number of particles in a given size range on the membrane,

N = total number of particles counted in F unit fields,

F = number of unit fields counted,

a = area of one unit field, and

A = total effective filtering area of the membrane.

A80. Reporting. Subtract the background count from the total number of particles on the membrane. Calculate the airborne particulate concentration of the air sampled by dividing the number of particles collected by the sample volume. Results may be expressed for each size range of interest.

A90. Factors affecting precision and accuracy. The precision and accuracy of this method are subject to human and mechanical error. To minimize human error, technicians must be trained in microscopy and in the sizing and counting of particles. Experienced technicians are also more likely to note deficiencies in equipment, further reducing the possibility of error. Standard specimens may be obtained or prepared for use in training technicians in the counting and sizing of particles.

For a given location, the repeatability of this method can be improved by increasing the number of samples or increasing the volume of air sampled, or both.

APPENDIX B

OPERATION OF A DISCRETE-PARTICLE COUNTER

B10. Scope and limitations.

B10.1 Scope. This appendix describes methods for the testing and operation of discrete-particle counters (DPC's) used to satisfy the requirements of this Standard. DPC's provide data on the concentration and size distribution of airborne particles within the approximate range 0.01 to 10 μm on a near-real-time basis. A DPC will correctly size only those particles within the limits of its dynamic range. The optical particle counter and the condensation nucleus counter are representative of single particle counting instruments.

B10.2 Limitations. Data related to the size and size distribution of particles, obtained through the primary calibration of a DPC, are dependent upon the type of particles used for calibration and upon the design of the DPC's.

Care must be exercised when comparing data from samples containing particles that vary significantly in composition or shape from the particles used for calibration.

Differences in the design of DPC's which can lead to differences in counting include dissimilar optical and electronic systems, predetection sample processing systems, and sample handling systems.

Potential causes of difference such as the foregoing should be recognized and minimized by using a standard primary calibration method and by minimizing the variability of sample acquisition procedures for instruments of the same type. In view of the significance of these effects, a detailed description of each DPC in use should be recorded.

B10.3 Qualifications of personnel. Individuals supervising or performing the procedures described herein should be trained in the use of DPC's and should understand the operation, capabilities, and limitations of the instruments.

B20. References.

B20.1 ASTM F50, Standard Practice for Continuous Sizing and Counting of Airborne Particles in Dust-Controlled Areas and Clean Rooms Using Instruments Capable of Detecting Single Sub-Micrometer and Larger Particles.

B20.2 ASTM F328, Practice for Determining Counting and Sizing Accuracy of an Airborne Particle Counter Using Near-Monodisperse Spherical Particulate Materials.

B20.3 ASTM F649, Practice for Secondary Calibration of Airborne Particle Counter Using Comparison Procedures.

B20.4 IES-RP-CC013, Recommended Practice for Equipment Calibration or Validation Procedures, Institute of Environmental Sciences.

B20.5 Scheibel, H. G., and Porstendorfer, J., "Generation of Monodisperse Ag- and NaCl Aerosols with Particle Diameters between 2 and 300 nm," J. Aerosol Sci., 14(2), 113-125 (1983).

B20.6 Bartz, H., et al, "A New Generator for Ultrafine Aerosols below 10 nm," Aerosol Sci. Technol., 6(2), 163-171 (1987).

B20.7 Keady, P. B., and Nelson, P. A., "Monodisperse Particle Generators for Calibrating Aerosol Instrumentation," Proc. IES Ann. Tech. Mtg., Orlando, Florida, May 1, 1984.

B20.8 Liu, B. Y. H., Pui, D. Y. H., Rubow, K. L., and Szymanski, W. W., "Electrostatic Effects in Aerosol Sampling and Filtration," Ann. Occup. Hyg., 29(2), 251-269 (1985).

B20.9 Raasch, J., and H. Umhauer, "Errors in the Determination of Particle Size Distribution Caused by Coincidence in Optical Particle Counters," Particle Characterization, 1(1), 53-58 (1984).

B20.10 Niida, T., et al, "Counting Efficiency of Condensation Nuclei Counters in N_2, Ar, CO_2 and He," J. Aerosol Sci., 19(7), 1417-1420 (1988).

B20.11 Gebhart, J., and Roth, C., "Background Noise and Counting Efficiency of Single Optical Particle Counters," Aerosols: Formation and Reactivity (Proc. Second International Aerosol Conference, West Berlin, Germany, 1986), Pergamon Journals, Ltd., Oxford, England (1986) 607-611.

B20.12 Ramey, T. C., "Measuring Air Flow Electronically," Mechanical Engineering, 107(5), 29-33 (1986).

B20.13 Baker, W. C., and Pouchot, J. F., "The Measurement of Gas Flow, Part I," J. Air Pollution Control Association, 33(1), 1983.

B20.14 Baker, W. C., and Pouchot, J. F., "The Measurement of Gas Flow, Part II," J. Air Pollution Control Association, 33(2), 1983.

B30. Summary of method.

B30.1 Specifying a procedure. A sample acquisition procedure should be established based on the level of cleanliness of the air that is to be verified or monitored. This program should include a description of the DPC or DPC's to be used, the sample transport system, the inlet probe, and any other features related to the operation of the DPC. The range of particle sizes to be measured should be identified as well as the sample volume and the location and frequency of sampling. If measurement is required over a very wide range of particle sizes, then more than one DPC may be required. The range for accurate measurement of particle size (dynamic range) by a DPC will vary with sensitivity. For a DPC used only to size particles smaller than 1 μm, a dynamic range of 20:1 is typical. For a DPC used to size particles larger than 1 μm, a dynamic range of up to 40:1 is typical. The dynamic range of a DPC depends upon the particle size distribution being measured and the gain of the data processing system.

B30.2 Calibration. Calibration of the DPC is required for the counting and sizing of particles and to verify the sample flow rate. Size calibration is performed with isotropic particles. Calibration for concentration is carried out with either monodisperse or polydisperse particles, as described in recognized standard methods (see, for example, B20.2 and B20.3). Latex spheres of well defined or certified mean diameter and standard deviation can be used to calibrate DPC's for particle size definition. Alternatively, calibration particles can be produced by physically separating a sized fraction of particles from a polydisperse suspension. The fraction may be defined either at the lower size limit or at both the upper and lower limits. The fractionating device should be defined and the size of the calibration particles stated with reference to the process used for fractionation. Monodisperse particles may also be produced by controlled condensation from a vapor (see, for example, 2.5 and 2.6) or by controlled atomization from a vibrating orifice (see 2.7). When calibration particles are produced by either of these methods from a material with a refractive index different from that of latex particles, it is important to note that the DPC being calibrated may indicate different particle sizes for the different materials, even though the particles are the same size.

Stable operation of the DPC can be achieved by standardizing against internal references built into the DPC or by other approved methods (see, for example, B20.1 through B20.4).

B30.3 Operation. Air in the cleanroom or clean zone to be verified or monitored is sampled at a known flow rate from the sample point or points of concern. Particles in the sampled air pass through the sensing zone of the DPC. Each particle produces a signal that can be related to its size, either directly or with reference to the operation of a predetection sample processing system. An electronic system sorts and counts the pulses, registering the number of particles of various sizes which have been recorded within the known volume of air sampled. The concentration and particle size data can be displayed, printed, or further processed locally or remotely.

B40. Apparatus and related documentation.

B40.1. Particle counting system. The apparatus should consist of a DPC selected on the basis of its ability to count and size single particles in the required size range. The DPC should include a sample airflow system, a particle sensing and measuring system, and a data processing system. The particle sensing and measuring system may include a means of size fractionation prior to particle sensing and measuring. The sensitivity of the DPC (minimum measurable particle size) should be selected consistent with the requirement for verifying that the air complies with the airborne particulate cleanliness class in the area of interest. For verification based on the measurement of particles approximately 0.1 μm and larger, an optical particle counter, a time-of-flight particle sizer, or an equivalent counter can be used. For verification based on the measurement of ultrafine particles, a counter such as a condensation nucleus counter, alone or in combination with a diffusion battery, a differential mobility analyzer, or an equivalent device can be used.

B40.2 Sample airflow system. The sample airflow system consists of a sampling probe with a sharp-edged inlet, a transit tube, a particle sensing and measuring chamber, an airflow metering or control system, and an exhaust system. No abrupt transitions in dimension should occur within the airflow system. The probe is connected to a transit tube which transports the sampled air to the particle sensing chamber. Probes that approach isokinetic sampling conditions can aid in reducing sampling bias (see Appendix C). The tube should have dimensions such that the transit time in the tube does not exceed 10 seconds.

B40.2.1 Particle transit considerations. The probe and transit tube should be configured so that the Reynolds number is between 5 000 and 25 000. For particles in the range of 0.1 to 1 μm and for a flow rate of 0.028 m^3/min (1.0 ft^3/min), a transit tube up to 30 m long may be used. For particles in the range of 2 to 10 μm the transit tube should be no longer than 3 m. Under these conditions, losses of small particles by diffusion and of large particles by sedimentation and impaction are predicted to be no more than 5% during transit through the tube (see Appendix C). For most applications, these tube configurations and flow conditions will be satisfactory. For special situations, more precise particle transit characteristics can be calculated (see B20.8).

B40.2.2 Flow control and exhaust air filtration. The sample airflow system should contain a flow induction device and a means of metering and controlling the flow. The flow induction device may be either a built-in or an external vacuum source. The system for metering and controlling the flow of sample air should be located after the particle sensing chamber in order to minimize particle losses and the generation of artifacts before sensing has taken place.

If a built-in vacuum pump is used, the air exhausted from the pump should be suitably filtered or vented to prevent particles in the sampled air stream, as well as those generated by the pump, from being exhausted into the controlled environment. In addition, particles may emanate from the interior of the DPC, for example from a cooling fan or by other movement of air through the counter. Such particle-laden air must be suitably filtered or vented to prevent it from contaminating the air being sampled as well as the clean zone in which the DPC is operating.

B40.3 Sensing and measuring chamber. The sensing system of the DPC is limited in volume so that the probability of more than one particle being present at any time (coincidence error) is less than 10% (see B20.9). The operation of the particle sensing chamber will be defined by the nature of the DPC. Since uncontained sample flow may occur within the chamber, its design should be such that minimum recirculation and recounting of particles occur in that chamber. If the particle characterization system includes any particle manipulation (e.g., diffusion battery, electrostatic charging system, or nucleation chamber) before sensing occurs, then the DPC element used to control or limit the size of the particles counted should be such that no significant undefined change in the number of countable particles takes place during that process. The detection elements within the sensing chamber should be designed to maintain stated accuracy, despite normal variation in specified operating line voltage and ambient temperature.

B40.4 Electronic system. The data processing system of the DPC should include components for counting and sizing (or merely counting) signals from the particles observed by the DPC, a means of converting signal levels to particle sizes, sufficient data processing capability to convert the number of particles counted and the volume of air sampled to particle concentration, and internal monitoring capability to verify that critical DPC components are operating correctly. Data should be available as front-panel display, on-board hard copy, or as signals that can be transmitted to a remote data reception device in a format that will allow either direct storage or further processing. The processing system should also include the necessary components to carry out standardization of the DPC. The standardization may be done either manually or automatically.

B40.5 Standardization. An internal standardization or secondary calibration system or other means of ensuring stability should be provided in the DPC. The standardization system should be capable of validating the stability of the DPC's operating parameters. The secondary calibration system is used to check the stability of the counting and sizing capability of the DPC and to provide a stable reference for any necessary adjustments in sensitivity.

B40.6 Documentation. Instructions which should be supplied with the DPC by the manufacturer include:

(a) Brief description of the DPC's operating principles
(b) Description of major components
(c) Environmental conditions (ambient temperature, relative humidity, and pressure) and line voltage range required for stable operation
(d) Size and concentration range of particles for which measurements are accurate
(e) Suggested maintenance procedures and recommended intervals for routine maintenance
(f) Operating procedure for counting and sizing particles
(g) Secondary calibration procedure (where applicable)
(h) Procedure and recommended interval for primary calibration, as well as provision for calibration by manufacturer upon request
(i) Field calibration procedures and capability
(j) Recommended supply and estimated usage of consumable items

B50. Preparations for sampling. The procedures described in the following paragraphs should be performed before using a DPC to verify the compliance of air to an airborne particulate cleanliness class. Each DPC has its own requirements with respect to the frequency for performing these procedures.

B50.1 Primary calibration. Primary calibration of a DPC entails characterizing its ability to size and count airborne particles with known accuracy in a measured volume of air. The following paragraphs contain guidelines to be considered when using calibration procedures for DPC's described in the literature (see, for example, B20.2, B20.3, B20.4, and B20.10). It may be necessary to deviate from the methods in such documents to achieve a specific objective. For a DPC that includes a pre-counting particle size fractionation system (such as a diffusion screen or a system that responds to electrostatic charge), operation of such a system may also require calibration.

B50.1.1 Particle sizing. Primary calibration of the particle sizing function of the DPC is carried out by registering its response to a monodisperse, homogeneous aerosol (containing predominantly spherical particles of known size and physical properties), and by setting the calibration control function so that the correct size is indicated. Thereafter, the internal secondary calibration system is adjusted, if necessary, to maintain a stable response to a reference aerosol suspension. Nonspherical particles may be used for primary calibration in specific applications. The particle size is then defined in terms of an appropriate dimension for the reference particles. Means of generating reference particles have been extensively described in the literature.

B50.1.2 Particle counting efficiency. The counting efficiency of a DPC is affected by a number of operating characteristics. For smaller particles, instrument sensitivity and background noise are important, and procedures for defining the counting efficiency of a DPC for such particles are discussed in B20.2.

For particles larger than approximately 5 μm, counting efficiency is also affected by the DPC's sampling efficiency and by transport effects. The counting efficiency of a DPC for such larger particles can be determined by means of a referee method. The referee method may be a sampling and measurement system which is identical (or not) to that of the DPC being tested. The procedure (see B20.11) consists of generating within a chamber an aerosol composed of large particles, drawing a sample of that aerosol into both the DPC and the referee measurement system, and determining the ratio of particles counted by the DPC and the referee system.

B50.1.3 Air sample volume. The air sample volume is calibrated by measuring the flow rate and the duration of the sampling interval (see B20.12, B20.13, and B20.14). If the DPC measures only those particles within a specified portion of the air sampled by the airflow system, information must be obtained from the manufacturer in order to calibrate both the inlet air sample volume and the air volume in which particles are measured. To avoid errors, equipment used for these measurements should not introduce an additional static pressure drop. All flow measurements should be referenced to ambient conditions of temperature and pressure or as otherwise specified.

B50.2 False count or background noise check. A check for false counts or the measurement of background noise, or both, should be performed in the cleanroom to be characterized. A filter capable of removing at least 99.97% of particles equal to and larger than the size of smallest particle detectable by the DPC is connected to the inlet. After adjusting the flow to the correct rate, the count rate is recorded for the smallest particle detectable by the DPC. The DPC should record no more than an average of one false count during the measuring period required to collect the minimum sample volume indicated in 5.1.3.4. If more than one count per period is registered in that size range, the DPC should be purged with the filter in place until an acceptable level of false counts is achieved.

B50.3 Field (secondary) calibration procedures. Standardize the DPC in accordance with the manufacturer's instructions. The count rate from background noise, recorded at the time of primary calibration, should also be checked during field calibration.

B60. Sampling. Perform the background noise check and the field calibration in accordance with B50.2 and B50.3. Check the sample flow rate and adjust it to the specified value, if applicable. Turn on the counting circuits and data processing components, if necessary. Collect data for the particle size(s) of concern.

B60.1 Sampling for verification. When sampling air for the purpose of verifying its compliance to an airborne particulate cleanliness class, sufficient data should be obtained to satisfy the statistical requirements of 5.4. Sample locations should be established in accordance with 5.1.3. Proper orientation of the probe should be established in accordance with 5.3. Recommendations for proper lengths of sample transit tubes should be observed in accordance with B40.2.1.

B60.2 Sampling for monitoring. Sampling procedures should be established in support of the monitoring plan described in 5.2.1. Sample locations may be established in accordance with 5.1.3, or as appropriate. Probe orientations may be established in accordance with 5.3, or as deemed appropriate for specific monitoring situations. Sampling in support of monitoring need not meet the rigid statistical criteria required for verification; the observation of trends and anomalies, without application of rigorous statistical limitations, is generally more appropriate. For monitoring purposes, the lengths of sample transit tubes may deviate from those recommended in B40.2.1.

B70. Reporting. Record the following information, as specified, for the verification of air in a cleanroom or clean zone to an airborne particulate cleanliness class, or for the monitoring of air cleanliness:

(a) Identification and location of the cleanroom (or clean zone)
(b) Identification of the DPC and its calibration status
(c) Background noise count for the DPC
(d) Date and time when the DPC was used
(e) Cleanroom (or clean zone) status: "As-built," "At-rest," "Operational," or as otherwise specified
(f) Type of test, verification or monitoring
(g) Target level of verification of the cleanroom or clean zone
(h) Range(s) of particle sizes measured
(i) DPC inlet sample flow and sensor measured sample flow
(j) Location of sampling points
(k) Sampling schedule for verification or sampling protocol for monitoring
(l) Raw data for each sample point, as required

APPENDIX C

ISOKINETIC AND ANISOKINETIC SAMPLING

C10. Scope. This appendix presents formulas for determining whether isokinetic sampling conditions exist and, if they do not, for estimating the artificial change in concentration caused by anisokinetic sampling.

C20. Reference.

C20.1 Hinds, W. C., Aerosol Technology: Properties, Behavior, and Measurement of Airborne Particles, John Wiley & Sons, New York (1982), 187-194.

C30. Background. When particles are sampled from a flowing air stream, a difference between the air velocity in the stream and the air velocity entering the probe inlet can cause a change in concentration because of particle inertia. When these velocities are the same, the sampling is isokinetic; otherwise, the sampling is anisokinetic.

Isokinetic sampling is achieved when the probe inlet is pointed into the direction from which the flow is coming and is parallel with (isoaxial to) that flow, and when the mean flow velocity into the inlet matches the mean flow velocity of the air at that location.

C40. Methods. The mean velocity of the air in the probe inlet is $v = Q/A$, where v is the velocity, Q is the volumetric rate of airflow into the inlet, and A is the cross-sectional area of the inlet.

Figures C.1 and C.2 show the diameters of circular inlets of probes that will produce isokinetic sampling at the indicated air velocities and volumetric flow rates. If the velocities are matched to within 5% of one another, isokinetic conditions are considered to exist and no correction is needed to determine the concentration of airborne particles.

If isokinetic conditions cannot be achieved, formulas are available for predicting the concentration in the sample, C, in terms of the concentration in the flowing air, C_o, the mean sampling velocity, v, and the free-stream velocity of the air, v_o. The formula of Belyaev and Levin as presented in C20.1 applies:

$$C/C_o = 1 + (v_o/v - 1)\bullet(1 - 1/[1 + \{2 + 0.62\bullet(v/v_o)\}\bullet Stk]) \qquad \text{(Equation C40-1)}$$

In this equation, the Stokes parameter,

$$Stk = \tau v_o/D_s, \qquad \text{(Equation C40-2)}$$

appears, which is based on the particle aerodynamic relaxation time, τ, the free-stream velocity of the air, v_o, and the inlet diameter of the probe, D_s.

The aerodynamic relaxation time for a spherical particle is:

$$\tau = C_c \rho d_p^2/18\eta, \qquad \text{(Equation C40-3)}$$

where C_c, the Cunningham correction, is expressed as

$$C_c = 1 + 0.16 \times 10^{-4}\ \text{cm}/d_p, \qquad \text{(Equation C40-4)}$$

and

d_p = the particle diameter (cm),

ρ = the density of the particle (g/cm^3), and

η = the viscosity of air (1.81×10^{-4} poise at 20 °C).

Therefore, for particles with the density of water and a diameter, **d**, at room temperature and pressure, the aerodynamic relaxation times are (see C20.1):

d (µm)	**τ** (s)
0.1	8.85×10^{-8}
0.2	2.30×10^{-7}
0.3	4.32×10^{-7}
0.5	1.02×10^{-6}
5.0	7.91×10^{-5}

For **Stk >> 1** (large particles, fast flows, probes with small inlet diameter), inertial effects predominate and $\mathbf{C/C_0}$ becomes $\mathbf{v_0/v}$. For **Stk << 1**, inertial effects are negligible, and $\mathbf{C/C_0}$ is nearly equal to 1.0. Between these limits, calculations can be made to gauge the importance of mismatches in velocities.

Where one is free to choose **Q** or $\mathbf{D_s}$ or both, the velocities can be matched by setting:

$$Q/A = Q/(\pi/4)\bullet D_s^2 = v_0 \qquad \text{(Equation C40-5)}$$

Often, with **Q** fixed and with limited choices for the diameter of the probe inlet, this degree of flexibility is not available. In such cases, select $\mathbf{D_s}$ as close to the optimum as possible, then determine if $\mathbf{C/C_0}$ is close enough to unity such that no further correction is needed.

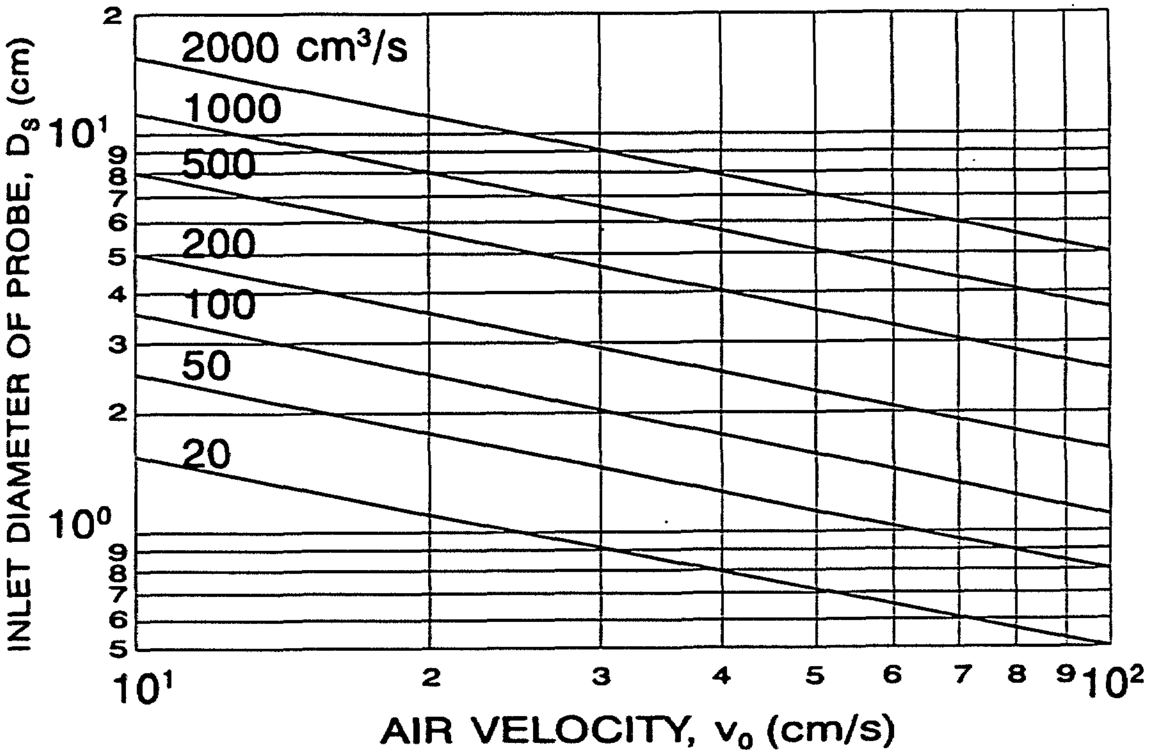

Figure C.1. Probe inlet diameters (metric units) for isokinetic sampling, $v = v_o$ (volumetric flow rates shown parametrically)

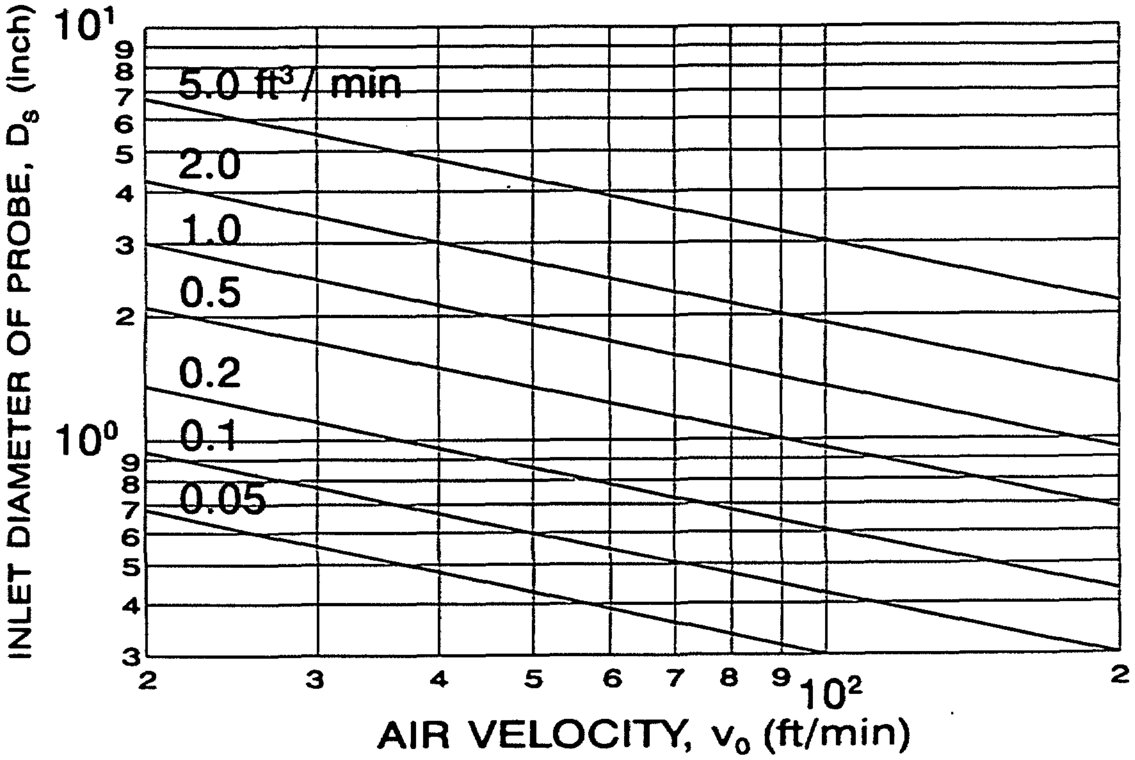

Figure C.2. Probe inlet diameters (English units) for isokinetic sampling, $v = v_o$ (volumetric flow rates shown parametrically)

In Figure C.3 the velocity ratios, $\mathbf{v/v_0}$, are plotted vs. **Stk** for those conditions which result in sampling bias contours for $\mathbf{C/C_0}$ that are within ±5% of 1.0, i.e., 0.95 and 1.05. The smaller the particle, the smaller τ, thus the smaller **Stk**, and the wider the range of acceptable velocities.

Two particle diameters are of particular interest: 0.5 µm and 5 µm. It can be shown that anisokinetic sampling is unlikely to have a significant effect on particles 0.5 µm and smaller. If the air is being sampled for the total concentration of particles 0.5 µm and larger, typically the count will be dominated by particles with diameters near 0.5 µm; if these particles are not much affected by anisokinetic conditions, neither will the total count be affected. Thus, anisokinetic sampling in clean zones is likely to be significant only when sampling at 5 µm and larger.

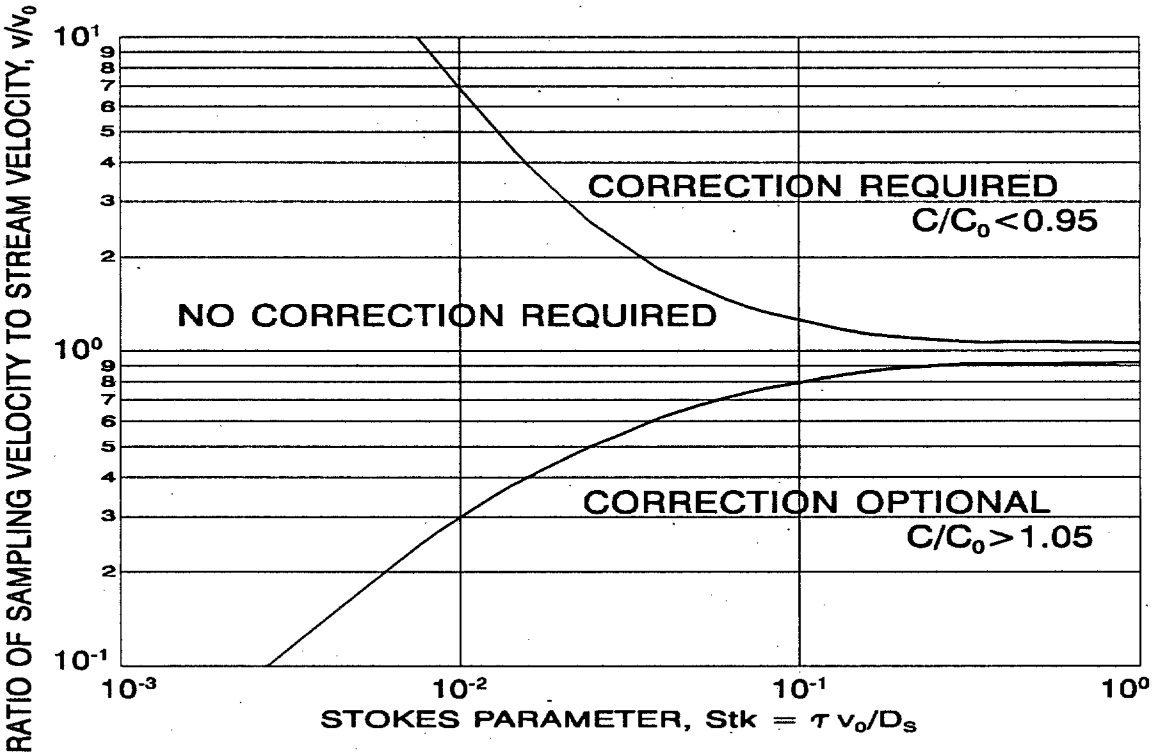

Figure C.3. Contours of sampling bias, $\mathbf{C/C_0}$ **= 0.95, 1.05**

In a clean zone with unidirectional flow, $\mathbf{v_0}$ is typically 50 cm/s (100 feet per minute) or less. Under such conditions, values of **Stk** for probes of several selected inlet diameters, $\mathbf{D_s}$, and two particle diameters, **d**, are as follows:

$\mathbf{D_s}$	**Stk**	
(cm)	**(d = 0.5 µm)**	**(d = 5 µm)**
0.1	0.00051	0.040
0.2	0.00026	0.020
0.5	0.00010	0.0080
1.0	0.00005	0.0040
2.5	0.00002	0.0016

Under these conditions, velocity ratios as extreme as $v/v_0 = 10$ and $v/v_0 = 0.1$ will not cause so much as a 5% sampling error for 0.5-μm particles. Under these same conditions, for 5-μm particles, a probe with an inlet diameter greater than 0.5 cm would allow velocity ratios between about 0.3:1 and 7:1 without giving a predicted error greater than 5%, but a probe with an inlet diameter as small as 0.1 cm would allow velocity ratios only between about 0.7:1.0 and 1.8:1 for 5% or less sampling error.

The analysis indicates that anisokinetic sampling of particles 0.5 μm and smaller is not a problem in typical clean zones and will rarely be a problem when sampling at 5 μm unless sampling is carried out to detect a point source of particles.

If one is sampling particles 5 μm and larger in a clean zone and if the mismatch in velocities is greater than 5%, then the equation for C/C_0 (or Figure C.3) should be used to calculate the magnitude of the correction. If the correction is greater than 5%, then it should be applied to the observed concentration if doing so raises the observed concentration, as in the case where the sampling velocity is more than the air free-stream velocity. The correction may also be applied to the observed concentration if doing so **decreases** the observed concentration, as in the case where the sampling velocity is less than the air free-stream velocity.

C50. Example. Assume one plans to sample particles 5 μm and larger in a flow that has a velocity, $v_0 = 1$ m/s (100 cm/s) using a probe with an inlet diameter of 1 cm.

From the table, the aerodynamic relaxation time for a particle with a 5-μm aerodynamic diameter is 7.91×10^{-5} s. The Stokes parameter, then, becomes Stk = 0.00791.

The mean sample flow velocity is $v = Q/A$. If $v = 10$ cm/s, then the volumetric flow rate through the probe is 7.85 cm^3/s (since $Q = v \bullet A$), and $v/v_0 = 0.1$. Thus an artificially high concentration will be produced:

$$C/C_0 = 1 + 9 \bullet (1 - 1/[1 + (2.062)(0.00791)])$$

$$= 1.144$$

In this example, the anisokinetic bias in the sample of air is corrected by dividing the observed concentration of particles, C, by 1.144 to obtain C_0, the concentration of particles in the flowing air stream.

APPENDIX D

METHOD FOR MEASURING THE CONCENTRATION OF ULTRAFINE PARTICLES

D10. Scope. This appendix describes procedures for measuring the concentration of ultrafine airborne particles, particles larger than approximately 0.02 μm, for comparison with the specified U descriptor. It also defines the cutoff characteristic required for discrete-particle counters (DPC's) to be used to measure the U descriptor.

D20. References.

D20.1 Cheng, Y. S., and Yeh, H. C., "Theory of a Screen-Type Diffusion Battery," J. Aerosol Science, 11, 313-320 (1980).

D20.2 Cheng, Y. S., and Yeh, H. C., Aerosols in the Mining and Industrial Work Environments, Marple, V. A., and Liu, B. Y. H., Eds.; Ann Arbor Science Publishers, 1077-1094 (1983).

D20.3 Hinds, W. C., Aerosol Technology: Properties, Behavior, and Measurement of Airborne Particles, John Wiley & Sons, New York (1982).

D20.4 Liu, B. Y. H., and Pui, D. Y. H., "A Submicron Aerosol Standard and the Primary, Absolute Calibration of the Condensation Nuclei Counter," J. Colloid and Interface Science, 47(1), 155-171 (1974).

D30. Apparatus. To verify the U descriptor, a condensation nucleus counter (or other DPC as described in Appendix B) having a dynamic size range of at least 0.02 to 1.0 μm shall be used. Only a DPC whose counting efficiency curve meets the criteria specified in D30.1 should be used.

D30.1 Counting efficiency. The counting efficiency characteristic of the DPC used to verify a U descriptor must fall within the shaded envelope of Figure D.1. This region of acceptable performance centers on a counting efficiency of 50% at 0.02 μm and includes a tolerance band of 0.002 μm on either side of 0.02 μm. The minimum and maximum counting efficiencies that are acceptable outside the 0.018-to-0.022-μm tolerance band are based on the calculated penetration of a diffusion element (see D20.1) having either 40% efficiency at 0.02 μm (the branch for particles with diameters larger than 0.022 μm) or 60% efficiency at 0.02 μm (the branch for particles with diameters smaller than 0.018 μm).

The counting efficiency curve of a DPC can be determined using the methods of Liu and Pui (see D20.4). Manufacturers of DPC's will normally provide this information on request.

If the DPC has a counting efficiency curve that falls to the right of the envelope in Figure D.1, the DPC cannot be used to verify the U descriptor. If the curve falls to the left of the envelope in Figure D.1, then the DPC may be used to verify the U descriptor if it is subsequently modified with a size cutoff inlet device as described in D30.2, in which case the overall counting efficiency of the modified DPC becomes the product of the counting efficiency of the unmodified DPC and the fractional penetration of the cutoff inlet.

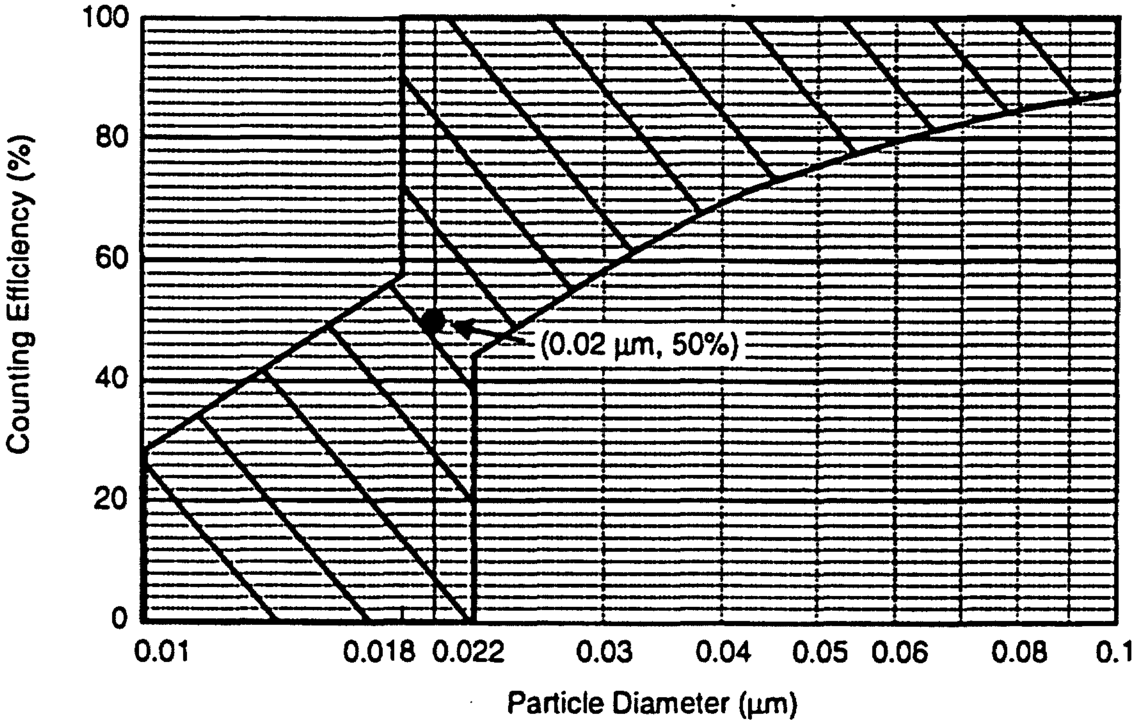

Figure D.1. Envelope of acceptability for the counting efficiency of a DPC used to verify the U descriptor.

D30.2 Size cutoff inlet device. To achieve the 0.02-µm cutoff characteristic required to verify conformance of air to a U descriptor, a size cutoff device can be placed on the sampling probe of a DPC whose size detection efficiency curve falls to the left of the acceptable shaded envelope of Figure D.1. The counting efficiency is thus reduced in this region so that the overall cutoff characteristic for the combined instrument, sampling probe, and inlet device falls within the shaded envelope. Cutoff devices remove small particles by diffusional capture in a well-defined and reproducible manner.

The required penetration characteristic is achieved through diffusional capture of small particles by means of a tube, parallel plate, or fine-mesh screen. Other possible devices include those with collimated hole structures, packed beds, and porous carbon disks. A wide variety of sizes and configurations of inlet devices is possible and acceptable, providing they produce the required penetration characteristics. Cutoff devices are commercially available; one type is based upon the equations of Cheng and Yeh (see D20.1).

The penetration of particles through cutoff devices is a function of the volumetric flow rate. The device should not be used at flow rates different from those for which it was designed. To avoid accumulation of static charge, the device should be made of electrically conductive material and grounded.

D40. Determining the concentration of ultrafine particles. With the cutoff device (if needed) fitted to the probe of the DPC as described above, sample the air in accordance with section 5 of this Standard. Divide the total number of particles by the volume of air sampled. Report the concentration in particles per cubic meter.

APPENDIX E

RATIONALE FOR THE STATISTICAL RULES USED IN FED-STD-209E

E10. Scope. This discussion surveys the two statistical rules (see 5.4.1) embedded in this Standard, describes what the rules accomplish in practice, and summarizes the rationale for each.

E20. The statistical rules. The first rule requires that, for each location sampled, the average particle concentration not exceed the class limit or U descriptor. The second rule requires that an upper 95% confidence limit, constructed from all of the location averages, not exceed the class limit or U descriptor; this rule applies only when fewer than ten locations are sampled.

The rationale for the first rule is that the cleanliness of the air must be checked at multiple locations in a cleanroom or clean area. The number of locations is a function of the size of the area to be checked. The average of all measurements taken at a given location was selected as the statistical unit. This unit was chosen from the perspective that FED-STD-209E is targeted at an average level of performance rather than at an absolute one. Thus the average particle concentration at each sampling location is the base level of statistical summarization found in the Standard.

All variation among the measurements taken at each location is ignored, except for the extent to which it affects the average at that location and the two statistical rules. It **may** be possible, therefore, to average out sampling variability, spikes, and time trends in data collected at a given location. Minimizing the impact of sampling variability is a desirable consequence of using an average. The potential for obscuring real changes in particle concentration (spikes, cyclicity, or other time-related trends) is an undesirable consequence of using an average.

The Standard also specifies a minimum sampling volume for measurements taken at any location. This serves to ensure that (1) sufficient data are collected to allow a reasonable evaluation of the cleanliness of the air in accordance with the intent of the Standard, and (2) a sufficiently large volume is sampled to allow the approximate application of normal distribution theory to the measurements collected at a given location. The second condition occurs only when actual particle concentrations are near or above the class limit or U descriptor. This does not present a problem when a location has a very low concentration, compared to the specified limit, and statistical analysis of the measurements at that location is not critical.

Requiring a minimum sampling volume does not average out all sampling variability. It is likely, therefore, that if the average air cleanliness is near the class limit or U descriptor and if one or a few measurements are made at each location, that some locations will be found which exceed the specified limit. The only statistical fix for such locations is to collect additional measurements at those locations. Thus, the Standard implicitly requires more, sometimes many more, measurements to be made when average performance is near the specified limit.

The rule requiring that the average particle concentration at each location meet the class limit or U descriptor is the **dominant statistical rule** for all but the smallest facilities. Because this rule implicitly ignores the effect of sampling variability, it becomes increasingly difficult to obtain a passing result as more locations are required to be sampled. Thus, the number of locations sampled will affect the probability of passing the Standard. This rule also has the undesirable effect of discouraging sampling at any more than the minimal number of locations required by the Standard whenever the number of locations equals or exceeds five.

The highest level of statistical summarization used in the Standard is the 95% upper confidence limit placed on the grand average of all the averages obtained at each of the locations sampled. All variation among the location averages is ignored other than how it impacts the calculation of the upper confidence limit. It **may** be possible, therefore, to average out real differences in average cleanliness from location to location or differences observed over time so long as the average at each location stays below the specified limit.

Construction of the upper confidence limit is based on use of a t-table which is provided (Table II) as part of the Standard. This rule implicitly assumes that the distribution of the averages at each location originates from the same normal distribution or that sufficient locations have been sampled for the central limit theorem to be invoked. Sometimes neither of these implicit assumptions will be met. However, the UCL based on the t-statistic is reasonably robust even to moderate violations of these implicit assumptions.

The selection of the 95% level of confidence is by convention. Traditionally, many statistical analyses allow for a 5% error rate. If the exercise of building the 95% upper confidence limit were to be repeated many times for the facility in question, 95% of the time this upper limit would exceed the true **unknown** overall average level of particle concentration. Other less commonly employed levels of confidence are 90% and 99%. Intermediate and more extreme levels of confidence are possible as well. Selection of an extremely high level of confidence greatly increases the risk of failing the Standard, even when the average at all locations sampled meets the nominal class limit or U descriptor. The tradeoff involved with this second type of risk is the reason for not simply choosing an arbitrarily high confidence level.

The rationale behind the second rule is to require greater uniformity in results (less variability from location to location). It also reduces the chance of falsely passing the Standard when limited data are required by the Standard. When trouble is encountered with this rule, there are two possible statistical fixes for the problem. These include (a) collecting data at more locations and (b) taking additional measurements at one or more locations.

This second statistical rule affects only small facilities, those for which fewer than ten locations need to be sampled. For such facilities, this rule makes passing the Standard more difficult than it would be otherwise, especially when only two locations are required. The thrust of the second rule is to have a high degree of confidence that the grand average of the cleanliness of the air in the entire facility is less than the stated class limit or U descriptor.

From a statistical standpoint, the Standard is not targeted at defects that impact small areas relative to the sampling plan (e.g., leaks in filters). If there were many such leaks, it is likely that some would be detected; however, the likelihood of detecting any single leak is small.

E30. Sequential sampling. For situations in which exactly 20 particles would be expected in a single measurement taken at the class limit or U descriptor, this Standard allows the option of using a sequential sampling plan (see 5.1.3.4.4 and Appendix F). Sequential sampling **may** reduce on average the sample volume (and therefore the time) required for making each measurement. At most, the truncated sequential sampling plan described in Appendix F will result in the collection of the full sample volume that would otherwise be obtained if a single sampling plan were in effect.

If the air being sampled is much cleaner or much more contaminated than the class limit or U descriptor, the sequential sampling plan will require (on average) dramatically smaller sample volumes per measurement. Even when the cleanliness of the air is at or near the specified limit, some economy is normally achieved by using the sequential sampling plan. Furthermore, **for a given measurement**, the sequential sampling plan typically provides (prior to testing), a nearly identical probability of that measurement's either exceeding or failing to exceed the class limit or U descriptor as compared to the fixed sample size approach.

The main limitations of the sequential sampling plan are: (a) the plan applies only when the Standard is targeted at exactly 20 particles per measurement at the class limit or U descriptor, (b) each measurement requires additional monitoring and data analysis (although this can be minimized through computerization), and (c) the average particle concentration as calculated from a given measurement typically will not be determined as precisely (a direct result of collecting a smaller sample volume).

Result (c) has an impact on the Standard's statistical rules. On average, it will be somewhat more difficult to pass the upper 95% confidence limit rule (for fewer than 10 locations) when the sequential sampling plan is used.

E40. Sample calculation to determine statistical validity of a verification. The data and calculations presented in the following paragraphs are intended to serve as a working example, illustrating the statistical procedures involved in the verification of air in cleanrooms and clean zones. The example is based upon air sampled for particles 0.3 μm and larger in an effort to verify that the air sampled complies with airborne particulate cleanliness Class M 2.5 (Class 10), for which it is required (Table I) that the UCL not exceed 1060 particles, 0.3 μm and larger, per cubic meter.

The data for the example, presented in the table in E40.1, include the measured particle concentrations, $\mathbf{C_i}$, obtained for different numbers of samples, **N**, taken at each of five locations, **L**. The calculated average particle concentrations, $\mathbf{A_i}$, at each location are also listed in the table. Calculations follow in E40.2 through E40.5 of: the mean of the average concentrations, **M**, the standard deviation of the averages, **SD**, the standard error of the mean of the averages, **SE**, and the upper control limit, **UCL**.

E40.1 Tabulation of data.

	Particle Concentrations C_i					No. of samples at each location N	Average concentration at each location A_i
Location	1	2	3	4	5		
1	530	NR	NR	NR	NR	1	530
2	1200	850	320	530	NR	4	725
3	640	100	420	850	NR	4	503
4	1400	640	320	1200	210	5	754
5	0	950	210	0	NR	4	290

(NR: no reading taken)

E40.2 Mean of the averages.

$$M = (A_1 + A_2 + \ldots + A_L)/L \qquad \text{(Equation 5-2)}$$

$$M = (530 + 725 + 503 + 754 + 290)/5 = 560$$

E40.3 Standard deviation of the averages.

$$SD=\sqrt{\frac{(A_1-M)^2+(A_2-M)^2+\ldots+(A_L-M)^2}{L-1}} \qquad \text{(Equation 5-3)}$$

$$SD=\sqrt{\frac{(530-560)^2+(725-560)^2+(503-560)^2+(754-560)^2+(290-560)^2}{5-1}}$$

$$SD = 188$$

E40.4 Standard error of the mean of the averages.

$$SE=\frac{SD}{\sqrt{L}} \qquad \text{(Equation 5-4)}$$

$$SE=\frac{188}{\sqrt{5}}=84$$

E40.5 Upper confidence limit (UCL).

$$UCL = M + (UCL\ Factor \times SE) \qquad \text{(Equation 5-5)}$$

For 5 locations, the UCL factor is 2.13 (see Table II).

$$UCL = 560 + (2.13 \times 84) = 739$$

E40.6 Conclusion. Since the 95% upper confidence limit (UCL) is less than 1060 and since the average particle concentration, A_i, at each location is less than 1060, the air sampled is verified as complying with airborne particulate cleanliness Class M 2.5 (Class 10), even though some of the individual particle concentrations are above 1060.

APPENDIX F

SEQUENTIAL SAMPLING: AN OPTIONAL METHOD FOR VERIFYING THE COMPLIANCE OF AIR TO THE LIMITS OF AIRBORNE PARTICULATE CLEANLINESS CLASSES M 2.5 AND CLEANER

F10. Scope. This appendix presents a sequential sampling plan which may be used to verify the cleanliness of air to airborne particulate cleanliness Classes M 2.5 and cleaner (Classes 10 and cleaner). This plan matches the properties of this Standard's single sampling plan (see 5.1.3.4.1 through 5.1.3.4.3), which requires a sample duration sufficient to produce an expected 20 counts (**E = 20**) in air with a particle concentration exactly at the class limit or U descriptor. Use of sequential sampling may reduce substantially the sample volumes required at each location.

F20. References.

F20.1 Cooper, D. W., and Milholland, D. C., "Sequential Sampling for Federal Standard 209 for Cleanrooms," J. Inst. Environ. Sci., 33(5), 28-32 (1990).

F20.2 Duncan, A. J., Quality Control and Industrial Statistics, 4th ed., Irwin, Homewood, Illinois (1974).

F20.3 Siegmund, D., "Estimation Following Sequential Tests," Biometrika, 65, 341-349 (1978).

F20.4 Wald, A., Sequential Analysis, John Wiley & Sons, New York (1947).

F30. Background. The advantages of sequential sampling in comparison to single sampling have been described and demonstrated (see F20.4). In sequential sampling, the running total of the particles counted is compared with a reference count limit that is a function of the amount of sampling done. Sequential sampling typically requires less sampling than any single sampling plan having the same probability of false acceptance and false rejection. This particular sequential sampling scheme has been presented in the literature for use in this Standard (see F20.1).

F40. Method. Figure F.1 (see F20.1) illustrates the boundaries of the sequential sampling plan that has been designed for use in this Standard. The observed number of counts, **C**, is plotted vs. the expected number of counts, **E**, for air which is precisely at the class limit or U descriptor. A full single sample corresponds to **E = 20**. The domains in Figure F.1 were derived from published formulas (see F20.4 and F20.2). The upper and lower lines are:

Upper: $C = 3.96 + 1.03\,E$ (Equation F40-1)

Lower: $C = -3.96 + 1.03\,E$ (Equation F40-2)

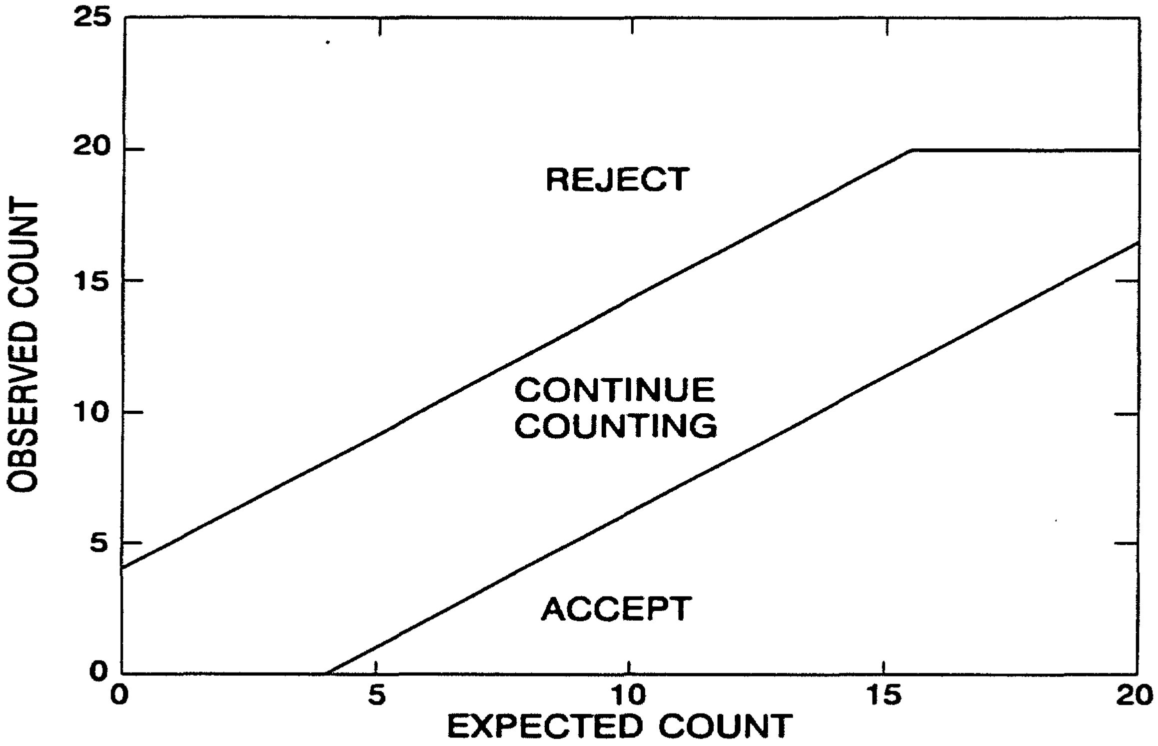

Figure F.1. Observed count, C, vs. expected count, E, for sequential sampling. The labels delineate those regions where the cumulative observed count indicates that the air either exceeds the class limit or U descriptor (REJECT), meets the class limit or U descriptor (ACCEPT), or is indeterminate (CONTINUE COUNTING).

Table F.1 gives the upper and lower times at which C = 0, 1, 2, etc., mean PASS or FAIL, derived from these equations. The times are listed both in terms of E (E = 20 for full sample) and t (t = 1.00 for full sample corresponding to E = 20).

This plan has been truncated by design so that the conventional single-sample time (E = 20) is its longest time. A third limit was found to be needed, C = 20, to match the operating characteristics for the single-sample plan.

To use the sequential sampling plan, record the number of particles observed as a function of time. Compare the count, as sampling continues, with the upper and lower limits, using either equations F40-1 and F40-2, or a chart such as Figure F.1, or Table F.1. Computerized analysis of the data is usually helpful.

If the cumulative observed count for the sample crosses one of the upper lines, then sampling is stopped and the air is judged to have FAILED. If the cumulative observed count crosses the lower line, then sampling is stopped and the air is judged to have PASSED. If the cumulative observed counts equal 20 or less at the end of the sample duration, not having crossed the upper line, the air is also judged to have PASSED.

Table F.1. Upper and lower limits for time at which **C** counts should arrive. Times are given in units of expected count (**E** = **20** at the class limit or U descriptor) and as the fraction of total time (**t** = **1** at the class limit or U descriptor).

	FAIL IF COUNT, C, COMES EARLIER THAN EXPECTED		PASS IF COUNT, C, COMES LATER THAN EXPECTED	
Count, C	Expected, E	Time, t	Expected, E	Time, t
0	-----	-----	3.844	0.1922
1	-----	-----	4.815	0.2407
2	-----	-----	5.786	0.2893
3	-----	-----	6.757	0.3378
4	0.038	0.0019	7.728	0.3864
5	1.010	0.0505	8.699	0.4349
6	1.981	0.0992	9.669	0.4834
7	2.951	0.1476	10.640	0.5320
8	3.922	0.1961	11.611	0.5805
9	4.893	0.2447	12.582	0.6291
10	5.864	0.2932	13.553	0.6676
11	6.834	0.3417	14.524	0.7262
12	7.805	0.3902	15.495	0.7747
13	8.776	0.4388	16.466	0.8233
14	9.747	0.4873	17.436	0.8718
15	10.718	0.5359	18.407	0.9203
16	11.689	0.5844	19.378	0.9689
17	12.660	0.6330	PASS	1.0000
18	13.631	0.6815	PASS	1.0000
19	14.601	0.7300	PASS	1.0000
20	15.572	0.7786	PASS	1.0000
21	FAIL	1.0000	PASS	1.0000

An equivalent method is to compare the time at which count **C** occurs with the times shown in Table F.1. If the count occurs earlier than expected, as indicated in Table F.1, then the location FAILS. If the count occurs later than expected, as indicated in Table F.1, then the location PASSES. This requires at most 21 comparisons of arrival time of particles with the limiting times.

Where a first sample leads to a decision to PASS or FAIL, but it is desired to test the air further, subsequent samples should be taken as single samples of duration such that **E** = **20** for each. Then combine the counts of the single sample(s) at the location with those of the sequential sample and divide the sum by the total volume of the sequential and single sample(s). The result is the mean concentration at that location, to be compared to the concentration for the class limit or U descriptor.

To determine the concentration for the entire clean zone from a set of sequential samples at the designated locations, divide the total number of particles counted by the total volume of air sampled. A more advanced method of treating the data can be found in the literature (see F20.3).

F50. Examples. For further investigation, a reference in the literature (see F20.1) gives three examples of procedures for sequential sampling.

F60. Reporting. The data should include an identifier for each location, the volume of air sampled and the count for each sample, and whether the location passed or failed for that sample. If a location that failed is resampled, then the total counts and the total volume (of both the original sample and the repeated sample) should be reported along with the concentration derived from their ratio.

APPENDIX G

SOURCES OF SUPPLEMENTAL INFORMATION

G10. Scope. This appendix lists organizations and other sources from which supplemental information may be obtained for instruction or guidance in preparing documents related to the design, acquisition, testing, operation, and maintenance of cleanrooms and clean zones.

G20. Sources of supplemental information.

G20.1 American Institute of Aeronautics and Astronautics (AIAA)
370 L'Enfant Promenade, S. W.
Washington, DC 20024

G20.2 American National Standards Institute (ANSI)
11 West 42nd Street, 13th Floor
New York, NY 10036

G20.3 American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE)
1791 Tullie Circle, NE
Atlanta, GA 30329

G20.4 American Society of Mechanical Engineers (ASME)
345 E. 47th Street
New York, NY 10017

G20.5 American Society for Testing and Materials (ASTM)
1916 Race Street
Philadelphia, PA 19103-1187

G20.6 Association pour la Prevention et l'Etudie de la Contamination (ASPEC)
Secretariate d'ASPEC
1, Cite Paradis, rue Paradis
75010 Paris
France

G20.7 British Standards Institution (BSI)
2 Park Street
London W1A 2BS
England

G20.8 Commission of the European Communities (CEC)
Office for Official Publications of the European Communities
2 rue Mercier
L 2985, Luxembourg

G20.9 Defence Research Establishment, Suffield (DRES)
National Defence
Ralston, Alberta
Canada

G20.10 Deutsches Institut fur Normung (DIN)
(German Institute for Standardization)
Postfach 1107
Burggrafenstrasse 6
1000 Berlin 30
Germany

G20.11 Food and Drug Administration (FDA)
Division of Drug Quality Compliance
Center for Drugs and Biologics
5600 Fishers Lane
Rockville, MD 20857

G20.12 Institute of Electrical and Electronics Engineers (IEEE)
445 Hoes Lane
PO Box 1331
Piscataway, NJ 08855-1331

G20.13 Institute of Environmental Sciences (IES)
940 E. Northwest Highway
Mount Prospect, IL 60056

G20.14 International Organization for Standardization (ISO)
1, rue de Varembe
Case Postale 56
CH-1211 Geneva 20
Switzerland

G20.15 International Society of Pharmaceutical Engineers (ISPE)
3816 West Linebaugh Avenue
Suite 412
Tampa, FL 33624

G20.16 Japan Air Cleaning Association (JACA)
Tomoe-Ya Building No. 2-14
1-Chome, Uchi-Kanda
Chiyodaku, Tokyo, 101
Japan

G20.17 Japanese Standards Association (JSA)
1-24-4, Akasaka
Minato-Ku
Tokyo, 107
Japan

G20.18 National Technical Information Service (NTIS)
U. S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

G20.19	Nordic Association for Contamination Control (R^3-NORDIC) R^3-kansliet, Paronvagen 15 S-262 62 Angelholm Sweden
G20.20	Schweizerische Gesellschaft fur Reinraumtechnik Seestrasse 5 Postfach CH-8700 Kusnacht ZH Switzerland
G20.21	Society of Automotive Engineers (SAE) 400 Commonwealth Drive Warrendale, PA 15096
G20.22	Standards Association of Australia (SAA) Standards House 80 Arthur Street North Sydney, NSW 2060 Australia
G20.23	Verein Deutscher Ingenieure (VDI) VDI-Gesellschaft Technische Gebaude Ausrustung Graf-Recke Strasse 84 4000 Dusseldorf 1 Germany