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# ISO 14644-1

## Cleanrooms and associated controlled environments
## 洁净室和相关的受控环境

Part 1:

第一部分:

## Classification of air cleanliness by particle concentration
## 通过粒子浓度对空气洁净度进行分级

第二版本

**2015-12-15**

# Contents 目录

# Foreword 前言

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

ISO（国际标准化组织）为全球各国标准化团体的联合会（ISO 会员团体）。其国际标准工作一般是由ISO各技术委员会执行。每个会员团体若对技术委员会的某一课题感兴趣，均有权作为此技术委员会的代表。任何与ISO保持联系的国际组织，无论是政府的还是非政府的组织，同样可参加此项工作。ISO与国际电气技术委员会（IEC）在电气技术标准化方面进行紧密合作。

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

该程序用来开发本文件并且意图对其进一步的维护，这些在ISO/IEC指示的第一部分有所描述。尤其是应注意不同的审批标准所需的不同类型的ISO文件。该文件是按照ISO/IEC第二部分的编辑规则进行起草（参见www.iso.org/directives）。

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO’s adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

为了解释ISO特定术语的意思以及说明相关符合性评估，以及ISO和WTO原则在技术性贸易壁垒（TBT）方面的联系可参见下面的URL：前言的补充信息。

The committee responsible for this document is ISO/TC 209, Cleanrooms and associated controlled environments.

委员会负责的文件是ISO/TC 209，洁净室和相关的控制环境。

This second edition cancels and replaces the first edition (ISO 14644-1:1999), which has been technically revised throughout.

该第二版取消并代替了第一版(ISO 14644-1:1999)，在技术上进行了彻底的修改。

ISO 14644 consists of the following parts, under the general title Cleanrooms and associated controlled environments:

ISO 14644 由下面部分组成，在大标题洁净室和相关受控环境 之下：

— Part 1: Classification of air cleanliness by particle concentration

— 第一部分：根据粒子浓度对空气洁净度分级

— Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

— 第二部分：通过监控对和洁净室性能相关的以粒子浓度对空气洁净度分级的证据

— Part 3: Test methods

— 第三部分：测试方法

— Part 4: Design, construction and start-up

— 第四部分：设计、施工和启动

— Part 5: Operations

— 第五部分：操作

— Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

— 第七部分：单独装置（清洁空气容器、手套箱、隔离器和mini-环境）

— Part 8: Classification of air cleanliness by chemical concentration (ACC)

— 第八部分：基于化学浓度的空气洁净分级（ACC）

— Part 9: Classification of surface cleanliness by particle concentration

— 第九部分：基于粒子浓度的表面清洁分类

— Part 10: Classification of surface cleanliness by chemical concentration

— 第十部分：基于化学浓度的表面清洁分类

Attention is also drawn to ISO 14698, Cleanrooms and associated controlled environments — Biocontamination control:

同样受到关注的还有ISO 14698，洁净室和相关受控环境----微生物污染控制：

— Part 1: General principles and methods

— 第一部分：总则和方法

— Part 2: Evaluation and interpretation of biocontamination data

— 第二部分：微生物污染数据评价和解释

# Introduction 介绍

Cleanrooms and associated controlled environments provide for the control of contamination of air and, if appropriate, surfaces, to levels appropriate for accomplishing contamination-sensitive activities. Contamination control can be beneficial for protection of product or process integrity in applications in industries such as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare and food.

洁净室和相关的受控环境提供空气污染物的控制，和，如果使用，表面，来完成对污染敏感的活动提供适当的水平。污染控制对保护产品或在工艺中保持工艺完整是有益的，比如航空航天、微电子学、制药、医疗设备、医疗保健和食品行业。

This part of ISO 14644 specifies classes of air cleanliness in terms of the number of particles expressed as a concentration in air volume.  It also specifies the standard method of testing to determine cleanliness class, including selection of sampling locations.

ISO 14644的该部分说明将空气洁净级别为单位空气体积的浓度用粒子数量进行表述。它也同样说明了确定洁净级别测试方法的标准，包括选择取样位置。

This edition is the result of a response to an ISO Systematic Review and includes changes in response to user and expert feedback validated by international enquiry. The title has been revised to “Classification of air cleanliness by particle concentration” to be consistent with other parts of ISO 14644. The nine ISO cleanliness classes are retained with minor revisions.  Table 1 defines the particle concentration at various particle sizes for the nine integer classes. Table E.1 defines the maximum particle concentration at various particle sizes for intermediate classes. The use of these tables ensures better definition of the appropriate particle-size ranges for the different classes. This part of ISO 14644 retains the macroparticle descriptor concept; however, consideration of nano-scale particles (formerly defined as ultrafine particles) will be addressed in a separate standard.

该版本是对ISO系统回顾响应的结果并包含使用者和专家经过国际咨询后的经过验证的变化。标题已经改为“通过粒子浓度对空气洁净度的分级”来和其他ISO 14644部分保持一致。9个ISO洁净级别经过小幅修改得以保留。表1针对9个级别定义了不同粒径的粒子浓度。表E.1 定义了在不同等级不同大小的粒子的最大浓度。该表格的使用确保了针对不同等级下适当粒子范围的更好定义。ISO 14644的这部分保留了大粒子描述内容；可是，对纳米范围粒子（以前定义为超细微粒子）的考虑将会在单独的标准中给出。

The most significant change is the adoption of a more consistent statistical approach to the selection and the number of sampling locations; and the evaluation of the data collected. The statistical model is based on adaptation of the hypergeometric sampling model technique, where samples are drawn randomly without replacement from a finite population. The new approach allows each location to be treated independently with at least a 95 % level of confidence that at least 90 % of the cleanroom or clean zone areas will comply with the maximum particle concentration limit for the target class of air cleanliness. No assumptions are made regarding the distribution of the actual particle counts over the area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling to be used in rooms where the particle counts vary in a more complex manner. In the process of revision it has been recognized that the 95 % UCL was neither appropriate nor was applied consistently in ISO 14644-1:1999. The minimum number of sampling locations required has been changed, compared with ISO 14644-1:1999. A reference table, Table A.1, is provided to define the minimum number of sampling locations required based on a practical adaptation of the sampling model technique. An assumption is made that the area immediately surrounding each sampling location has a homogeneous particle concentration. The cleanroom or clean zone area is divided up into a grid of sections of near equal area, whose number is equal to the number of sampling locations derived from Table A.1. A sampling location is placed within each grid section, so as to be representative of that grid section.

最重要的变化是采用更一致的统计方法来选择取样位置和取样数量；并对选择的数据进行评价。统计模型是基于超几何抽样模型的适应性技术，从有限样本中随机抽取样品。新的方法允许每个位置可独立处理并在95%置信区间水平，至少90%的洁净室或洁净区将会符合目标洁净级别下最大粒子浓度。没有针对实际分布在洁净室或洁净区的粒子进行假设；1999年版的ISO 14644-1中一个基本的假设是粒子计数遵循相同的正态分布穿过房间，该假设目前已经废除，允许以更加复杂的方式在粒子数变化很大的房间进行取样。在ISO 14644-1 1999年版的修改过程中已经认识到95%的UCL既不合适且应用也不一致。相对于ISO 14644-1：1999，最小数量的取样位置要求已经改变。一个参考表格，表A.1，已经在一个实际取样模型的适应性技术中进行提供，以定义需要的最小数量的取样位置。假设在每个取样位置附近有均匀的粒子浓度。洁净室或洁净区域被分割为近乎均等的网格区域，它的数量和根据表A.1推断的取样位置数量是相同的。一个取样位置就放在一个网格部分，以便代表该网格部分。

It is assumed for practical purposes that the locations are chosen representatively; a “representative” location (see A.4.2) means that features such as cleanroom or clean zone layout, equipment disposition and air flow systems should be considered when selecting sampling locations. Additional sampling locations may be added to the minimum number of sampling locations.

它是以实际目的来假定选择的位置是典型的；一个“典型”的位置（见A.4.2）意味着特性，比如洁净室或洁净区布局、设备处置和气流系统在选择取样位置时应该考虑。针对最少取样数量的位置可以增加额外的取样。

Finally, the annexes have been reordered to improve the logic of this part of ISO 14644 and portions of the content of certain annexes concerning testing and test instruments have been included from ISO 14644-3:2005.

最后，附录已经进行再排序以改善ISO 14644该部分的逻辑，该附录的部分内容关于测试和测试仪器已经包括在ISO 14644:2005版中。

The revised version of this part of ISO 14644 addresses the ≥ 5 μm particle limits for ISO Class 5 in the sterile products annexes of the EU, PIC/S and WHO GMPs by way of an adaptation of the macroparticle concept.

修订的ISO 14644部分对≥5μm粒径的粒子限度是按照ISO 5级，在EU无菌产品附录、PIC/S和WHO GMP中当做大粒子的内容。

The revised version of this part of ISO 14644 now includes all matters related to classification of air cleanliness by particle concentration. The revised version of ISO 14644-2:2015 now deals exclusively with the monitoring of air cleanliness by particle concentration.

现在修订版本的ISO 14644部分包括所有基于粒子浓度的相关空气洁净等级的事项。2015年修订的ISO 14644-2现在专门处理关于粒子浓度洁净等级的监测。

Cleanrooms may also be characterized by attributes in addition to the classification of air cleanliness by particle concentration. Other attributes, such as air cleanliness in terms of chemical concentration, may be monitored and the attribute’s grade or level may be designated along with the classification of the ISO Class of cleanliness. These additional attributes do not suffice alone to classify a cleanroom or clean zone.

洁净室也可以具有除了基于粒子浓度的空气洁净度外的其他属性。其他的属性，如基于化学浓度的空气洁净度，可能监测并且属性的等级或水平可能被制定为ISO洁净度级别。这些附加的属性并不能单独对洁净室或洁净区进行分级。

# Cleanrooms and associated controlled environments

# 洁净室和相关受控环境

## Part 1:

## Classification of air cleanliness by particle concentration

## 第一部分：由粒子浓度确定的洁净度分级

## 1 Scope 范围

This part of ISO 14644 specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones; and separative devices as defined in ISO 14644-7.

ISO 14644本部分规定了洁净室和洁净区、以及ISO14644-7定义的隔离装置中的空气洁净度等级是根据空气中悬浮粒子浓度来划分的。

Only particle populations having cumulative distributions based on threshold (lower limit) particle sizes ranging from 0,1 µm to 5 µm are considered for classification purposes.

只有在0.1µm-0.5µm的阈值（低于阈值）粒径范围内呈累积分布的粒子群体才可供分级用。

The use of light scattering (discrete) airborne particle counters (LSAPC) is the basis for determination of the concentration of airborne particles, equal to and greater than the specified sizes, at designated sampling locations.

光散射（离散）空气粒子计数器（LSAPC）的使用是确定悬浮粒子浓度的基础，在设计的取样点，等于和超过规定的粒径。

This part of ISO 14644 does not provide for classification of particle populations that are outside the specified lower threshold particle-size range, 0,1 µm to 5 µm. Concentrations of ultrafine particles (particles smaller than 0,1 µm) will be addressed in a separate standard to specify air cleanliness by  nano-scale particles. An M descriptor (see Annex C) may be used to quantify populations of macroparticles (particles larger than 5 µm).

ISO14644本部分并不提供超出规定的低于阈值的粒径范围，即0.1µm-5µm粒子数的分级。超细粒子浓度（小于0.1µm的粒子）将在纳米级颗粒专门的空气洁净度的单独标准中进行描述。一个M描述符（见附录C）用于量化大颗粒群（粒子超过5µm）。

This part of ISO 14644 cannot be used to characterize the physical, chemical, radiological, viable or other nature of airborne particles.

ISO14644本部分不能被用于表征物理、化学、放射性、生存性或其他空气粒子特性。

## 2 Normative references 引用标准

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

以下文件，整体或部分，在本文中被规范的参考并成为必要的应用。对于参考日期，仅引用的版本适用。对无限期的参考文件，适用参考文件最新的版本（包含最新的修订）。

ISO 14644-2:2015, Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

ISO14644-2：2015 洁净室和相关的受控环境—第二部分：通过粒子浓度对空气洁净度有关的洁净室性能提供证据的监测

ISO 14644-7, Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

ISO14644-7，洁净室和相关的受控环境—第七部分：隔离装置（洁净空气罩、手套箱、隔离器和微型环境）

## 3 Terms and definitions 3 术语和定义

For the purposes of this document, the following terms and definitions apply.

本文所用术语和定义描述如下。

### 3.1 General 通则

#### 3.1.1

**Cleanroom 洁净室**

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

房间中悬浮粒子浓度的数量是受控的和有级别的，以某种方式对房间进行设计、建造和使用，以控制室内粒子的引入、产生和滞留。

Note 1 to entry: The class of airborne particle concentration is specified.

注1：指定悬浮粒子浓度分级。

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

注2：其他洁净度属性水平，如在空气中化学的、活性的或纳米级的浓度，以及依据颗粒表面洁净度，纳米级、化学和活性的浓度可能也被规定和受控。

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

注3：其他有关物理属性可能也根据需要受控，如温度、湿度、压力、振动和静电。

### 3.1.2

**clean zone　洁净区**

defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

悬浮粒子浓度受控和分级的限定空间，以某种方式对空间进行建造和使用，以控制室内粒子的引入、产生和滞留。

Note 1 to entry: The class of airborne particle concentration is specified.

注释1：指定悬浮粒子浓度分级。

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

注释2：其他洁净度属性水平，如在空气中化学的、活性的或纳米级的浓度，以及依据颗粒表面洁净度，纳米级、化学和活性的浓度可能也被规定和受控。

Note 3 to entry: A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

注释3：被限定的洁净区可以在洁净室内或或是由隔离装置实现，这类装置可以位于或不位于洁净室内。

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

注释4：其他有关物理属性可能也根据需要受控，如温度、湿度、压力、振动和静电。

### 3.1.3

**Installation 建筑**

cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities
洁净室或一个或多个洁净区，与所有的建造物，空气处理系统，配套设施和公用工程。

### 3.1.4

**Classification级别**

method of assessing level of cleanliness against a specification for a cleanroom or clean zone
针对洁净室或洁净区的一个标准的洁净度水平的评估方法。

Note 1 to entry: Levels should be expressed in terms of an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air.
注释1：应以ISO级别表述水平，代表了单位空气体积中粒子最大允许浓度。

## 3.2 Airborne particles　悬浮粒子

### 3.2.1

**Particle　粒子**

minute piece of matter with defined physical boundaries

物理边界被指定的小的物质碎片。

**3.2.2**

**particle size 粒径**

diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the particle being measured

使得一个指定的粒径测定仪产生与被测粒子所产生的相等同的响应的球体的直径。

Note 1 to entry: For discrete-particle light-scattering instruments, the equivalent optical diameter is used.

注1：对离散颗粒光散射仪，使用当量光学直径。

**3.2.3**

**particle concentration 粒子浓度**

number of individual particles per unit volume of air

单位体积空气中独立的粒子数量

**3.2.4**

**particle size distribution粒径分布**

cumulative distribution of particle concentration as a function of particle size

作为粒径函数的粒子浓度的累积分布

**3.2.5**

**Macroparticle 大粒子**

particle with an equivalent diameter greater than 5 µm

当量直径大于5µm的粒子

**3.2.6**

**M descriptor M 描述符号**

designation for measured or specified concentration of macroparticles per cubic metre of air, expressed in terms of the equivalent diameter that is characteristic of the measurement method used

测得或规定的每立方米空气中大粒子的浓度，以作为所用测试方法特性的当量直径来表示。

Note 1 to entry: The M descriptor can be regarded as an upper limit for the averages at sampling locations. M descriptors cannot be used to define ISO Classes, but the M descriptor may be quoted independently or in conjunction with ISO Classes.

注1：M描述符号可认为是采样点平均值的上限，不能用M描述符号来定义ISO等级，但可以单独引用或与ISO等级一起引用。

**3.2.7**

**unidirectional airflow 单向流**

controlled airf low through the entire cross-section of a cleanroom or a clean zone with a steady velocity and airstreams that are considered to be parallel

受控气流以稳定速度和被认为是平行的气流，穿过全部洁净室或洁净区的横截面

**3.2.8**

**non-undirectional airf low** 非单向流

air distribution where the supply air entering the cleanroom or clean zone mixes with the internal air by means of induction

送风进入洁净室或洁净区的气流组织与内部空气借助感应方式混合。

## 3.3 Occupancy states 使用状态

**3.3.1**

**as-built** 空态

condition where the cleanroom or clean zone is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present

洁净室或洁净区已经建成，所有连接的配套设施和运行功能就位，但无设备、家具、材料或人员在场的状态。

**3.3.2**

**at-rest** 静态

condition where the cleanroom or clean zone is complete with equipment installed and operating in a manner agreed upon, but with no personnel present

洁净室或洁净区已经建成，生产设备已经安装好，并以协定的方式运行，但没有人员在场的状态。

**3.3.3**

**Operational** 动态

agreed condition where the cleanroom or clean zone is functioning in the specified manner, with equipment operating and with the specified number of personnel present

洁净室或洁净区以规定的方式运行，有设备运行并有规定数目的人员在场的约定状态。

## 3.4 Testing instrumentation (see Annex F) 测试仪器（见附录F）

**3.4.1**

**Resolution** 分辨率

smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

引起对应的示值产生可见变化的被测量值的最小变化。

Note 1 to entry: Resolution can depend on, for example, noise (internal or external) or friction. It may also depend on the value of a quantity being measured.

注1：分辨率能取决于，例如，噪声（内部或外部的）或摩擦力。他可能取决于被测量的值。

[SOURCE: ISO/IEC Guide 99:2007, 4.14]

**3.4.2**

**maximum permissible measurement error** 允许最大测量误差

extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system

对于一次指定的测量、一个指定的测量仪器或一个指定的测量系统，相对于一个已知的标准量值而言，标准或规定所允许的测量误差的极值。

Note 1 to entry: Usually, the term “maximum permissible errors” or “limits of error” is used where there are two extreme values.

注1：通常，术语“最大允许误差”或“误差限度”被用于两个极值。

Note 2 to entry: The term “tolerance” should not be used to designate “maximum permissible error”.

注2：不应把术语“容差”用于命名 “最大允许误差”。

[SOURCE: ISO/IEC Guide 99:2007, 4.26]

## 3.5 Instrument specifications 仪器规格

### 3.5.1

**LSAPC**

**light scattering airborne particle counter 光散射空气粒子计数器**

**light scattering discrete airborne particle counter 光散射离散空气粒子计数器**

instrument capable of counting and sizing single airborne particles and reporting size data in terms of equivalent optical diameter

仪器能够计算并分级单一的悬浮粒子和报告数据等效光学直径的大小

Note 1 to entry: The specifications for the LSAPC are given in ISO 21501-4:2007.

注1： LSAPC的标准在ISO 21501-4:2007中给出。

### 3.5.2

**discrete-macroparticle counter 离散大粒子计数器**

instrument capable of counting and sizing single airborne macroparticles

能够计数并测量单个空气悬浮大粒子粒径的仪器

Note 1 to entry: See Table F.1 for specifications.

注释1：参见表F.1标准

### 3.5.3

**time-of-flight particle sizing apparatus** 飞行时间粒径检测仪

discrete-particle counting and sizing apparatus that defines the aerodynamic diameter of particles by measuring the time for a particle to accommodate to a change in air velocity

分散粒子计数和分级设备，定义了空气动力学粒径粒子通过测量时间适应气流速度的变化

Note 1 to entry: This is usually done by measuring the particle transit time optically after a fluid stream velocity change.

注1：这通常是通过测量粒子飞行时间后光流流速的变化。

Note 2 to entry: See Table F.2 for specifications.

注2：参见表F.2标准。

# 4 Classification 分级

## 4.1 Occupancy state(s) 使用状态

The air cleanliness class by particle concentration of air in a cleanroom or clean zone shall be defined in one or more of three occupancy states, viz. “as-built,” “at-rest” or “operational” (see 3.3).

空气洁净度级别通过一个洁净室或洁净区内的空气粒子浓度，将会被定义为三种状态“空态”、“静态”或“动态”中的一种或是多种（见3.3）。

## 4.2 Particle size(s) 粒径

One, or more than one, threshold (lower limit) particle sizes situated within the range from ≥0.1µm to ≥5 µm are to be used to determine air cleanliness particle concentration for classification.

一个，或是超过一个，阈值(下限)粒径范围内从≥0.1 µm至≥5 µm是用于确定洁净级别的空气洁净度微粒浓度。

## 4.3 ISO Class number/ISO 等级

Air cleanliness class by particle concentration shall be designated by an ISO Class number, N. The maximum permitted concentration of particles for each considered particle size is determined from Table 1.

空气洁净度级别由一个ISO类别，N，通过微粒浓度确定。最大允许的微粒浓度在表1中进行了粒径的确定。

Particle number concentrations for different threshold sizes in Table 1 do not reflect actual particle size and number distribution in the air and serve as criteria for classification only. Examples of classification calculations are included in Annex B.

表1中的不同阈值的粒子数浓度不能反映实际分布在空气中的粒径和数量，只作为分级标准。分级计算方法的案例在附录B中进行说明。

**Table 1 — ISO Classes of air cleanliness by particle concentration**
**表1-通过粒子浓度进行的空气洁净度ISO分级**

| O Class number (*N*) ISO 等级（*N*） | Maximum allowable concentrations (particles/m3) for particles equal to and greater than the considered sizes, shown belowa 等于和大于粒径的最大可允许浓度（粒子/ m3），在下表a中说明 | | | | | |
|---|---|---|---|---|---|---|
| | 0,1 µm | 0,2 µm | 0,3 µm | 0,5 µm | 1 µm | 5 µm |
| 1 | *10*b | d | d | d | d | e |
| 2 | 100 | *24*b | *10*b | d | d | e |
| 3 | 1 000 | 237 | 102 | *35*b | d | e |
| 4 | 10 000 | 2 370 | 1 020 | 352 | *83*b | e |
| 5 | 100 000 | 23 700 | 10 200 | 3 520 | 832 | d, e, f |
| 6 | 1 000 000 | 237 000 | 102 000 | 35 200 | 8 320 | 293 |
| 7 | c | c | c | 352 000 | 83 200 | 2 930 |
| 8 | c | c | c | 3 520 000 | 832 000 | 29 300 |
| 9g | c | c | c | 35 200 000 | 8 320 000 | 293 000 |

a. All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 µm include all particles equal to and greater than this size.
表中所有的浓度是累积的，例如：ISO 5级 0.3µm的10 200粒子包含了所有等于或是超过该粒径的所有粒子。

b. These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see Annex D.
这些浓度会导致大量空气样本分级。可能实施连续的取样程序；参见附录D。

c. Concentration limits are not applicable in this region of the table due to very high particle concentration.
表格中极限浓度不适用于该区域，是因为粒子浓度非常大。

d. Sampling and statistical limitations for particles in low concentrations make classification inappropriate.
粒子的取样和统计学局限性，在低粒子浓度区域会造成分级不当。

e. Sample collection limitations for both particles in low concentrations and sizes greater than 1µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.
在低浓度时所有粒子都有样品收集局限性，并且粒径大于1µm使该粒径下的洁净度级别不适用，导致粒子取样系统潜在的失效。

f. In order to specifyy this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See C.7.)
为了规定ISO 5级的粒径，大粒子M可能适应并与至少一种其他的粒径连同确认。（参见C.7）

g. This class is only applicable for the in-operation state.
该级别仅适用于动态测试。

## 4.4 Designation 命名

The designation of airborne particle concentration for cleanrooms and clean zones shall include

洁净室和洁净区内的悬浮粒子命名需包含

a) the ISO Class number, expressed as “ISO Class N”,
ISO等级，以“ISO N级”表示，

b) the occupancy state to which the classification applies, and
使用状态分级，及

c) the considered particle size(s).
确定的粒径

If measurements are to be made at more than one considered particle size, each larger particle diameter (e.g. *D*2) shall be at least 1,5 times the next smaller particle diameter (e.g. *D*1), i.e. $D2 \geq 1{,}5 \times D1$.

如果是在多个粒径下进行测量，每一个大的粒子直径（例如：*D2*）应当至少是1.5倍下一个较小的子直径（例如：*D1*），也就是$D2 \geq 1.5 \times D1$。

EXAMPLE ISO Class number; occupancy state; considered particle size(s) ISO Class 4; at rest; 0,2µm, 0,5µm

例如： ISO等级；使用状态，确定的粒径，ISO4级；静态；0.2µm； 0.5µm

### 4.5 Intermediate decimal cleanliness classes and particle size thresholds 中间洁净级别和粒径阈值

Where intermediate classes or intermediate particle size thresholds for integer and intermediate classes are required, refer to informative Annex E.

如果需要采用中级级别，或整数和中间级别的中间粒径阈值时，请参见参考信息附录E。

## 5 Demonstration of compliance 符合性证明

### 5.1 Principle 原则

Compliance with air cleanliness (ISO Class) requirements specified by the customer is verified by performing specified testing procedures and by providing documentation of the results and conditions of testing.

空气洁净度符合性(ISO 级别) 需要客户通过执行指定的测试程序验证并提供测试的结果和条件的文件。

At-rest or operational classification may be performed periodically based upon risk assessment of the application, typically on an annual basis.

静态或操作分级可能定期执行基于风险评估的应用程序，通常是每年进行。

For monitoring cleanrooms, clean zones and separative devices, ISO 14644-2:2015 shall be used.

对于洁净室和洁净区，和分离设备的监测， ISO 14644-2:2015也会应用。

NOTE Where the installation is equipped with instrumentation for continuous or frequent monitoring of air cleanliness by particle concentration and other parameters of performance as applicable, the time intervals between classification may be extended provided that the results of the monitoring remain within the specified limits.

注：如果洁净区内装配了通过测量粒子浓度和其它参考来连续或间歇监测空气洁净度的仪器，并且监测结果保持符合指定的限度，则对该洁净区进行级别判定的测试时间间隔可以延长。

### 5.2 Testing 测试

The reference test method for demonstrating compliance is given in Annex A (normative). Alternative methods or instrumentation (or both), having at least comparable performance, may be specified. If no alternative is specified or agreed upon, the reference method shall be used.

在附录A中给出了参考的测试方法用来测定符合性。替代方法或仪器(或两者)，至少有相当的性能，可能会被指定。如果没有指定替代或商定，应当使用的参考方法。

Tests performed to demonstrate compliance shall be conducted using instruments which are in compliance with calibration requirements at the time of testing.

测试执行符合性示范如何进行使用仪器应当是符合校准需求的测试。

### 5.3 Airborne particle concentration evaluation悬浮粒子浓度评价

Upon completion of testing in accordance with Annex A, the concentration of particles (expressed as number of particles per cubic metre) in a single sample volume at each sampling location shall not exceed the concentration limit(s) given in Table 1 or Table E.1 for intermediate decimal classes for the considered size(s). If multiple single sample volumes are taken at a sampling location, the concentrations shall be averaged and the average concentration must not exceed the concentration limits given in Table 1 or Table E 1. Intermediate particle sizes shall be derived from Formula (E.1).

根据附录A完成测试，在每个采样位置取得的单个样本的粒子浓度(每立方米表示为粒子数)不得超过在表1中给出的极限浓度，或是表E.1中给出的指定粒径粒子的中间级别的浓度限度。如果在同一个采样位置有多个样本体积，则应计算平均浓度，且均浓度不得超过表1或表E.1中的极限浓度。中间粒径应根据公式（E.1）计算。

Particle concentrations used for determination of compliance with ISO Classes shall be measured by the same method for all considered particle sizes.

用于确定ISO级别符合性的粒子浓度需要用相同的方法对所有粒径进行测定。

### 5.4 Test report 测试报告

The results from testing each cleanroom or clean zone shall be recorded and submitted as a comprehensive report, along with a statement of compliance or non-compliance with the specified designation of air cleanliness class by particle concentration.

每一个洁净室或是洁净区的测试结果需要记录并做成一个综合报告进行提交，同时还要提交一份根据粒子浓度结果判定的受测空间是否符合指定的空气洁净度级别的声明。

The test report shall include 测试报告应包含

a) the name and address of the testing organization, and the date on which the test was performed,
测试组织的名称和地址，执行测试日期，

b) the number and year of publication of this part of ISO 14644, i.e. ISO 14644-1:2015,
ISO 14644部分的号码和年份，如：ISO 14644-1：2015，

c) a clear identification of the physical location of the cleanroom or clean zone tested (including reference to adjacent areas if necessary), and specific designations for coordinates of all sampling locations (a diagrammatic representation can be helpful),
明确识别的实际位置的洁净室或洁净区进行测试（如果需要的话还要包含相邻区域），和所有取样位置的坐标的具体名称（图解表示可以是有帮助的），

d) the specified designation criteria for the cleanroom or clean zone, including the ISO Class number, the relevant occupancy state(s), and the considered particle size(s),
指定的标准洁净室或洁净区名称，包括ISO级别，相关的占用状态，考虑粒径，

e) details of the test method used, with any special conditions relating to the test, or departures from the test method, and identification of the test instrument and its current calibration certificate, and
使用的测试方法的细节，与任何特殊条件有关测试，或与下述要求背离的

f) the test results, including particle concentration data for all sampling locations.
测试结果，包含所有取样位置的粒子浓度数据

If concentrations of macroparticles are quantified, as described in Annex C, the relevant information should be included with the test report.

如果大粒子的浓度是可以量化的，就像附录C中的描述，相关信息应该包含在测试报告。

# Annex A 附录A

## (Normative) 标准规定

### Reference method for classification of air cleanliness by particle concentration 采用粒子浓度对空气洁净等级分类的参考方法

## A.1 Principle 原则

A discrete-particle-counting instrument is used to determine the concentration of airborne particles, equal to and greater than the specified sizes, at designated sampling locations.

使用离散粒子计数测定在指定的采样点上，大于或等于规定粒径，的悬浮粒子的浓度。

## A.2 Apparatus requirements 仪器要求

### A.2.1 Particle-counting instrument 粒子计数仪

The instrument shall have a means of displaying or recording the count and size of discrete particles in air with a size discrimination capability to detect the total particle concentration in the appropriate particle size ranges for the class under consideration.

离散粒子计数器，具有显示或记录空气中离散粒子的数目和粒径的能力和粒径鉴别能力，可检测到被测级别之适当粒径范围内的总粒子浓度，以及适当的采样系统.

NOTE Light scattering (discrete) airborne particle counters (LSAPC) are commonly used for undertaking air cleanliness classification.

备注：光散射（离散的）悬浮粒子计数器（LSAPC）通常用于空气洁净度的分类。

### A.2.2 Instrument calibration 仪器校正

The particle counter shall have a valid calibration certificate: the frequency and method of calibration should be based upon current accepted practice as specified in ISO 21501-4.[1]

仪器应该有有效的校正证书；校正的频率和方法应按ISO 21501-4现行版本中列出的现可接受规范来执行。

NOTE Some particle counters cannot be calibrated to all of the required tests in ISO 21501-4. If this is the case, record the decision to use the counter in the test report.

备注：有些粒子计数器不能被标定用于所有ISO21501-4中要求的测试。如果情况如此，要记录下测试报告中使用该计数器的决定。

## A.3 Preparation for particle count testing 粒子计数的测试准备

Prior to testing, verify that all relevant aspects of the cleanroom or clean zone that contribute to its integrity are complete and functioning in accordance with its performance specification.

测试前，应按照技术性能要求认证洁净室或洁净区作为一个运行的整体，是完整的、功能是正常的。

Care should be taken when determining the sequence for performing supporting tests for cleanroom performance. ISO 14644-3, Annex A provides a checklist.

在确认执行洁净区性能支持性测试的时候要注意确定顺序。ISO14644-3，附录A有检查表。

## A.4 Establishment of sampling locations 确定采样点位置

### A.4.1 Deriving the number of sampling locations 得到采样点的数量

Derive the minimum number of sampling locations, *N*L, from Table A.1. Table A.1 provides the number of sampling locations related to the area of each cleanroom or clean zone to be classified and provides at least 95 % confidence that at least 90 % of the cleanroom or clean zone area does not exceed the class limits.

根据表格 A.1.得到最少的取样点数量 NL。表格 A.1.提供了将要被分类的洁净室或洁净区的面积相关的取样点的数量，而且至少 95%置信区间来保证至少洁净区或洁净室的 90%面积不超过分类限度。

**Table A.1 — Sampling locations related to cleanroom area**

表 A.1. 与洁净间面积相关的取样点

| Area of cleanroom (m2) less than or equal to<br>洁净室的面积（m²）少于或等于 | Minimum number of sampling locations to be tested (NL)<br>取样点的最少数量 NL |
|---|---|
| 2 | 1 |
| 4 | 2 |
| 6 | 3 |
| 8 | 4 |
| 10 | 5 |
| 24 | 6 |
| 28 | 7 |
| 32 | 8 |
| 36 | 9 |
| 52 | 10 |
| 56 | 11 |
| 64 | 12 |
| 68 | 13 |
| 72 | 14 |
| 76 | 15 |
| 104 | 16 |
| 108 | 17 |
| 116 | 18 |
| 148 | 19 |
| 156 | 20 |
| 192 | 21 |
| 232 | 22 |
| 276 | 23 |
| 352 | 24 |
| 436 | 25 |
| 636 | 26 |
| 1000 | 27 |
| >1000 | 见公式 |

NOTE 1 If the considered area falls between two values in the table, the greater of the two should be selected.

注1：如果要考虑的面积在上述两个值中间，那么这两个中要选择大的数值；

NOTE 2 In the case of unidirectional airflow, the area may be considered as the cross section of the moving air perpendicular to the direction of the airflow. In all other cases the area may be considered as the horizontal plan area of the cleanroom or clean zone.

注 2：在水平单向层流时，面积 A 可以看作是与气流方向呈垂直流动的空气的截面积。其它所有情况面积是洁净室或洁净区的水平平面面积。

### A.4.2 Positioning the sampling locations 选定取样点位置

In order to position the sampling locations

为了定位取样点的位置

a) use the minimum number of sampling locations NL derived from Table A.1,
使用由表格 A.1.中得到的最少的取样数量 NL

b) then divide the whole cleanroom or clean zone into NL sections of equal area,
然后将真个洁净区或者洁净室分为 NL 等份

c) select within each section a sampling location considered to be representative of the characteristics of the section, and
从每个等份中选择取样点作为该等份中的特征的代表

d) at each location, position the particle counter probe in the plane of the work activity or another specified point.
在每个点，将计数器的探头放在工作平面或者其它指定点。

Additional sampling locations may be selected for locations considered critical. Their number and positions shall also be agreed and specified.

其它的取样点可以选择那些认为重要的。他们的数量和位置应该被统一和说明。

Additional sections and associated sampling locations may be included to facilitate subdivision into equal sections.

其它面积或者相关联的取样点可能要便于将其化成相同面积

For non-unidirectional airflow cleanrooms or clean zones, locations may not be representative if they are located directly beneath non-diffused supply air sources.

对于非单向流的洁净区或者洁净室，如果它位于非扩散气源的正下方，那么这个位置可能不具有代表性。

### A.4.3 Sampling locations for large cleanrooms or clean zones 对于大面积洁净室或洁净区的取样点

When the area of the cleanroom or clean zone is greater than 1 000 m2, apply Formula (A.1) to determine the minimum number of sampling locations required.

当洁净室或洁净区的面积大于 1000 ㎡的时候，用公式 A.1.来确定要求的取样点的最少数量。

$$N_L = 27 \times \left(\frac{A}{1000}\right) \qquad (A.1)$$

| | |
|---|---|
| where<br>*N*L is the minimum number of sampling locations to be evaluated, rounded up to the next whole number;<br>*A* is the area of the cleanroom in m2. | 其中<br>NL是需要评估的最少取样点数，向上修约至整数；<br>A是洁净室的面积 |

### A.4.4 Establishment of single sample volume and sampling time per location 确定各采样点的每次采样量和取样时间

At each sampling location, sample a volume of air sufficient to detect a minimum of 20 particles if the particle concentration for the largest selected particle size were at the class limit for the designated ISO Class.

指定的 ISO 等级如最大被考虑粒径的粒子浓度的限值时，在每个采样点要采集足够的空气量，保证能检测出至少 20 个粒子。

The single sample volume, Vs, per sampling location is determined by using Formula (A.2):

每个采样点的每次采样量 VS 用下式确定：

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000 \qquad (A.2)$$

| | |
|---|---|
| where | 其中 |
| Vs is the minimum single sample volume per location, expressed in litres (except see Annex D); | Vs 是每个采样点每次最少采样量，用升表示（例如参见附录 D） |
| Cn,m is the class limit (number of particles per cubic metre) for the largest considered particle size specified for the relevant class; | Cn,m 是相关等级规定的被考虑最大粒径之等级限值（个/立方米空气）。 |
| 20 is the number of particles that could be counted if the particle concentration were at the class limit. | 20 是当粒子浓度处于该等级限值时，可被检测到的粒子数。 |

The volume sampled at each location shall be at least 2 l, with a minimum sampling time of 1 min for each sample at each location. Each single sample volume at each sampling location shall be the same.
每个采样点的采样量至少为 2 升，采样时间最少为 1 分钟。每个取样点单个取样体积应该相同。

When Vs is very large, the time required for sampling can be substantial. By using the optional sequential sampling procedure (see Annex D), both the required sample volume and the time required to obtain samples may be reduced.

当 Vs 很大的时候，需要取样的时间很长。要使用可选择的顺序取样程序（见附录 D），取样体积和时间都可能被减少。

### A.5 Sampling procedure 取样程序

**A.5.1** Set up the particle counter (see A.2) in accordance with the manufacturer's instructions including performing a zero count check.
按照厂家说明书对粒子计数器进行设置，包括给粒子计数器调零。

**A.5.2** The sampling probe shall be positioned pointing into the airflow. If the direction of the airflow being sampled is not controlled or predictable (e.g. non-unidirectional airflow), the inlet of the sampling probe shall be directed vertically upward.
采样探头的位置应插入空气流。若被采样的气流方向是未受控的或不可预计的（如非单向流），采样探头的入口应垂直向上。

**A.5.3** Ensure normal conditions for the selected occupancy state are established before sampling.
取样前确保是取样环境在指定状态下运行稳定。

**A.5.4** Sample the volume of air determined in A.4.4, as a minimum, for each sample at each sampling location.
在每个点取样，取样量最少应达到按照 A.4.4 中确定的气体体积。

**A.5.5** If an out-of-specification count is found at a location due to an identified abnormal occurrence, then that count can be discarded and noted as such on the test report and a new sample taken.

如果因为确定的异常情况导致采样点出现 OOS 计数，那么这个计数可以丢弃，在测试报告中如实备注，并重新采样。

**A.5.6** If an out-of-specification count found at a location is attributed to a technical failure of the cleanroom or equipment, then the cause should be identified, remedial action taken and retesting performed of the failed sampling location, the immediate surrounding locations and any other locations affected. The choice shall be clearly documented and justified.

如果取样点发现的 OOS 计数是由于洁净室或者设备的技术失败造成的，那么要确定原因，采取补救行动，并且在失败的采样点上、紧邻周边位置和其它任何受影响的位置进行复测。要清晰的记录和说明选择。

## A.6 Processing of results 结果处理

### A.6.1 Recording of results 结果的记录

Record the result of each sample measurement as the number of particles in each single sample volume at each of the considered particle size(s) appropriate to the relevant ISO Class of air cleanliness.

把每次采样测量的结果与 ISO 的空气洁净度等级相关的各个被考虑粒径的浓度记录下来。

NOTE For particle counters with a concentration calculation mode, the manual evaluation may not be necessary.

备注：如果粒子计数器具有浓度计算模式，那么没必要进行人工评估。

#### A.6.1.1 Average concentration of particles at each sampling location 计算每个取样点的粒子浓度的平均值

When two or more single sample volumes are taken at a location, calculate and record the average number of particles per location at each considered particle size from the individual sample particle concentrations, according to Formula (A.3).

当在一个采样点进行两次或更多次采样时，根据公式（A.3）计算和记录每个要考虑的粒径的单个样品粒子浓度的平均值。

$$\overline{x_i} = \left[\frac{x_{i,1} + x_{i,2} + \cdots x_{i,n}}{n}\right] \qquad (A.3)$$

| | |
|---|---|
| *Where*<br>$X_i$ -is the average number of particles at location *i*, representing any location;<br>$x_{i.1}$ to $x_{i.n}$ are the number of particles in individual samples;<br>*n* is the number of samples taken at location *i*. | 其中<br>$X_i$ 指采样点i（代表任何位置）的平均粒子浓度<br>$x_{i,1}$至$x_{i,n}$ 表示每次采样的粒子浓度<br>n 在采样点i的采样次数 |

#### A.6.1.2 Calculate the concentration per cubic metre 计算每立方米的浓度

$$c_i = \frac{\overline{x_i} \times 1000}{V_t} \qquad (A.4)$$

| | |
|---|---|
| Where<br>Ci is the concentration of particles per cubic metre;<br>Xi is the average number of particles at location i, representing each location;<br>Vt is the selected single sample volume in litres. | 其中<br>Ci是每立方米的粒子浓度<br>Xi是第i个取样点的平均粒子数，i代表任意取样点<br>Vt代表所选单个样品体积，单位升 |

### A.6.2 Interpretation of results 结果的解释

#### A.6.2.1 Classification requirements 分级要求

The cleanroom or clean zone is deemed to have met the specified air cleanliness classification requirements if the average of the particle concentrations (expressed as number of particles per cubic metre) measured at each of the sampling locations does not exceed the concentration limits determined from Table 1.

如果在各个取样点测量的粒子浓度的平均值并没有超过由表 1 确定的浓度限度，那么洁净室或洁净区被认为满足了专门的空气洁净度的分类要求。

If intermediate classes or particle sizes are used, as defined in Annex E, appropriate limits derived from Table E.1 or Formula (E.1) should be used.

使用附录 E 中定义的中间级别或粒径的时候，应该用表 E.1.或公式（E.1）计算所得的适当限值。

#### A.6.2.2 Out-of-specification result OOS 结果

In the event of an out-of-specification count, an investigation shall be undertaken. The result of the investigation and remedial action shall be noted in the test report (see 5.4).
出现 OOS 结果时，需要进行调查。调查结果和弥补措施应在测试报告中注明（参见 5.4）。

## Annex B 附录 B

**(informative 仅供参考)**

## Examples of classification calculations 级别计算的例子

### B.1 Example 1 例 1

B.1.1 A cleanroom has a floor area of 18 $m^2$ and is specified to be ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 l per minute. Two particle sizes are considered: D ≥ 0.3μm and D ≥ 0.5μm.

被测的洁净室房屋面积为 18$m^2$，该洁净室规定动态的空气洁净度等级为 ISO Class 5（5 级）。将采用流速为 28.3L/min 的离散粒子计数器来进行级别确认。要考虑的两种粒径：D ≥ 0,3μm and D ≥ 0,5μm。

The number of sampling locations, NL, is determined to be six, based on Table A.1.

根据表 A.1，取样点的数量 NL 确定为 6.

**B.1.2** The particle concentration limits for ISO Class 5 are taken from Table 1:

ISO 的 Class5 的粒子浓度的限度来自于表格 1

Cn(⩾0.3μm) = 10,200 particles/$m^3$

Cn(⩾0.5μm) = 3,520 particles/$m^3$

**B.1.3** The required single sample volume can be calculated from Formula (A.2) as follows:

要求的单一取样量可以通过以下公式进行计算

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{3520}\right) \times 1000$$

$$V_s = (0.00568) \times 1000$$

$$V_s = 5.68 \text{litres}$$

The single sample volume has been calculated to be 5,68 l. As the LSAPC being used for this test had a flow rate of 28,3 litres per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

单一取样体积计算结果是 5.68L。因为 LSAPC 用于测试且流速为每分钟 28.3L，要求取样 1 分钟，因而每个单取样体积将是 28.3L。

NOTE In A.4.4, the minimum sample volume for the procedure is set by calculating the minimum sample volume as shown above and then determining the sample volume obtained for the operation of the particle counter in the time period of 1 min. The sampling at each position must occur for at least 1 min; if the minimum sample volume as calculated is satisfied within the 1-min period, then the sampling process can be stopped at the end of 1 min. If the calculated minimum volume cannot be obtained within the 1-min period with the flow rate of the instrument to be used, then the sampling must continue for a longer time period until at least the minimum sample volume has been obtained. Because there are several possible flow rates for particle counters, users are cautioned to verify the flow rate of the specific instrument(s) to be used when determining the sampling time needed to satisfy both the 1-min requirement and the calculated minimum sample volume.

注：在 A.4.4，程序要求的最少取样体积是通过如上所述的方法来计算的，然后根据操作粒子计数器 1min 的时间的取样体积来确定。每个点的取样至少进行一分钟；如果计算得到的最少的取样体积满足在 1min 以内，那么取样过程就在 1min 的时候停止。如果使用一定流速的仪器在一分钟内无法满足最少取样体积的要求，那么就要持续更长一点时间值到最少取样体积满足。因为粒子计数器有几种可能的流速，用户要注意确认某一仪器的里露宿，以确保取样时间满足至少一分钟而且能够满足最少的取样体积。

**B.1.4** At each sampling location only one sample volume is taken. The number of particles per cubic metre, xi, is calculated for each location and each particle size as shown in Tables B.1 and B.2.

每个取样点位置只取一个样。针对每个取样点和每个粒径来计算每立方米的粒子的数量 xi，如表格 B.1 和 B.2 所示。

Table B.1----Sampling data for particles ⩾0.3μm

表 B.1-------粒径≥0.3um 的取样数据

| Sampling location | Sample 1 xi⩾0.3μm (counts per 28.3L) | Location sample average (counts per 28.3L) | Location concentration average (counts per $m^3$ = location average X 35.3) | ISO Class 5 limit for 0.3μm particle size | Pass/fail |
|---|---|---|---|---|---|
| 取样点 | 样品 1 xi⩾ 0.3μm（每 28.3L 计数） | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.3μm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 245 | 245 | 8,649 | 10,200 | Pass 合格 |
| 2 | 185 | 185 | 6,531 | 10,200 | Pass 合格 |
| 3 | 59 | 59 | 2,083 | 10,200 | Pass 合格 |
| 4 | 106 | 106 | 3,742 | 10,200 | Pass 合格 |
| 5 | 164 | 164 | 5,789 | 10,200 | Pass 合格 |
| 6 | 196 | 196 | 6,919 | 10,200 | Pass 合格 |

Table B.2----Sampling data for particles ⩾0.5μm

表 B.2-------粒径≥0.5um 的取样数据

| Sampling location | Sample 1 xi⩾0.5μm (counts per 28.3L) | Location sample average (counts per 28.3L) | Location concentration average (counts per $m^3$ = location average X 35.3) | ISO Class 5 limit for 0.5μm particle size | Pass/fail |
|---|---|---|---|---|---|
| 取样点 | 样品 1 xi⩾ 0.5μm（每 28.3L 计数） | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.5μm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 21 | 21 | 741 | 3,520 | Pass 合格 |
| 2 | 24 | 24 | 847 | 3,520 | Pass 合格 |
| 3 | 0 | 0 | 0 | 3,520 | Pass 合格 |
| 4 | 7 | 7 | 247 | 3,520 | Pass 合格 |
| 5 | 22 | 22 | 777 | 3,520 | Pass 合格 |
| 6 | 25 | 25 | 883 | 3,520 | Pass 合格 |

**B.1.5** Each value of the concentration for D ≥ 0,3 μm is less than the limit of 10 200 particles/m3 and D ≥ 0,5 μm is less than the limit of 3 520 particles/m3 as established in B.1.2; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

B.1.2 中确立了 D ≥ 0,3 μm 都小于 10 200 particles/m3，粒径 D ≥ 0,5 μm 都小于 3 520 particles/m3 的浓度值。因此，洁净室粒子浓度确立的空气洁净度满足 ISO 分类要求。

**B.2 Example 2 例 2**

B.2.1 A cleanroom has a floor area of 9 m2 and is specified to be ISO Class 3 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 50,0 l per minute. Only one particle size (D ≥ 0,1 μm) is considered.

被测的洁净室房屋面积为 9m2，该洁净室规定动态的空气洁净度等级为 ISO Class 3（3 级）。将采用流速为 50.0L/min 的离散粒子计数器来进行级别确认。只考察一种粒径(D ≥ 0,1 μm)。

The number of sampling locations, NL, is determined to be five, based on Table A.1.

取样点的数量确定为 5，基于表格 A.1。

**B.2.2** The particle concentration limit for ISO Class 3 at ≥ 0,1 μm is taken from Table 1:

ISO Class 3 环境下粒径 ≥ 0,1 μm 的浓度限度值来自于表格 1。

Cn (≥ 0,1 μm) = 1 000 particles/m3

**B.2.3** The required single sample volume can be calculated from Formula (A.2) as follows:

取样量可根据以下公式进行计算：

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{1000}\right) \times 1000$$

$$V_s = (0.02) \times 1000$$

$$V_s = 20.0\text{litres}$$

The single sample volume has been calculated to be 20,0 l. As the discrete-particle counter being used for this test had a flow rate of 50,0 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 50,0 l would be sampled for each single sample volume.

单一取样体积计算结果是 20.0L。用于测试的离散粒子计数器流速为每分钟 50.0L，要求取样 1 分钟，因而每个单取样体积将是 50.0L。

**B.2.4** At each sampling location only one sample volume is taken. The number of particles per cubic metre, xi, is calculated for each location and recorded in Table B.3.

每个取样点位置只取一个样。针对每个取样点和每个粒径来计算每立方米的粒子的数量 xi，如表格 B.3。

Table B.3----Sampling data for particles ≥0.1μm

表 B.3-------粒径≥0.1um 的取样数据

| Sampling location | Sample 1 xi≥0.1μm (counts per 50.0L) | Location sample average (counts per 50.0L) | Location concentration average (counts per $m^3$ = location average X 20) | ISO Class 3 limit for 0.1μm particle size | Pass/fail |
|---|---|---|---|---|---|
| 取样点 | 样品 1 xi≥0.5μm(每 28.3L 计数) | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.5μm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 46 | 46 | 920 | 1,000 | Pass 合格 |

| | | | | | |
|---|---|---|---|---|---|
| 2 | 47 | 47 | 940 | 1,000 | Pass 合格 |
| 3 | 46 | 46 | 920 | 1,000 | Pass 合格 |
| 4 | 44 | 44 | 880 | 1,000 | Pass 合格 |
| 5 | 9 | 9 | 180 | 1,000 | Pass 合格 |

**B.2.5** Each value of the concentration for D ≥ 0,1 µm is less than the limit of 1 000 particles/m$^3$ established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

D ≥ 0,1 µm 的浓度值都小于限度 1 000 particles/m$^3$。因此，洁净室粒子浓度确立的空气洁净度满足 ISO 分类要求。

**B.3 Example 3 例 3**

**B.3.1** A cleanroom has a floor area of 64 m2 and is specified ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 l per minute. Only one particle size (D ≥ 0,5 µm) is considered.

被测的洁净室房屋面积为 64m2，该洁净室规定动态的空气洁净度等级为 ISO Class 5（5 级）。将采用流速为 28.3L/min 的离散粒子计数器来进行级别确认。只考察一种粒径(D ≥ 0,5 µm)。

The number of sampling locations, NL, is determined to be 12, based on Table A.1.

基于表格 A.1 取样点的数量确定为 12。

**B.3.2** The particle concentration limit for ISO Class 5 at ≥ 0,5 µm is taken from Table 1:

Class 5 环境下粒径 ≥ 0,5µm 的浓度限度值来自于表格 1,如下:

Cn (≥ 0,5 µm) = 3 520 particles/m3

**B.3.3** The required single sample volume can be calculated from Formula (A.2) as follows:

取样量可根据以下公式进行计算：

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{3520}\right) \times 1000$$

$$V_s = (0.00568) \times 1000$$

$$V_s = 5.68\text{litres}$$

The single sample volume has been calculated to be 5,68 l. As the discrete-particle counter used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

单一取样体积计算结果是 5.68L。用于测试的离散粒子计数器流速为每分钟 28.3L，要求取样 1 分钟，因而每个单取样体积将是 28.3L。

**B.3.4** At each sampling location only one sample volume is taken. The number of particles per cubic metre, xi, is calculated for each location and recorded in Table B.4.

每个取样点位置只取一个样。针对每个取样点和每个粒径来计算每立方米的粒子的数量 xi，如表格 B.4。

Table B.4----Sampling data for particles ≥0.5μm

表 B.4-------粒径≥0.5um 的取样数据

| Sampling location | Sample 1 xi≥0.5μm | Location sample average (counts per 28.3L) | Location concentration average (counts per $m^3$ = location average X 35.3) | ISO Class 5 limit for 0.5μm particle size | Pass/fail |
|---|---|---|---|---|---|
| 取样点 | 样品 1 xi≥ 0.5μm(每 28.3L 计数) | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.5μm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 35 | 35 | 1,236 | 3,520 | Pass 合格 |
| 2 | 22 | 22 | 777 | 3,520 | Pass 合格 |
| 3 | 89 | 89 | 3,142 | 3,520 | Pass 合格 |
| 4 | 49 | 49 | 1,730 | 3,520 | Pass 合格 |
| 5 | 10 | 10 | 353 | 3,520 | Pass 合格 |
| 6 | 60 | 60 | 2,118 | 3,520 | Pass 合格 |
| 7 | 18 | 18 | 635 | 3,520 | Pass 合格 |
| 8 | 44 | 44 | 1,553 | 3,520 | Pass 合格 |
| 9 | 59 | 59 | 2,083 | 3,520 | Pass 合格 |
| 10 | 51 | 51 | 1,800 | 3,520 | Pass 合格 |
| 11 | 6 | 6 | 212 | 3,520 | Pass 合格 |
| 12 | 31 | 31 | 1,094 | 3,520 | Pass 合格 |

**B.3.5** Each value of the concentration for D = 0,5 μm is less than the limit of 3 520 particles/m3 established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

D ≥ 0,5 μm 的浓度值都小于限度 3520 particles/m3。因此，洁净室粒子浓度确立的空气洁净度满足 ISO 分类要求。

**B.4 Example 4 例 4**

**B.4.1** A cleanroom has a floor area of 25 m2 and is specified to be ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28.3 l per minute. Only one particle size (D ≥ 0.5μm) is considered.

被测的洁净室房屋面积为 25$m^2$，该洁净室规定动态的空气洁净度等级为 ISO Class 5。将采用流速为 28.3L/min 的离散粒子计数器来进行级别确认。只考察一种粒径(D ≥ 0,5μm)。

The minimum number of sampling locations from Table A.1 is 7.

基于表格 A.1 取样点的数量确定为 7。

**B.4.2** The particle concentration limit for ISO Class 5 at ≥ 0,5 μm is obtained from Table 1 as follows:

Class 5 环境下粒径 ≥ 0,5μm 的浓度限度值来自于表格 1,如下:

Cn (≥ 0,5 μm) = 3 520 particles/m3

**B.4.3** The required single sample volume can be calculated from Formula (A.2) as follows:

取样量可根据以下公式进行计算：

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{3520}\right) \times 1000$$

$$V_s = (0.00568) \times 1000$$

$$V_s = 5.68\text{litres}$$

The single sample volume has been calculated to be 5,68 l. As the discrete-particle counter being used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

单一取样体积计算结果是 5.68L。用于测试的离散粒子计数器流速为每分钟 28.3L，要求取样 1 分钟，因而每个单一取样体积将是 28.3L。

B.4.4 The number of sampling locations required from Table A.1 is 7, however, this example shows that the customer and supplier have agreed to add an additional 3 locations, making 10 in total. At each sampling location the number of single sample volumes varies from 1 to 3.

从表格 A.1 中要求的取样点数量是 7,然而,这个例子显示顾客和供应商同意额外增加 3 个点,总共 10 个点。每个取样点的取样次数从 1 到 3。

B.4.5 For recording purposes, the number of particles (concentration) per cubic metre, xi, is calculated from the average count per unit volume (28,3 l) at each location (28,3 × 35,3) as in Table B.5.

为了记录，每立方米的粒子数量（浓度），xi，是由表 B.5 中每个取样点（28.3X35.3）的单位体积（28.3L）的平均值计算得到的。

Table B.5----Sampling data for particles ≥0.5μm

表 B.5-------粒径≥0.5um 的取样数据

| Sampling location | Sample 1 xi≥0.5μm | Sample 2 xi≥0.5μm | Sample 3 xi≥0.5μm | Location sample average (counts per 28.3L) | Location concentration average (counts per m³ = location average X 35.3) | ISO Class 5 limit for 0.5μm particle size | Pass/fail |
|---|---|---|---|---|---|---|---|
| 取样点 | 样品 1 xi≥0.5μm（每 28.3L 计数） | 样品 2 xi≥0.5μm（每 28.3L 计数） | 样品 3 xi≥0.5μm（每 28.3L 计数） | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.5μm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 47 | 57 | | 52 | 1,836 | 3,520 | Pass 合格 |
| 2 | 12 | | | 12 | 424 | 3,520 | Pass 合格 |
| 3 | 162 | 78 | 32 | 91 | 3,201 | 3,520 | Pass 合格 |
| 4 | 148 | 74 | 132 | 118 | 4,165 | 3,520 | Pass 合格 |
| 5 | 1 | 0 | | 0.5 | 18 | 3,520 | Pass 合格 |
| 6 | 19 | 22 | 17 | 19 | 682 | 3,520 | Pass 合格 |
| 7 | 5 | 15 | 3 | 8 | 271 | 3,520 | Pass 合格 |
| 8 | 38 | 21 | | 30 | 1,041 | 3,520 | Pass 合格 |
| 9 | 54 | 159 | 78 | 97 | 3,424 | 3,520 | Pass 合格 |
| 10 | 48 | 62 | 53 | 54 | 1,918 | 3,520 | Pass 合格 |

**B.4.6** At sampling location 4, the average sample volume concentration of 4 165 does not meet ISO Class 5 maximum particle count criteria of 3 520. At location 3 and location 9, one of the individual particle count concentrations does not meet the limit established in Table 1; however, the average particle concentration for location 3 and the average particle concentration for location 9 do meet the limit established in Table 1. Because location 4 does not meet the air cleanliness by particle concentration, the cleanroom does not meet the required ISO Class.

在取样点 4，平均粒子浓度 4165 不满足 ISO Class5 的最大粒子计数标准 3520.在取样点 3 和 9，各有一个粒子计数浓度不满足表格 1 中确立的标准；然而，取样点 3 和 9 的平均粒子浓度满足了表格 1 中确立的要求。因为取样点 4 不满足由粒子浓度确立的空气洁净度，故洁净室不满足 ISO 级别。

### B.5 Example 5 例 5

**B.5.1** A cleanroom has a floor area of 10,7 m2 and is specified to be ISO Class 7,5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 litres per minute. Only one particle size (D ≥ 0,5 μm) is considered.

被测的洁净室房屋面积为 10.7m2，该洁净室规定动态的空气洁净度等级为 ISO Class 7.5。将采用流速为 28.3L/min 的离散粒子计数器来进行级别确认。只考察一种粒径(D ≥ 0,5 μm)。

The number of sampling locations is determined to be 6, based on Table A.1.

基于表格 A.1 取样点的数量确定为 6。

**B.5.2** The particle concentration limit for ISO Class 7,5 at ≥ 0,5 μm is obtained from Table E.1.

Class 7.5 环境下粒径 ≥ 0,5μm 的浓度限度值来自于表格 E.1,如下:

$$C_n(\geq 0.5\mu m) = 10^N \times \left(\frac{0.1}{D}\right)^{2.08} \qquad where \text{ 其中 N = 7.5，D = 0.5μm}$$

$$C_n(\geq 0.5\mu m) = 10^{7.5} \times \left(\frac{0.1}{0.5}\right)^{2.08}$$

$$C_n(\geq 0.5\mu m) = 31{,}622{,}777 \times 0.03516757$$

$$C_n(\geq 0.5\mu m) = 1{,}112{,}096 \; rounded\ to\ three\ significant\ digits \text{修约到三位有效数字} \\ = 1{,}110{,}000\ particles/m^3$$

**B.5.3** The required single sample volume can be calculated from Formula (A.2) as follows:

取样量可根据以下公式进行计算：

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{1112000}\right) \times 1000 = 0.01799\ litres$$

The single sample volume has been calculated to be 0,01799 l. As the discrete-particle counter being used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

单一取样体积计算结果是 0.01799 L。用于测试的离散粒子计数器流速为每分钟 28.3L，要求取样 1 分钟，因而每个单一取样体积将是 28.3L。

**B.5.4** At each sampling location the number of single sample volumes varies from 1 to 3. The number of particles per cubic metre, xi, is calculated for each location and recorded in Table B.6.

每个取样点的取样次数从 1 到 3。每立方米的粒子数量，xi，是从每个取样点计算得到的,并记录在表 B.6 中。

Table B.6----Sampling data for particles ≥0.5μm

表 B.6-------粒径≥0.5um 的取样数据

| Sampling location | Sample 1 xi≥0.5μm | Sample 2 xi≥0.5μm | Sample 3 xi≥0.5μm | Location sample average (counts per 28.3L) | Location concentration average (counts per $m^3$ = location average X 35.3) | ISO Class 7.5 limit for 0.5μm particle size | Pass/fail |
|---|---|---|---|---|---|---|---|
| 取样点 | 样品 1 xi≥0.5μm（每 28.3L 计数） | 样品 2 xi≥0.5μm（每 28.3L 计数） | 样品 3 xi≥0.5μm（每 28.3L 计数） | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.5μm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 11,679 | | | 11,679 | 412,269 | 1,110,000 | Pass 合格 |
| 2 | 9,045 | | | 9,045 | 319,289 | 1,110,000 | Pass 合格 |
| 3 | 12,699 | | | 12,699 | 448,275 | 1,110,000 | Pass 合格 |
| 4 | 26,232 | 27,555 | 34,632 | 29,473 | 1,040,397 | 1,110,000 | Pass 合格 |
| 5 | 7,839 | | | 7,839 | 276,717 | 1,110,000 | Pass 合格 |
| 6 | 13,669 | | | 13,669 | 482,516 | 1,110,000 | Pass 合格 |

**B.5.5** At sampling location 4, the third sample volume concentration of 1 222 507 (34 632 × 35,3) did not meet the ISO Class 7,5 maximum particle count criteria of 1 110 000. The concentration of each single sample volume does not meet the limit established by using Table E.1; however, the average particle concentration for each of the sampling locations does meet the limit established by application of Table E.1. Therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

在取样点 4，第三粒子浓度为平均粒子浓度 1 222 507 (34 632 × 35,3) 不满足 ISO Class7.5 的最大粒子计数标准 1110000。单个粒子计数浓度不满足表格 E.1 中确立的标准；然而，每个取样点的平均粒子浓度满足了表格 E.1 中确立的要求。故洁净室满足 ISO 级别。

**B.6 Example 6 例 6**

B.6.1 A cleanroom has a floor area of 2 100 m2 and is specified to be ISO Class 7 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 litres per minute. Only one particle size (D ≥ 0,5 μm) is considered.

被测的洁净室房屋面积为 2100 洁净室规定动态的空气洁净度等级为 ISO Class 7。将采用流速为 28.3L/min 的离散粒子计数器来进行级别确认。只考察一种粒径(D ≥ 0,5 μm)。

The number of sampling locations, NL, given by Table A.1 is limited to cleanrooms of 1 000 $m^2$ area. For a cleanroom of 2 100 $m^2$, the number of sampling locations, NL, is derived from Formula (A.1):

根据表格 A.1，取样点的数量 NL 限制到 1000 ㎡的面积。对于面积为 2100 ㎡的洁净间，取样点的数量确定为 6。

$$2100 \times \left(\frac{27}{1000}\right) = 56.7 \text{ rounded to 修约至 } 57$$

**B.6.2** The particle concentration limit for ISO Class 7 at ≥ 0,5 μm is taken from Table 1:

Class 7 环境下粒径 ≥ 0,5μm 的浓度限度值来自于表格 1,如下:

Cn (≥ 0,5 μm) = 352 000 particles/m3

**B.6.3** The required single sample volume can be calculated from Formula (A.2) as follows:

取样量可根据以下公式进行计算：

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{352000}\right) \times 1000$$

$$V_s = (0.0000568) \times 1000$$

$$V_s = 0.0568\text{litres}$$

The single sample volume has been calculated to be 0,0568 l. As the discrete-particle counter being used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

单一取样体积计算结果是 0,0568 L。用于测试的离散粒子计数器流速为每分钟 28.3L，要求取样 1 分钟，因而每个单一取样体积将是 28.3L。

B.6.4 At each sampling location only one sample volume is taken. The number of particles per cubic metre, xi, is calculated for each location and recorded in Table B.7.

每个取样点只取样一次。每立方米的粒子数量（浓度），xi，是由每个取样点计算得到的,并记录在表格 B.7 中。

Table B.7----Sampling data for particles ≥0.5µm

表 B.7-------粒径≥0.5um 的取样数据

| Sampling location | Sample 1 xi≥0.5µm | Location sample average (counts per 28.3L) | Location concentration average (counts per $m^3$ = location average X 35.3) | ISO Class 5 limit for 0.5µm particle size | Pass/fail |
|---|---|---|---|---|---|
| 取样点 | 样品 1 xi≥0.5µm(每 28.3L 计数） | 该取样点样品值平均（每 28.3L 计数） | 取样点平均浓度（每立方米计数=取样点平均值 X35.3） | ISO 5 级对 0.5µm 粒径粒子的限度值 | 合格/不合格 |
| 1 | 5,678 | 5,678 | 200,434 | 352,000 | Pass 合格 |
| 2 | 7,654 | 7,654 | 270,187 | 352,000 | Pass 合格 |
| 3 | 2,398 | 2,398 | 84,650 | 352,000 | Pass 合格 |
| 4 | 4,578 | 4,578 | 161,604 | 352,000 | Pass 合格 |
| 5 | 8,765 | 8,765 | 309,405 | 352,000 | Pass 合格 |
| 6 | 4,877 | 4,877 | 172,159 | 352,000 | Pass 合格 |
| 7 | 8,723 | 8,723 | 307,922 | 352,000 | Pass 合格 |
| 8 | 7,632 | 7,632 | 269,410 | 352,000 | Pass 合格 |
| 9 | 7,643 | 7,643 | 269,798 | 352,000 | Pass 合格 |
| 10 | 6,756 | 6,756 | 238,487 | 352,000 | Pass 合格 |
| 11 | 5,678 | 5,678 | 200,434 | 352,000 | Pass 合格 |
| 12 | 5,476 | 5,476 | 193,303 | 352,000 | Pass 合格 |
| 13 | 8,576 | 8,576 | 302,733 | 352,000 | Pass 合格 |
| 14 | 7,765 | 7,765 | 274,105 | 352,000 | Pass 合格 |
| 15 | 3,456 | 3,456 | 121,997 | 352,000 | Pass 合格 |
| 16 | 5,888 | 5,888 | 207,47 | 352,000 | Pass 合格 |
| 17 | 3,459 | 3,459 | 122,103 | 352,000 | Pass 合格 |
| 18 | 7,666 | 7,666 | 270,610 | 352,000 | Pass 合格 |
| 19 | 8,567 | 8,567 | 302,416 | 352,000 | Pass 合格 |

| | | | | | |
|---|---|---|---|---|---|
| 20 | 8,345 | 8,345 | 294,579 | 352,000 | Pass 合格 |
| 21 | 7,998 | 7,998 | 282,330 | 352,000 | Pass 合格 |
| 22 | 7,665 | 7,665 | 270,575 | 352,000 | Pass 合格 |
| 23 | 7,789 | 7,789 | 274,952 | 352,000 | Pass 合格 |
| 24 | 8,446 | 8,446 | 298,144 | 352,000 | Pass 合格 |
| 25 | 8,335 | 8,335 | 294,226 | 352,000 | Pass 合格 |
| 26 | 7,998 | 7,998 | 281,977 | 352,000 | Pass 合格 |
| 27 | 7,823 | 7,823 | 276,152 | 352,000 | Pass 合格 |
| 28 | 7,911 | 7,911 | 279,259 | 352,000 | Pass 合格 |
| 29 | 7,683 | 7,683 | 271,210 | 352,000 | Pass 合格 |
| 30 | 7,935 | 7,935 | 280,106 | 352,000 | Pass 合格 |
| 31 | 6,534 | 6,534 | 230,651 | 352,000 | Pass 合格 |
| 32 | 4,667 | 4,667 | 164,746 | 352,000 | Pass 合格 |
| 33 | 6,565 | 6,565 | 231,745 | 352,000 | Pass 合格 |
| 34 | 8,771 | 8,771 | 309,617 | 352,000 | Pass 合格 |
| 35 | 5,076 | 5,076 | 179,183 | 352,000 | Pass 合格 |
| 36 | 6,678 | 6,678 | 235,734 | 352,000 | Pass 合格 |
| 37 | 7,100 | 7,100 | 250,630 | 352,000 | Pass 合格 |
| 38 | 8,603 | 8,603 | 303,686 | 352,000 | Pass 合格 |
| 39 | 7,609 | 7,609 | 268,598 | 352,000 | Pass 合格 |
| 40 | 7,956 | 7,956 | 280,847 | 352,000 | Pass 合格 |
| 41 | 7,477 | 7,477 | 263,939 | 352,000 | Pass 合格 |
| 42 | 7,145 | 7,145 | 252,219 | 352,000 | Pass 合格 |
| 43 | 6,998 | 6,998 | 247,029 | 352,000 | Pass 合格 |
| 44 | 7,653 | 7,653 | 270,151 | 352,000 | Pass 合格 |
| 45 | 6,538 | 6,538 | 230,792 | 352,000 | Pass 合格 |
| 46 | 3,679 | 3,679 | 129,869 | 352,000 | Pass 合格 |
| 47 | 4,887 | 4,887 | 172,512 | 352,000 | Pass 合格 |
| 48 | 7,648 | 7,648 | 269,975 | 352,000 | Pass 合格 |
| 49 | 8,748 | 8,748 | 308,805 | 352,000 | Pass 合格 |
| 50 | 7,689 | 7,689 | 271,422 | 352,000 | Pass 合格 |
| 51 | 7,345 | 7,345 | 259,279 | 352,000 | Pass 合格 |
| 52 | 7,888 | 7,888 | 278,447 | 352,000 | Pass 合格 |
| 53 | 7,765 | 7,765 | 274,105 | 352,000 | Pass 合格 |
| 54 | 6,997 | 6,997 | 246,995 | 352,000 | Pass 合格 |
| 55 | 6,913 | 6,913 | 244,029 | 352,000 | Pass 合格 |
| 56 | 7,474 | 7,474 | 263,833 | 352,000 | Pass 合格 |
| 57 | 8,776 | 8,776 | 309,793 | 352,000 | Pass 合格 |

**B.6.5** Each value of the concentration for D ≥ 0,5 μm is less than the limit of 352 000 particles/m3 established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

粒径 D ≥ 0,5 μm 的浓度值都小于表格 1 中确立的限度 352 000 particles/m3 ；因此由离子浓度确定的空气洁净度满足 ISO 级别。

# Annex C 附录C

## (informative) 仅供参考

# Counting and sizing of airborne macroparticles

**空气中悬浮大粒子的计数和粒径测量**

## C.1 Principle通则

In some situations, typically those related to specific process requirements, alternative levels of aircleanliness may be specified on the basis of particle populations that are not within the size rangeapplicable to classification. The maximum permitted concentration of such particles and the choice oftest method to verify compliance are matters for agreement between the customer and the supplier. Considerations for test methods and prescribed formats for specification are given in C.2.

在某些情况下，特别是与具体工艺要求相关联的情况下，可以依据等级表粒径范围之外的粒子群体规定另外适用的空气洁净度级别。用户和供应商应就这类粒子的最大允许浓度和选择验证相符性的测试方法等问题达成协议。在C.2中给出了关于测试方法和标准的描述方式需要考虑的内容。

## C.2 Consideration of particles larger than 5 μm (macroparticles) — M descriptor 大于5μm的粒子（大粒子）的考量——M信息

### C.2.1 Application 应用

If contamination risks caused by particles larger than 5 μm are to be assessed, sampling devices andmeasurement procedures appropriate to the specific characteristics of such particles should be employed.

如果需要评估由大于5μm的微粒引起的污染风险，则应采用适合于此类微粒特性的取样装置和测量程序。

The measurement of airborne particle concentrations with size distributions having a thresholdsize between 5 μm and 20 μm can be made in any of three defined occupancy states: as-built, at-restand operational.

粒度在5μm和20μm之间的空气颗粒浓度和粒径分布的测量按其运行状态可以分为三种：空态、静态和动态。

As particle liberation within the process environment normally dominates the macroparticle fraction of the airborne particle population, the identification of an appropriate sampling device and measurement procedure should be addressed on an application-specific basis. Factors such as density, shape, volume and aerodynamic behaviour of the particles need to be taken into account. Also, it may be necessary to put special emphasis on specific components of the total airborne population, such as fibres.

由于空气悬浮粒子中大颗粒成分里占主导数量的通常是工艺环境释放的颗粒，因此应该根据实际应用

环境来确定适当的取样装置和测量程序。这时要考虑一些因素，如颗粒物的比重、形状、体积和空气动力学表现。同时，可能还需要重点考虑空气总悬浮粒子中的特定成分，如纤维。

### C.2.2 M descriptor format /M信息格式

The M descriptor may be specified as a complement to the air cleanliness class by particle concentration.

M信息可以作为采用颗粒物浓度来决定的空气洁净级别的补充。

The M descriptor is expressed in the format

M信息表述形式为：

"ISO *M* (*a*; *b*); *c*"

Where其中

*a* is the maximum permitted concentration of macroparticles (expressed as macroparticles per cubic metre of air);

a是大颗粒物的最大允许浓度（表述为每立方米空气中含有的颗粒物数量）。

*b* is the equivalent diameter (or diameters) associated with the specified method for measuring macroparticles (expressed in micrometres);

b是采用指定的大颗粒测量方式测得的等同直径（以μm为单位）

*c* is the specified measurement method.

c是指定的测量方法。

EXAMPLE 1 To express an airborne concentration of 29 particles/m3 in the particle size range ≥ 5 μm basedon the use of an LSAPC, the designation would be: "ISO *M* (29; ≥ 5 μm); LSAPC".

例1

采用LSAPC方法测得粒径范围≥ 5 μm空气中颗粒物浓度为29个/立方米，表述为"ISO M (29; ≥ 5 μm); LSAPC"。

EXAMPLE 2 To express an airborne particle concentration of 2 500 particles/m3 in the particle size rangeof > 10 μm based on the use of a time-of-flight aerosol particle counter to determine the aerodynamic diameter ofthe particles, the designation would be: "ISO *M* (2 500; ≥ 10 μm); time-of-flight aerosol particle counter".

例2

采用飞行时间（TOF）气溶胶颗粒计数器测定气动颗粒直径，测得粒径范围>10μm空气中颗粒物浓度为2500个/立方米，表述为"ISO M (2 500; ≥ 10 μm); 飞行时间气溶颗粒计数器"。

EXAMPLE 3 To express an airborne particle concentration of 1 000 particles/m3 in the particle size range of10 to 20 μm, based on the use of a cascade impactor followed by microscopic sizing and counting, the designationwould be: "ISO *M* (1 000; 10 to 20 μm); cascade impactor followed by microscopic sizing and counting".

例3

采用多级撞击取样器然后进行微粒直径测量和计数，测得粒径范围10-20μm空气中颗粒物浓度为1000个/立方米，表述为"ISO M (1 000; 10 to 20 μm); 多级撞击取样器然后进行微粒直径测量和计数"。

NOTE 1 If the population of airborne particles being sampled contains fibres, they can be accounted for by supplementing the M descriptor with a separate descriptor for fibres, which has the format "$M_{fibre}$(*a*; *b*); *c*".

NOTE 2 Suitable methods of test for concentrations of airborne particles larger than 5 μm are given in IEST-G-CC1003.[2]

注1 如果取样得到的空气中颗粒物含有纤维，可以在M信息中进行补充，单独描述纤维情况，其格式表述为“M纤维（a,b）; c”。

注2 适于测量大于5μm的空气悬浮粒子浓度的测试方法在IEST-G-CC1003中给出。

## C.3 Airborne particle count for macroparticles 大颗粒物的空气悬浮粒子计数

### C.3.1 Principle 通则

This test method describes the measurement of airborne particles with a threshold size larger than 5 μm in diameter (macroparticles). The procedure given in C.3 has been adapted from IEST-GCC1003:1999.[2] Measurements can be made in a cleanroom or clean zone installation in any of the three designated occupancy states: as-built, at-rest or operational. The measurements are made to define the concentration of macroparticles, and the principles in 5.1, 5.2 and 5.4 may be applied. The need for proper sample acquisition and handling to minimize losses of macroparticles in the sample handling operations is emphasized.

本测试方法描述了粒径大于5μm的空气中悬浮粒子的测量方法。在C.3中给出的测量方法来自IEST-GCC1003:1999。测量方法可以在三种状态（空态、静态和动态）的任何一种情形下对清洁间或洁净区进行测量。测量方式是用来界定大颗粒物的浓度的，可以使用5.1、5.2和5.4中的原则。要强调的是样品采集和处理过程要尽量减少大颗粒物的损失。

### C.3.2 General 一般操作

The number of sampling locations, location selection and quantity of data required should bein accordance with A.4. The customer and supplier should agree upon the maximum permittedconcentration of macro-particles, the equivalent diameter of the particles and the specifiedmeasurement method. Other appropriate methods of equivalent accuracy and which provide equivalent data may be used by agreement between customer and supplier. If no other method has been agreedupon, or in case of dispute, the reference method in Annex C should be used.

取样点的数量、取样点的选择和所需数据的数量应符合A.4中的要求。客户和供应商应协调一致关于大颗粒的最大允许浓度，颗粒物的等同直径和指定的测量方法。如果客户和供应商双方同意，可以使用其它具有等同准确度且能提供等同数据的适当其它方法。

### C.3.3 Sample handling considerations 样品处理时的考虑

Careful sample collection and handling is required when working with macroparticles. A complete discussion of the requirements for systems, which can be used for isokinetic or anisokinetic sampling and particle transport to the point of measurement, is provided in IEST-G-CC1003:1999.[2]

在处理大颗粒时，样品的收集和处理都需要非常小心。在IEST-G-CC1003:1999中给出了系统要求的完整讨论，它可以用于等速和非等速度取样和颗粒传送至测量点。

### C.3.4 Measurement methods for macroparticles 大颗粒测量方法

There are two general categories of macroparticle measurement methods. Comparable results may not be produced if different measurement methods are used. Correlation between different methods may not be possible for this reason. The methods and particle size information produced by the various methods is summarized in C.3.4.1 and C.3.4.2.

大颗粒测量方法总体来说分为两类。如果采用的是不同的测量方法，则结果可能无法比较。不同方法之间的因此可能无法相互关联。不同的方法和这些方法产生的粒径信息在C.3.4.1和C.3.4.2中进行了总结。

#### C.3.4.1 *In situ* measurement 原位测试

Using *in situ* measurement of the concentration and size of macroparticles with a time-of-flight particle counter or an LSAPC:

使用飞行时间颗粒计数器或LSAPC在现场测试大颗粒物的浓度和粒径：

a) LSAPC measurement (C.4.1.2) will report macroparticles using particle size based upon an equivalent optical diameter;

LSAPC测量方法（C.4.1.2）会基于等同光学直径使用粒径来报告大颗粒。

b) time-of-flight particle size measurement (C.4.1.3) will report macroparticles using particle size based upon an aerodynamic diameter.

飞行时间粒径测量（C.4.1.3）会基于空气动力学直径使用粒径来报告大颗粒。

#### C.3.4.2 Collection 收集

Collection by filtration or inertial effects, followed by microscopic measurement of the number and size of collected particles:

采用过滤或惯性效应，对收集到的颗粒数量个数和大小进行大颗粒测量。

a) filter collection and microscopic measurement (C.4.2.2) will report macroparticles using particlesize based upon the agreed diameter;

过滤收集和大颗粒测量（C.4.2.2）会根据协商一致的直径使用粒径报告大颗粒。

b) cascade impactor collection and microscopic measurement (C.4.2.3) will report macroparticles using particle size based upon the choice of reported particle diameter.

级联冲击取样器收集和大颗粒测量（C.4.2.3）会根据对报告粒径的选择，使用粒径报告大颗粒。

## C.4 Methods for macroparticle measurement 大颗粒测量方法

### C.4.1 Macroparticle measurement without particle collection不需要收集颗粒的大颗粒测量

#### C.4.1.1 General通则

Macroparticles can be measured without collecting particles from the air. The process involves optical measurement of the particles suspended in the air. An air sample is moved at a specific flow rateth rough a LSAPC, which reports either the equivalent optical diameter or the aerodynamic diameter of the particles.

大颗粒可以不需要从空气中收集颗粒即进行测量。这种测量是对空气中悬浮颗粒进行光学测量。一份空气样品以指定的流速通过一个LSAPC，它报告等同的光学直径，或颗粒的空气动力学直径。

#### C.4.1.2 Light-scattering particle counter (LSAPC) measurement 光散射粒子计数器（LSAPC）测量

Procedures for macroparticle measurement using an LSAPC are the same as those in Annex A for airborne particle count with one exception. The exception is that the LSAPC in this case does not require sensitivity for detection of particles less than 1 μm since data are required only for macroparticle counting. Care is required to ensure that the LSAPC samples directly from the air at the sampling location. The LSAPC should have a sample flow rate of at least 28,3 l/min and should be fitted with an inlet probe sized for isokinetic sampling in unidirectional flow zones. In areas where non-unidirectional flow exists, the LSAPC should be located with the sample inlet facing vertically upward.

大粒子使用LSAPC测量的方法与附录A中LSAPC用于空气中悬浮粒子计数的方法一样，只是有一个例外。这个例外就是这时LSPAC不需要具备对1μm以下粒子的检出能力，因为只需要大粒子的计数数据。要注意的是需要确保LSAPC样品是从取样点直接取样。LSAPC取样速度应至少达到28.3升/分钟，在单向流区域取样时应装配有等速取样进口探头。如果有非单向流存在时，LSAPC放置位置应使得进口面垂直向上。

A sampling probe should be selected to permit close to isokinetic sampling in areas with unidirectional flow. If this is not possible, set the sampling probe inlet facing into the predominant direction of the airflow; in locations where the airflow being sampled is not controlled or predictable (e.g. nonunidirectional air flow), the inlet of the sampling probe shall be directed vertically upward. The transit tube from the sampling probe inlet to the LSAPC sensor should be as short as possible. For sampling of particles larger than and equal to 1 μm, the transit tube length should not exceed the manufacturer's recommended length and diameter, and will typically be no longer than 1 m in length. Sampling errors due to large particle loss in sampling systems should be minimised.

取样探头选择应使得单向流区域的取样接近等速取样。如果不可能做到，则要将取样探头进口面向气流的主要方向。如果取样点的气流不受控制或没有主流，则取样探头的进口应垂直向上。从取样探头进口连接到LSAPC感应头的传送管应尽可能短。如果取样的粒子大于等于1μm，则传送管的长度应不得超过生产商推荐的长度和直径，一般不能超过1米。应该尽量减少由于在取样系统中的粒子损失引起的取样误差。

The LSAPC size range settings are established so that only macroparticles are detected. The data from one size below 5 μm should be recorded to ensure that the concentration of detected particles below the macroparticle size is not sufficiently high to cause coincidence error in the LSAPC measurement. The particle concentration in that lower size range, when added to the macroparticle concentration, should not exceed 50 % of the maximum recommended particle concentration specified for the LSAPC being used.

LSAPC粒径范围设定使得计数器只能测出大颗粒。低于5μm的粒子数据应记录下来以确保所检出的低于大颗粒粒径的粒子浓度不会高到足以导致LSAPC测量中产生偶然误差的地步。在较低粒径范围的颗粒浓度，如果加到大颗粒浓度里，应不得超过LSAPC使用所指定的最大建议颗粒浓度的50%。

#### C.4.1.3 Time-of-flight particle size measurement 飞行时间粒径测量

Macroparticle dimensions can be measured with time-of-flight apparatus. An air sample is drawn into the apparatus and accelerated by expansion through a nozzle into a partial vacuum, where the measurement region is located. Any particle in that air sample will accelerate to match the air velocity in the measurement region. The particles' acceleration rate will vary inversely with mass of particle.

大颗粒尺寸可以使用飞行时间装置进行测量。一个空气样品被取到装置里，通过一个喷嘴喷入局部真空的测量区域里膨胀加速。所有在这个空气样品中的颗粒都会加速至与测量区域里的空气同样的速度。颗粒加速速度会根据颗粒的质量产生差异。

The relationship between the air velocity and the particle velocity at the point of measurement can be used to determine the aerodynamic diameter of the particle. With knowledge of the pressure difference between the ambient air and the pressure at the measurement region, the air velocity can be calculated directly. The particle velocity is measured by the time of flight between two laser beams. The time-of-flight apparatus should measure aerodynamic diameters of particles up to 20 μm. Sample acquisition procedures are the same as those required when using a LSAPC to measure macroparticles. In addition, the same procedures as for the LSAPC are used with this apparatus in order to establish the particle size ranges to be reported.

空气速度和颗粒速度在测量点之间的关系可以用来确定颗粒的空气动力力学直径。已知大气空气和测量区域之间的压力差，空气速度可以直接计算获得。颗粒速度则采用两个激光束之间的飞行时间来测量。飞行时间测量器应可以测量高达20μm的颗粒的空气动力学直径。取样程序与使用LSAPC测量大颗粒时一样。除此之外，此仪器使用的程序与LSAPC相同，以建立需要报告的粒径范围。

### C.4.2 Macroparticle measurement with particle collection 收集颗粒后进行大颗粒测量

#### C.4.2.1 General 通则

Macroparticles can be measured by collecting particles from the air. An air sample is transported at a specific flow rate through a collection device. Microscopic analysis is used to count the collected particles.

大颗粒可以通过从空气中采集颗粒来测量。一份空气样品以指定的流速通过一个收集装置进行传送。大颗粒分析用来对收集到的颗粒进行计数。

NOTE The mass of the collected particles can also be determined but since the air cleanliness is determined by number concentration this is not addressed in this part of ISO 14644.

注：收集到的颗粒物也可以进行测量，但由于空气清洁度是使用个数浓度来测定的，因此在ISO14644的本部分没有进行说明。

#### C.4.2.2 Filter collection and microscopic measurement 过滤收集和大颗粒测量

Select a membrane filter and a holder or a pre-assembled aerosol monitor; a membrane with pore size of 2 μm or fewer should be used. Label the filter holder to identify the filter holder location and installation. Connect the outlet to a vacuum source that will draw air at the required flow rate. If the sampling location in which macroparticle concentration is to be determined is a unidirectional flow area, the flow rate should be established to permit isokinetic sampling into the filter holder or aerosol monitor inlet and the inlet should face into the unidirectional flow.

选择一个膜过滤器和一个容器或一个预先装配也的气溶胶监测器，应使用孔径为2μm或更小的膜。将膜容器进行标识，以区别膜容器位置和安装地。连接出口到真空进口，按所需的流速排出空气。如果取样位置待测定的大颗粒浓度是单向流区域，气流速度应该能够让等速样品进入过滤器容器，或进入气溶胶监测器入口，并且进口应面对单向流气流。

Determine the sample volume required by using Formula (C.1).

使用公式（C.1）计算所需的样品体积。

Remove the cover from the membrane filter holder or aerosol monitor and store in a clean location. Sample the air at the sampling locations as determined by agreement between the customer and supplier. If a portable vacuum pump is used to draw air through the membrane filter, the exhaust from that pump should be vented outside the clean installation or through a suitable filter. After the sample collection has been completed, replace the cover on the filter holder or aerosol monitor. The sample holder should be transported in such a manner that the filter membrane is maintained in a horizontal position at all times and is not subjected to vibration or shock between the time the sample is captured and when it is analysed. Count the particles on the filter surface (see ASTM

F312-08).[3]

从膜过滤器的容器或气溶胶监测器取下盖子，放在清洁位置。在客户和供应商一致同意的取样点取样。如果使用的是手持式真空泵通过膜过滤器抽取空气，从泵中排出的气应排到洁净场所的外部，或通过适当的过滤器。在样品收集完成之后，替换过滤器容器或气溶胶监测器上面的兽子。样品容器在传送时，应让过滤膜一直维持在水平位置，在取样和分析时均不能震动或摆动。在过滤器表面对粒子进行计数。（参见ASTM F312-08）

#### C.4.2.3 Cascade impactor collection and measurement 级联冲击取样和测量

In a cascade impactor particle separation is carried out by inertial impaction of particles. The sampled airflow passes through a series of jets of decreasing orifice size. The larger particles are deposited directly below the largest orifices and smaller particles are deposited at each successive stage of the impactor. The aerodynamic diameter correlates directly with the regional collection of particles in the impactor flow path.

在级联冲击器中，颗粒分离是由颗粒内部冲击形成的。样品气流通过一系列递减孔径的气流喷射。较大的颗粒在最大的孔下直接处理，较小的颗粒则在冲击器的连续不同阶段被处理。空气动力学直径与冲击器流动路径里的区域性颗粒表现直接相关联。

For the measurement of the air cleanliness by particle concentration a type of cascade impactor meant for collection and counting of macroparticles can be used. In this one the particles are deposited upon the surfaces of removable plates that are removed for subsequent microscopic examination. Sampling flow rates of 0,47 litres/sec or more are typically used for this type of cascade impactor.

对于采用粒子浓度来进行空气洁净度测量的，可以使用一种级联冲击器用于大颗粒的取样和计数。在此测量中，颗粒在可移动的碟子表面进行处理，然后移除用于之后的大颗粒检查。此类级联冲击器一般使用的取样流速为0.47升/称或更高。

## C.5 Procedure for macroparticle count 大颗粒计数程序

Determine the “ISO *M* (*a*; *b*); *c*” descriptor concentration in the selected particle size range(s), as agreed between customer and supplier, and report the data.

根据客户和供应商之间协商一致的所选粒径范围，测量“ISO M（a,b）, c”信息浓度，报告数据。

At each sampling location, sample a volume of air sufficient to detect a minimum of 20 particles for the selected particle size at the determined concentration limit.

在每个取样点，取一定体积的空气，保证其足以检测到在预定的浓度限度所选粒径最少 20 个粒子。

The single sample volume, $V_s$, per sampling location is determined by using Formula (C.1):

单个样品体积，Vs，每个取样点采用以下公式计算（C.1）：

$$V_s = \left[\frac{20}{C_{n,m}}\right] \times 1000 \qquad (C.1)$$

| Where | 其中 |
|---|---|
| $V_s$ is the minimum single sample volume per location, expressed in litres (except see D.4.2); | Vs 是每个地点的最小单个样品体积，表达为升（例外参见D.4.2） |
| $C_{n,m}$ is the class limit (number of particles per cubic metre) for the largest considered particle | Cn,m 是相对级别中指定的考虑的最大粒径的洁净度限度（每立方米空间内粒子个数） |

| | |
|---|---|
| size specified for the relevant class;<br>20 is the number of particles that could be counted if the particle concentration were at the class limit. | 20 是如果粒子浓度在洁净级别的限度时，可以计算的粒子数量 |

Where information on the stability of macroparticle concentration is required, make three or more measurements at selected locations at time intervals agreed between customer and supplier.

如果需要大颗粒浓度的稳定性信息，则要按照客户和供应商之间协商一致的时间间隔，在选定的地点进行三次或更多次测量。

Set up the sample inlet probe of the selected apparatus and undertake the test.

设立所先仪器的取样进口探头，进行测试。

## C.6 Test reports for macroparticle sampling 大颗粒取样的测试报告

The following test information and data should be recorded:

以下测试信息和数据要进行记录：

a) definition of the particle sizes to which the apparatus responds;
仪器响应的粒径定义

b) measurement method;
测量方法

c) method of measurement of M descriptor level or limit as an adjunct to the ISO Class;
M信息水平或限度测量方法作为ISO级别的附件

d) type designations of each measurement instrument and apparatus used and its calibration status;
所用的每个测量仪器和装置类型及其校验状态

e) ISO Class of the installation;
设施ISO级别

f) macroparticle size range(s) and the counts for each size range reported;
大颗粒粒径范围和所报告的每个粒径范围的计数

g) apparatus inlet sample flow rate and flow rate through sensing volume;
仪器进口样品流速和通过感应体积的流速

h) sampling location(s);
取样位置

i) sampling schedule plan for classification or sampling protocol plan for testing;
分别取样计划或测试的取样方案

j) occupancy state(s);
测试时状态

k) other relevant data for measurement such as stability of macroparticle concentration.
其它相关测量数据，例如大颗粒浓度的稳定性

## C.7 Adaptation of the macroparticle descriptor to accommodate consideration

### of ≥ 5 μm particle size for ISO Class 5 cleanrooms

### ISO5级洁净室里≥ 5 μm粒径的大颗粒信息表述

In order to express an airborne concentration of 29 particles/$m^3$ in the particle size range ≥ 5 μm based on the use of an LSAPC, the designation would be “ISO *M* (29; ≥ 5 μm); LSAPC” and for 20 particle/$m^3$ the designation would be “ISO *M* (20; ≥ 5 μm); LSAPC” (see Table 1, Note f).

采用LSAPC方法，粒径范围为 ≥ 5 μm，测得空气中悬浮粒子浓度为29个/立方米，则会表达为“ISO M(29, ≥ 5 μm)；LSAPC”，而如果浓度为20个/立方米，则表述为“ISO M(20; ≥ 5 μm); LSAPC”（参见表1，注释f）。

# Annex D 附录D

(informative) 仅供参考

# Sequential sampling procedure

# 顺序采样法

## D.1 Background and limitations 背景和局限性

### D.1.1 Background 背景

In some circumstances where it is necessary or required to classify a clean controlled environment with a very low particle concentration at the class limit, sequential sampling is a useful technique that allows reduction of the sample volume and sampling time. The sequential sampling technique measures the rate of counting and predicts the likelihood of passing or failing to meet the requirements of the ISO Class. If the air being sampled is significantly more or significantly less contaminated than the specified class concentration limit for the considered particle size, use of the sequential sampling procedure can reduce sample volumes and sampling times, often dramatically.

在有些情形下，如果有必要或要求将一个粒子浓度非常低的受控洁净环境定义在该级别的限度值上，采用顺序采样法就很有帮助，可以减少采样量和采样时间。顺序取样法技术测量的是计数的速度，它预测符合ISO级别要求的可能性。若采样的空气之污染程度显著大于或小于被考虑粒径的规定级别浓度，则使用顺序取样程序可以显著减少取样体积和取样时长。

Some savings may also to be realized when the concentration is near the specified limit. Sequential sampling is most appropriate for air cleanliness of ISO Class 4 or cleaner. It may also be used for other classes when the limit for the chosen particle size is low. In that case, the required sample volume maybe too high for detecting 20 expected counts.

当浓度接近指定限度时，可能也会发现一些 。洁净级别ISO4级或更高级别的空气洁净度最适用的取样方式是顺序采样法。如果所选的粒径限度很低，这种方法也可以用于其它洁净级别。这种情况下，检查20个预期的计数时所需的取样体积可能会太高。

NOTE For further information on sequential sampling, see IEST-G-CC1004[4] or JIS B 9920:2002.[5]

注 有关顺序采样法的进一步资料，见IEST-G-CC 1004[3]。

### D.1.2 Limitations局限性

The principal limitations of sequential sampling are

顺序取样法主要局限有：

a) the procedure is only applicable when expected counts from a single sample are < 20 for the largest particle size (see A.4.4),
此方法仅适用于单个样品中最大粒径的预期计数值<20时（参见A.4.4）。

b) each sample measurement requires supplementary monitoring and data analysis, which can be facilitated through computerised automation, and
每次采样测量要求辅助监测和数据分析，可以用计算机自动进行。

c) particle concentrations are not determined as precisely as with conventional sampling

procedures due to the reduced sample volume.
由于减少了采样量，粒子浓度的确定不如常规采样法精确。

## D.2 Basis for the procedure 顺序采样法的依据

The procedure is based on comparison of real-time cumulative particle counts to reference countvalues. Reference values are derived from formulae for upper- and lower-limit boundaries:

此方法基于实时累积粒子计数与参考计数值的对比。参考数值由求上下限值的公式得出：

upper limit: $C_{fail} = 3{,}96 + 1{,}03\,E$ (D.1)

上限值：C=3.96+1.03E (D.1)

lower limit: $C_{pass} = -3{,}96 + 1{,}03\,E$ (D.2)

下限值：C=-3.96+1.03E (D.2)

where 式中，

$C_{fail}$ is the upper limit for the observed count; Cfail 为观察到计数值的最高限度

$C_{pass}$ is the lower limit for the observed count; Cpass 为观察到计数值的最低限度

$E$ is the expected count (shown by Formula (D.5), the class limit). E 为期望计数值（公式（D.5）显示，洁净度限度）

According to Formula (A.2), the single sample volume, $V_s$, is calculated as follows:

根据公式（A.2），单个样品体积，Vs，计算如下：

$$Vs = \left(\frac{20}{C_{n,m}}\right) \times 1000 \qquad \text{(D.3)}$$

where 其中

$V_s$ is the minimum single sample volume per location, expressed in litres; Vsis 指每个取样点最小单个样品体积，单位升

$C_{n,m}$ is the class limit (number of particles per cubic metre) for the considered particle size specified for the relevant class; Cn,m 指相关级别被考虑的粒径粒子的级别限度（每立方米的粒子个数）

20 is the defined number of particles that could be counted if the particle concentration were at the class limit. 20 是如果粒子浓度正好处于级别限度值，可以被计数的粒子个数

The total sampling time $t_t$ is calculated as follows:

总的取样时间$t_t$计算如下：

$$t_t = \frac{V_S}{Q} \qquad \text{(D.4)}$$

where 其中：

$V_s$ is the accumulative sample volume (litres); Vs 是指累计样品体积（升）

$Q$ is the sampling flow rate of the particle counter Q 是指粒子计数器的取样流速（升/秒）

(litres/s).

The expected count is defined as follows:

预期计数值定义如下：

$$E = \frac{Q \times t \times C_{n,m}}{1000} \quad \text{(D.5)}$$

where

*t* is sampling time (in seconds).

其中：

t 是指取样时间（单位：秒）

To aid in understanding, a graphical illustration of the sequential sampling procedure is provided in Figure D.1. As air is being sampled at each designated sampling location, the running total particle count is continuously compared to the expected count for the proportion of the prescribed total volume that has been sampled. If the running total count is less than the lower limit $C_{pass}$ corresponding to the expected count, the air being sampled is found to meet the specified class or concentration limit, and sampling is halted.

为有助于理解，在图D.1中给出了一个图例解释顺序取样程序。在每个指定的取样位置进行取样，空气流中的粒子被连续计数，持续与取样总体积所计算的标准计数值进行比较。如果总计数值小于要求值所对应的下限Cpass，则空气样品被判定为符合所要求的级别或浓度限度，取样停止。

If the running count exceeds the upper limit $C_{fail}$ corresponding to the expected count, the air being sampled fails to meet the specified class or concentration limit, and sampling is halted. As long as the running count remains between the upper and lower limits, sampling continues until the observed count becomes 20 or the cumulative sample volume, *V*, becomes equal to the minimum single sample volume, $V_s$, where the expected count becomes 20.

如果连续计数值超出要求的计数上限值Cfail，则空气样品不符合要求的级别或浓度限值，取样停止。只要连续计数值保持在上限与下限值之间，取样就会持续直至所观察到的计数值变成20或累计进样体积，V，等于单个最小取样体积，Vs，这时所要求的计数值是20。

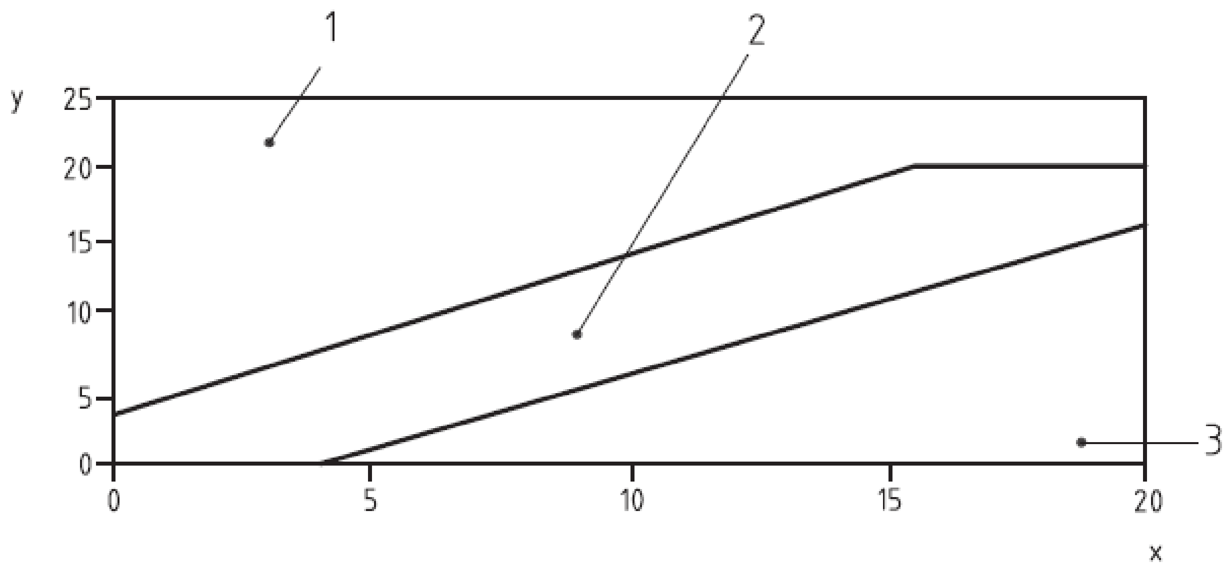
In Figure D.1, the number of observed counts, *C*, is plotted versus the expected count, *E*, until either the sampling is halted or the count reaches 20.

以图D.1中，观察到的计数值，C，对要求的计数值，E作图，直到取样停止或计数达到20。

## D.3 Procedure for sampling 取样程序

Figure D.1 illustrates the boundaries established in Formulae (D.1) and (D.2), as truncated by the limitations of *E* = 20, representing the time required to collect a full sample, and *C* = 20, the maximum observed count allowed.

图 D.1 中显示出了公式（D.1）和(D.2)所建立的边界限，被 E=20 的限值截面，代表了收集完整样品量所需的时间，C=20 则是允许最大观测计数。




**Key**

x expected count, *E*

y observed count, *C*

1 stop counting, FAIL ($C \geq 3{,}96 + 1{,}03E$)

2 continuous counting

3 stop counting, PASS ($C \leq -3{,}96 + 1{,}03E$)

图中

X 为要求的计数值，E

Y 为观察到的计数值，C

1 为停止计数，判定不符合（C≥3.96+1.03E）

2 为继续计数

3 为停止计数，判定符合（C≦-3.96+1.03E）

**Figure D.1 — Boundaries for pass or fail by the sequential sampling procedure**

**图D.1----顺序采样法合格与不合格的边界线**

The observed count is plotted versus the expected count for air having a particle concentration precisely at the specified class level. The passage of time corresponds to increasing numbers of expected counts, with *E* = 20 representing the time required to accumulate a full sample volume if the particle concentration were at the class limit.

针对粒子浓度正好处于指定的级别水平的空气状态，将观察到的计数值对要求的计数值进行了绘图。时间段对应的是持续增加的要求计数值，与E=20所代表的当粒子浓度正好在级别限度时，累积完整取样体积的要求时间，

The procedure for sequential sampling using Figure D.1 is as follows:

使用图D.1时顺序取样法是这样的：

1) record the total number of particles counted as a function of time;
记录所计数的粒子总数，作为时间的函数

2) calculate the expected count following the procedure described in D.2, Formula (D.5);
按照D.2中所述的程序和公式（D.5），计算要求的计数值

3) plot the total count versus the expected count as in Figure D.1;
将总计数值对按图D.1得到的要求计数值作图

4) compare the count with the upper and lower limit lines of Figure D.1;
将计数值与图D.1中最高和最低线进行比较

5) if the cumulative observed count crosses the upper line, sampling at the location is stopped and

the air is reported to have failed compliance with the specified class limit;
如果观察到的累计计数值穿过上限线，则停止对该位置取样，报告该位置的空气不符合指定的级别限要求

6) if the cumulative observed count crosses the lower line, sampling is stopped and the air passes compliance with the specified class limit;
如果观察到的累计计数值穿过下限线，则停止对该位置取样，判定空气符合指定的级别限度要求

7) if the cumulative observed count remains between the upper and lower lines, sampling will continue.
如果观察到的累计计数值保持在上限和下限线之间，继续取样

If the total count is 20 or fewer at the end of the prescribed sampling period and has not crossed the upper line, the air is judged to have complied with the class limit.

如果在所述的取样期间结束时，总计数值为20或更低，并且没有穿过上限线，则判定该空气符合级别限度。

## D.4 Examples of sequential sampling 顺序采取法举例

### D.4.1 Example 1 例1

a) Evaluation of a clean room with a target air cleanliness of ISO Class 3 (0,1μm, 1 000 particles/$m^3$) by the sequential sampling procedure. This procedure looks at the rate of count and seeks to predict likely pass or fail.

采用顺序取样法评估一个洁净间是否符合空气洁净度ISO 3级(0,1μm, 1 000 个/立方米)。此方法根据计数速度判定是否可能合格。

NOTE The sampling flow rate of particle counter is 0,0283 $m^3$/min (28,3 l/min or 0,47 l/s).

注：粒子计数器的取样流速为0.0283立方米/分钟（28.3升/分钟或0.47升/称）。

b) Preparation before measurement — method for calculation of limit values.

在测量之前的准备---限度值计算方法

Table D.1 shows the calculation result. First, the expected count is calculated based on samplingtime. Next, the upper reference count and the lower reference count are calculated by usingFormulae (D.1) and (D.2), or Figure D.1.

表D.1显示的是计算结果。首先，根据取样时间计算要求的计数值。然后，根据公式（D.1）和（D.2）或图D.1进行参考计数值的上下限。

**Table D.1 — Calculation tabulation of the upper and lower reference count**

表 D.1—上限和下限参考计数值计算表

| Measurement period 测量阶段 | Sampling time (s) 取样时间 | Total sampled air volume 总取样空气体积 | Expected count 要求计数值 | Upper limit for the observed count 观察计数值的上限值 | Lower limit for the observed count 观察计数值的下限值 |
|---|---|---|---|---|---|
| | t | Liter 升 | According to Formula (D.5) 根据公式（D.5）计算 | Cfail = 3.96+1.03E | Cpass= -3.96+1.03E |
| 1$^{st}$ | 5 | 2.4 | 2.4 | 7 (6.4) | N.A. （-1.5） |
| 2$^{nd}$ | 10 | 4.7 | 4.7 | 9 (8.8) | 0 (0.9) |
| 3$^{rd}$ | 15 | 7.1 | 7.1 | 12 (11.2) | 3 (3.3) |

| | | | | | |
|---|---|---|---|---|---|
| 4th | 20 | 9.4 | 9.4 | 14 (13.7) | 5 (5.8) |
| 5th | 25 | 11.8 | 11.8 | 17 (16.1) | 8 (8.2) |
| 6th | 30 | 14.2 | 14.2 | 19 (18.5) | 10 (10.6) |
| 7th | 35 | 16.5 | 16.5 | 20 (21.0) | 13 (13.0) |
| 8th | 40 | 18.9 | 18.9 | 20 (23.4) | 15 (15.5) |
| 9th | 45 | 21.2 | 21.2 | 21 | 20 |

NOTE The numeric value in parentheses shows the result of calculation of the upper and lower limits for the observed count to one decimal place. However, as the actual data are integer values, each calculated value is handled at the time of evaluation as the integer value shown.
注：括号里的数值表示的是观察计数上下限值计算结果，修约至一位小数。但是，由于实际数据是整数，因此每个计算值在评估时均使用所示的整数值来使用。
The upper limit for the observed count is rounded up to the first decimal place of calculated value.
观察计数值的上限值是计算结果向上修约至第一位小数。
The lower limit for the observed count is rounded down to the first decimal place of calculated value.
观察计数值的下限值是计算结果向下修约至第一位小数。
When $C_{pass}$ calculated according to Formula (D.2) is negative, it is denoted by 'N.A.' (not applicable). In this case, we cannot conclude that the air cleanliness satisfies the target ISO Class, even if the observed count is zero
如果根据公式（D.2）计算得到的 Cpass 值为负数，则表示为"N.A"（不适用）。此时，我们不能得到结论说空气洁净度满足目标的 ISO 级别要求，即使观察到的值是零。

c) Evaluation using sequential sampling procedure. 使用顺序采样程序的评估

The expected count provided in the first measurement is 2.4; it is judged to "FAIL" when the observed count is greater or equal to 7. However, when the observed count during this sampling period is between 0 and 6, the result cannot be judged. In this case, sampling is continued. When sampling is continued, the cumulative observed count may increase. Sampling is continued until either the prescribed single sample volume is achieved or the observed count has crossed one of the lines for $C_{pass}$ or $C_{fail}$, respectively. If the cumulative observed count is 20 or fewer at the end of the prescribed sampling period and has not crossed the upper line, the air cleanliness classification is judged to "PASS". If the cumulative observed count is less than or equal to the rounded down values for $C_{pass}$ before achieving the full sampling period, the sampling is stopped and the classification is judged to "PASS".

在第一个测量阶段里给出的要求计数值为2.4，如果观察到的计数值大于等于7的话，则判定为"不合格"。但是，如果在这个取样期间观察到的计数值介于0-6之间，结果无法做出判定。此时，要继续取样。当取样继续时，累计观察计数值会增加。取样持续直至单个样品体积达到指定值，或者观察到的计数值穿过合格线或不合格线。如果取样阶段完结时，累计观测计数值为20或更低，并且没有穿过上限线，则空气洁净度级别判定为"合格"。如果在达到最终取样阶段之前，累积观测计数值小于等于Cpass的向下修约值，则取样停止，判定结果为"合格"。

### D.4.2 Example 2 例2

Evaluation of a cleanroom with a target air cleanliness of ISO Class 3 (0,5µm, 35 particles/m3) by the sequential sampling procedure. The sampling flow rate of the particle counter (Q) is 0.0283 m3/min = 0.47 l/s.

采取顺序取样法评估一个洁净间是否符合要求的空气洁净度ISO 3级（0,5µm, 35 个/立方米）。粒子计数器（Q）的取样流速为0.0283立方米/分钟=0.47升/秒。

Calculate the single sample volume, Vs, according to Formula (D.3)

根据公式（D.3）计算单个样品体积，Vs

$$V_S = \left(\frac{20}{C_{n,m}}\right) \times 1000 = \frac{20}{35} \times 1000 = 571{,}429\ litres \qquad (D.6)$$

Calculate the total sampling time, $t_t$, according to Formula (D.4). this is the longest time necessary to evaluate the sampling location. The sequential sampling procedure should shorten this time.

根据公式（D.4）计算总取样时间，$t_t$，这是评估该取样点所需的最长取样时间。顺序取样法应缩短此时间。

$$t_t = \frac{V_s}{Q} = 1211.5s = 20.19\,\text{min} \qquad (D.7)$$

Calculate the result table: 计算结果表

1) calculate the expected count, E, according to Formula (D.5):
根据公式（D.5）计算预期计数值，E

$$\text{E} = \frac{Q \times t \times C_{n,m}}{1000} \qquad (D.8)$$

2) calculate the upper and lower limit for the observed count according to Formula (D.1) and (D.2);
根据公式（D.1）和（D.2）计算观察到计数值的上下限；

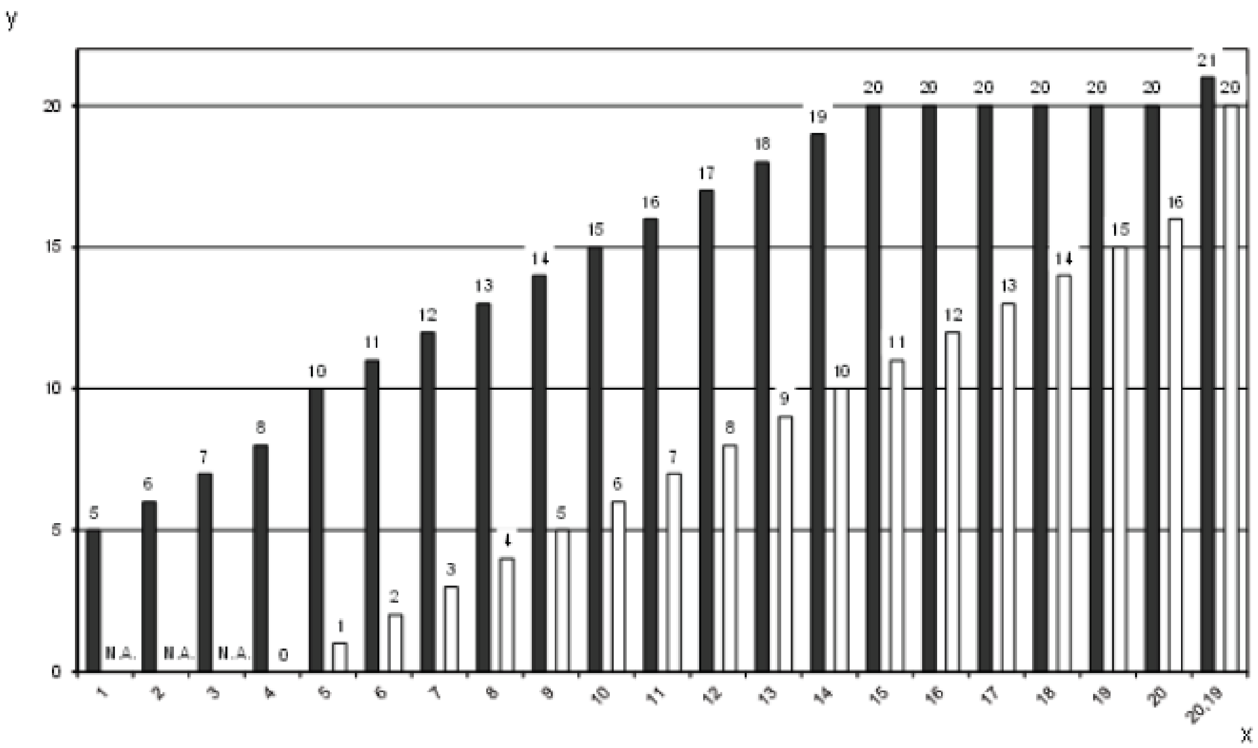
3) the calculation result is shown in Table D.2 and Figure D.2.
计算结果显示在表D.2和图D.2中。

Table D.2 --- Calculation result of the total sample air volume, expected count, upper limit and lower limit

| t (min) 时间（分钟） | t (s) 时间（秒） | Total sampled air volume, 总取样体积 Q X t | Expected count 要求计数值 E | Limits 限度 | |
|---|---|---|---|---|---|
| | | | | Upper, Cfail 上限值 | Lower, Cpass 下限值 |
| 1 | 60 | 28.3 | 1.0 | 5 (5,0) | N.A. (-2,9) |
| 2 | 120 | 56.6 | 2.0 | 7 (6,0) | N.A. (-1,9) |
| 3 | 180 | 84.9 | 3.0 | 8 (7,0) | N.A.(-0,9) |
| 4 | 240 | 113.2 | 4.0 | 9 (8,0) | 0 (0,1) |
| 5 | 300 | 141.5 | 5.0 | 10 (9,1) | 1 (1,1) |
| 6 | 360 | 169.8 | 5.9 | 11 (10,1) | 2 (2,2) |
| 7 | 420 | 198.1 | 6.9 | 12 (11,1) | 3 (3,2) |
| 8 | 480 | 226.4 | 7.9 | 13 (12,1) | 4 (4,2) |
| 9 | 540 | 254.7 | 8.9 | 14 (13,1) | 5 (5,2) |
| 10 | 600 | 283.0 | 9.9 | 15 (14,2) | 6 (6,2) |
| 11 | 660 | 311.3 | 10.9 | 16 (15,2) | 7 (7,3) |
| 12 | 720 | 229.6 | 11.9 | 17 (16,2) | 8 (8,3) |
| 13 | 780 | 267.9 | 12.9 | 18 (17,2) | 9 (9,3) |
| 14 | 840 | 296.2 | 13.9 | 19 (18,2) | 10 (10,3) |
| 15 | 900 | 424.5 | 14.9 | 20 (19,3) | 11 (11,3) |
| 16 | 960 | 452.8 | 15.8 | 20 (20,3) | 12 (12,4) |
| 17 | 1,020 | 281.1 | 16.8 | 20 (21,3) | 13 (13,4) |
| 18 | 1,080 | 509.4 | 17.8 | 20 (22,3) | 14 (14,4) |
| 19 | 1,140 | 537.7 | 18.8 | 20 (23,3) | 15 (15,4) |
| 20 | 1,200 | 566.0 | 19.8 | 20 (24,4) | 16 (16,4) |
| 20,19=tt | 1,211.5 | 571429 = Vs | 20 | 21 | 20 |

In Figure D.2 the upper and lower limits for the observed count are plotted versus the count acquisition time. Each vertical bar shows the limits (upper and lower) at 1-min intervals.

在图在 D.2 中，观察计数值的上限和下限对计数所需时间画图。每个垂直的条形显示的是 1 分钟时间间隔里的限度（上限和下限）。




KEY

X Count time (min)

Y Count limits (particles)

■ upper limit for the observed count

□ lower limit for the observed count

图中

X 计数时间（分钟）

Y 计数限度（粒子数）

■ 观察计数值的上限

□ 观察计数值的下限

**Figure D.2---Graphical representation of the pass or fail boundaries for sequential sampling**

**图 D.2---顺序取样法的通过不通过边界线图示**

Compare the cumulative observed count and the upper and lower limits and apply the procedure described in D.3.

比较累计观察计数值与上限和下限值

a) Fall situation see Table D.3 不合格情形参见表 D.3

| T (min) 时间（分钟） | T (s) 时间（秒） | Expected count, E 要求的计数 E | Limits for the cumulative observed count 累计观察计数限度 | | Observed count during interval 间隔中观察到的计数 | Cumulative observed count, C 累计观察的计数值 | Result 结果 |
|---|---|---|---|---|---|---|---|
| | | | Upper, Cfail 上限 | Lower, Cpass 下限 | | | |
| 1 | 60 | 1.0 | 5 | NA | 2 | 2 | Continue 继续 |
| 2 | 120 | 2.0 | 7 | NA | 3 | 5 | Continue 继续 |
| 3 | 180 | 3.0 | 8 | NA | 1 | 6 | Continue 继续 |
| 4 | 240 | 4.0 | 9 | 0 | 0 | 6 | Continue 继续 |
| 5 | 300 | 5.0 | 10 | 1 | 5 | 11 | FAIL 不合格 |

Table D.3 ---Example sequential sampling particle counts

表 D.3---顺序取样法粒子计数举例

The expected count provided in the first measurement is 1,0; the cumulative observed count is judged to “FAIL” when it is greater than or equal to 5. However, when the cumulative observed count is between 0 and 5, it cannot be judged. In the present example, the sampling has to be continued. When the sampling is continued, the cumulative observed count increases. However, it is easy to judge because both the expected count and the reference count increase. In the 5$^{th}$measurement (*t* = 300 s), the cumulative observed count is 11 and exceeds the upper limit (10). Then it is judged to “FAIL.”

在第一次测量中给出的计数值为1.0；累计观察计数值大于等于5时，则判定为“不合格”。但是，如果累计观察计数在0-5之间，则不能做出判定。在给出的例子里，必须继续取样。如果继续取样后，累计观察计数值增加。在第5次测量中（t=300秒），累计观察计数为11，而要求的上限为（10），因此这时判定为“不合格”。

b) Pass situation see Table D.4　合格的情形参见表 D.4

Table D.4 ---Example sequential sampling particle counts

表 D.4----顺序采样法粒子计数举例

| T (min) 时间（分钟） | T (s) 时间（秒） | Expected count, E 要求的计数 E | Limits for the cumulative observed count 累计观察计数限度 | | Observed count during interval 间隔中观察到的计数 | Cumulative observed count, C 累计观察的计数值 | Result 结果 |
|---|---|---|---|---|---|---|---|
| | | | Upper 上限, Cfail | Lower 下限, Cpass | | | |
| 1 | 60 | 1.0 | 5 | NA | 0 | 0 | Continue 继续 |
| 2 | 120 | 2.0 | 7 | NA | 0 | 0 | Continue 继续 |
| 3 | 180 | 3.0 | 8 | NA | 0 | 0 | Continue 继续 |
| 4 | 240 | 4.0 | 9 | 0 | 0 | 0 | PASS 合格 |

The expected count provided in the first measurement is 1,0, the cumulative observed count is judged to “FAIL” when it is greater than or equal to 5. However, when the observed count is between0 and 5, it cannot be judged. In the present example, the sampling is continued, but the cumulative observed count does not increase. In the 4th measurement (*t* = 240 s), the cumulative observed count is 0 and is equal to the lower limit (0). Then it is judged to “PASS.”

在第一个测量阶段要求的计数值为 1.0，累计观测计数值如果大于等于 5，则判定为“不合格”。但是，如果观测计数值在 0-5 之间，则无法判定。在本例中，继续取样，但累计观测计数值并未增加。在第 4 个测量阶段时（t=240 秒），累计观测计数值为 0，等于最低限度值（0）。因此判定为“合格”。

# Annex E 附录E

(informative) 仅供参考

# Specification of intermediate decimal cleanliness classes and particle size thresholds

# 中间洁净级别标准和粒径阈值

## E.1 Intermediate decimal cleanliness classes

## E．1 中间洁净级别

If intermediate decimal cleanliness classes are required, Table E.1 should be used.

如果需要使用中间洁净级别，应使用表E.1。

Table E.1 provides the permitted intermediate decimal air cleanliness classes. Uncertainties associated with particle measurement make increments of less than 0,5 inappropriate, and the notes beneath the table identify restrictions due to sampling and particle collection limitations.

表E.1给出了允许的中间洁净级别。粒子测量中的不确定度使得小于0.5的增量并不恰当。表下的注释指出了由于取样的粒子收集的局限性带来的限制。

**Table E.1 — Intermediate decimal air cleanliness classes by particle concentration**

**表E.1---按粒子浓度划分的中间空气洁净级别**

| | Concentration of particles (particles /m3) a 粒子浓度（个/立方米） | | | | | |
|---|---|---|---|---|---|---|
| IOS Class number (N)<br>ISO 级别号 (N) | 0.1 | 0.2 | 0.3 | 0.4 | 0.5 | 5.0 |
| ISO Class 1.5 | [32]b | d | d | d | d | e |
| ISO Class 2.5 | 316 | [75]b | [32]b | d | d | e |
| ISO Class 3.5 | 3,160 | 748 | 322 | 111 | d | e |
| ISO Class 4.5 | 31,600 | 7,480 | 3,220 | 1,110 | 263 | e |
| ISO Class 5.5 | 316,000 | 74,800 | 32,200 | 11,100 | 2,630 | e |
| ISO Class 6.5 | 3,160,000 | 748,000 | 322,000 | 111,000 | 26,300 | 925 |
| ISO Class 7.5 | c | c | c | 1,110,000 | 263,000 | 9,250 |
| ISO Class 8.5 f | c | c | c | 11,100,000 | 2,630,000 | 92,500 |

a. All concentrations in the table are cumulative, e.g. for ISO Class 5,5, the 11 100 particles shown at 0,5 μm include all particles equal to and greater than this size.
在表中的所有浓度均为累积浓度，如，ISO第5.5级，在0.5 μm时显示11,100的粒子，包括了大于和等于此粒径的所有粒子。

b. These concentrations will lead to large air sample volumes for classification. See Annex D, Sequential sampling procedure.
这些浓度会使得级别的取样体积很大。参见附录D，顺序取样法。

c. Concentration limits are not applicable in this region of the table due to very high particle concentration.
由于粒子浓度很高，浓度限度不适用于表中此区域。

d. Sampling and statistical limitations for particles in low concentrations make classification inappropriate.
在低浓度时，取样和统计学局限使得分组并不恰当。

e. Sample collection limitations for both particles in low concentrations and sizes greater than 1 μm make classification inappropriate, due to potential particle losses in the sampling system.
由于取样系统可能的粒子丢失，在低浓度或粒径大于1μm时，样品采集局限性使得分级并不恰当。

f. This class is only applicable for the in-operation state.
本级别仅适用于动态测试。

## E.2 Intermediate particle sizes 中间粒径

If intermediate particle sizes are required for any integer or decimal class, Formula (E.1) may be used to determine the maximum particle concentration at the considered particle size:

如果有任何十位整数或中间数级别需要有中间粒径，可以使用公式（E.1）来计算所考虑的粒径的最大粒子浓度。

$$\mathbf{Cn} = \mathbf{10}^{N} \times \left(\frac{k}{D}\right)^{2.08} \tag{E.1}$$

| | |
|---|---|
| where | 其中 |
| *Cn*is the maximum permitted concentration (particles per cubic metre) of airborne particles that are equal to and greater than the considered particle size. *Cn*is rounded to the nearest whole number, using no more than three significant figures; | Cn 是大于等于要考虑的粒径的空气悬浮粒子的最大允许浓度（个/立方米）。Cn修约至最近的整数，保持有效位数不大于三位； |
| *N* is the ISO Class number, which shall not exceed a value of 9 or be less than 1; | N 是ISO级别，不应大于9或小于1； |
| *D* is the considered particle size, in micrometres, that is not listed in Table 1; | D 是所考虑的粒径，单位微米，在表1中未列出； |
| K is a constant, 0,1, expressed in micrometres. | K 为常数0.1，单位微米 |

# Annex F 附录F

## (informative) 仅供参考

# Test instruments 测试仪器

## F.1 Introduction 概述

This annex describes the measuring apparatus that should be used for the recommended tests given in Annexes A, C and D.

本附录描述了附录A、C和D中给出的建议测试中所应使用的测量仪器。

In this annex, data given in Tables F.1 and F.2 indicate the minimum necessary requirements for each item of apparatus. Measuring apparatus should be chosen subject to agreement between the customer and supplier.

在本附录中，在表F.1和F.2中给出的数据表示的是仪器各项目所应达到的最低要求。客户和供应商应就测量仪器的选择达成一致。

This annex is informative, and should not prevent the use of improved apparatus as it becomes available.

本附录仅供参考，如果仪器在将来被改进，本附录并不会禁止使用。

Alternative test apparatus may be appropriate and may be used subject to agreement between customer and supplier.

也可以使用其它客户和供应商之间达成一致的测量仪器来代替。

## F.2 Instrument specifications 仪器标准

The following instruments should be used for the recommended tests given in Annexes A, C and D:

附录A、C和D中给出的建议测试应使用以下仪器：

a) light scattering (discrete) airborne particle counter (LSAPC);
光散射（不连续）空气悬浮粒子计数器（LSAPC）

NOTE The specifications for the LSAPC are given in ISO 21501-4:2007.[1]

注：ISO 21501-4:2007中给出了LSAPC的标准。

b) discrete-macroparticle counter;
不连续大颗粒计数器

c) time-of-flight particle sizing apparatus;
飞行时间粒径测量仪

d) microscopic measurement of particles collected on filter paper. See ASTM F312-8.[3]
采用滤纸采集的粒子的显微测量，参见ASTM F312-8。

The terms and definitions for these instruments are given in Clause 3.

第3款中给出了这些仪器的术语和定义。

**Table F.1 — Specifications for discrete-macroparticle counter**

**表 F.1---不连续大颗粒计数器的标准**

| **Item 项目** | **Specification 标准** |
|---|---|
| Measuring limits | The minimum detectable size should be in the range 5 to 80 µm and be appropriate for the particle size under consideration and the instrument capability. The maximum particle number concentration of the LSAPC should be equal to or higher than maximum expected concentration for the particles under consideration |
| 测量限度 | 最小检出粒径应在5-80µm，与所考量的粒径和仪器能力相当。LSAPC的最大粒子数浓度应大于或等于所考量粒子的最大预期浓度。 |
| Resolution | 20 % for calibration particles of a size specified by the manufacturer |
| 分辨率 | 生产商指定粒径的校正粒子数的20% |
| Maximum permissible error | 20 % for particle count at a specified size setting |
| 最大允许误差 | 指定的粒径设置下粒子计数的20% |

**Table F.2 — Specifications for time-of-flight particle sizing apparatus**

**表F。2----飞行时间粒径测定仪规格**

| **Item 项目** | **Specification 规格** |
|---|---|
| Measuring limits | Particle size 0,5 to 20 µm; Particle concentration 1,0 × 103/m3 to 1,0 × 108/m3 |
| 测量限度 | 粒径0.5-20 µm，粒子浓度1.0X103/立方米至1.0X108/立方米 |
| Resolution | aerodynamic diameter: 0,02 µm at 1,0 µm; 0,03 µm at 10 µm |
| 分辨率 | 空气动力学直径1.0时0.02 µm，10 µm时0.03 µm |
| Maximum permissible error | 10 % of full reading |
| 最大允许误差 | 所有读数10% |

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