INTERNATIONAL STANDARD

ISO 14644-2

Second edition
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Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

Partie 2: Surveillance du maintien des performances de la salle propre pour la propreté particulaire de l'air

洁净室及相关控制环境国际标准—

第 2 部分

用粒子浓度监测提供与空气洁净度相关的洁净室性能的证据

Reference number
ISO 14644-2:2015(E)

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目录

Contents

Page

Foreword 前言

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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).

该程序用于该份文件的升级以及进一步的完善，其在 ISO/IEC 第 1 部分中有描述。应予以注意的是不同的审批标准需要不同类型的 ISO 文件。该份文件的起草应符合 ISO/IEC 第 2 部分

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关于 ISO 具体条款和符合性评估相关表达的解释，以及关于 ISO 坚持对 WTO 技术贸易壁垒（TBT）的信息，请参阅以下网址：前言-补充信息

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

该委员会负责这个文件是 ISO/TC 209：洁净室和相关受控环境。

This second edition cancels and replaces the first edition (ISO 14644-2:2000), which has been technically revised throughout.

该文件第二版取代了第一版（ISO 14644-2:2000），已经全部进行了技术修订。

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

ISO 14644 由以下部分组成，但是是在“洁净室和相关受控环境”的总标题下。

— 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：用粒子浓度监测提供与空气洁净度相关的洁净室性能的证据

— 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：分离装置（空气层流罩，手套箱，隔离器和 mini-环境）

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

第八部分：通过化学浓度确定空气洁净度分级（ACC）

— Part 9: Classification of surface cleanliness by particle concentration

第九部分：通过粒子浓度确定表面洁净度分级

— Part 10: Classification of surface cleanliness by chemical concentration

第十部分：通过化学浓度确定表面洁净度分级

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

同样需要注意的还有 ISO14698：洁净室和相关受控环境 – 微生物污染控制中同样也有描述

— Part 1: General principles and methods

第一部分：总则和方法

— Part 2: Evaluation and interpretation of bio-contamination data

第二部分：微生物污染数据的评估和解释

Introduction 介绍

This revision of ISO 14644-2 emphasizes the need to consider a monitoring strategy in addition to the initial or periodic execution of the classification of a cleanroom or clean zone in accordance with ISO 14644-1:2015, 5.1. The monitoring activity provides a continuing flow of data over time, thereby providing a more detailed view

of the performance of the installation.

除了首次或者定期按照 ISO14644-1：2015，5.1 进行洁净房间或者洁净区域分级之外，这一版的 ISO14644-2 强调了需要考虑监控策略。监控将提供一个涵盖所有时间的持续流程，从而提供该装置性能更详细的视图。

Potential benefits gained from monitoring are

从监控获得的潜在好处是：

— faster response to adverse events and conditions,

更快的对不符合事件和条件的反应

— ability to develop trends from data over time,

从随着时间推移的数据去发展趋势的能力

— integration of data from multiple instruments,

对从多台仪器获得数据的整合

— enhanced knowledge of installation and process, which allows for more effective risk assessment, and

增强安装和过程知识，将能够行使更有效的风险评估

— improved control of operational costs and product losses.

提高运营成本和产品损耗的控制

ISO 14644-2 specifies the requirements of a monitoring plan, based on risk assessment of the intended use. The data obtained provide evidence of cleanroom or clean zone performance related to air cleanliness by particle concentration.

ISO 14644-2 规定，监测计划的要求是根据预定用途的风险评估进行的。通过获得的颗粒浓度数据，用于证明洁净室或者洁净区域的空气洁净度。

In some circumstances, relevant regulatory agencies may impose supplementary policies, requirements or restrictions. In such situations, appropriate adaptations of the monitoring procedures may be required. After a monitoring plan is initially established and implemented, it may be necessary to revise the plan when significant changes are made to the installation or process requirements. It is also prudent to conduct periodic reviews of a monitoring plan based on data obtained and experience in use.

在某些情况下，相关监管机构可以提出增补政策、要求或者限制条件。在这些情况下，监控程序可能需要适当的调整。在最初的监控计划建立并实施之后，当安装或者工艺要求发生显著变更时，可能需要修改监控计划。同时基于获得的数据和使用经验，谨慎的定期审核监控计划

Cleanrooms and associated controlled environments —

洁净室和相关受控环境—

Part 2:

Monitoring to provide evidence of cleanroom performance

related to air cleanliness by particle concentration

第二部分：用粒子浓度监测提供与空气洁净度相关的洁净室性能的证据

1 Scope 范围

This part of ISO 14644 specifies minimum requirements for a monitoring plan for cleanroom or clean zone performance related to air cleanliness by particle concentration, based upon parameters that measure or affect airborne particle concentration.

ISO14644 本部分定义了以粒子浓度进行空气分级的洁净室或洁净区性能的监控计划的最低要求，其是基于测量或者影响空气中粒子浓度参数。

This part of ISO 14644 does not address condition monitoring of aspects such as vibration or general maintenance of the engineering systems. It does not provide for monitoring of particle populations that are outside the specified lower threshold particle-size range, 0.1μ m to 5μ m. Concentrations of ultrafine particles (particles smaller than 0.1μm) will be addressed in a separate standard.

ISO14644 本部分不涉及监控条件，如：振动或者工程系统的维护保养。其不提供粒子群中粒

径范围在 0.1μm ~ 5μm 以外的监控。超细颗粒浓度（0.1um）将有单独的标准。

2 Normative references 应用标准

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，整体或者部分，在本文件中被引用。凡是注明日期的文件，仅引用版本适用；凡是不注明日期的引用文件，仅只有最新版本（包括所有修订版本）适用。

ISO 14644-1:2015, Cleanrooms and associated controlled environments — 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

3 Terms and definitions 术语和定义

For the purposes of this document, the terms and definitions given in ISO 14644 -1 and the following apply:

本文件所用的术语、定义在 ISO14644-1 以及以下描述：

3.1 test 测试

procedure undertaken in accordance with a defined method to determine the performance of an

installation or an element there of

按照规定方法测定一项设施或者其一部分的性能所完成的操作。

3.2 monitoring 监测

observations made by measurement in accordance with a defined method and plan to provide evidence of the performance of an installation

通过采用规定方法和计划进行测试以取得一项装置的性能数据而完成的监测。

Note 1 to entry: Monitoring may be continuous, sequential or periodic; and if periodic, the frequency shall be

specified.

Note 2 to entry: T his information may be used to detect trends in operational state and to provide process support.

注 1：检测可以是持续、持续的或者周期性的；如果是周期性的，检测频率应该被指定。

注 2：该信息可被用于检测操作状态的趋势和提供流程支持。

3.3 action level 行动限

Level of a parameter set by the user which, when exceeded, requires immediate intervention, including

investigation of cause, and corrective action

由用户设置一个参数限度，定义超限，需要立即干预时。包括原因调查和纠正措施。

3.4 alert level 警戒线

level of a parameter set by the user giving early warning of a drift from normal conditions, which, when

由用户定义的一个参数水平，用于提前的正常状况的漂移警戒。

4 Creating, implementing and maintaining a monitoring plan 创建、执行和维护监控计划

4.1 Principle 原理

In order to gain assurance that a cleanroom or clean zone is performing adequately by delivering the required control of air cleanliness by particle concentration, a monitoring plan shall be created, implemented and maintained.

为了保证洁净房间或者洁净区域的能够控制在所需洁净级别的例子浓度，应该建立、实施和维持一个监控计划。

A monitoring plan shall take into account the level of air cleanliness required, critical locations and performance attributes of the cleanroom or clean zone that affect the performance of the installation. The following steps shall be included in the creation, implementation and maintenance of the monitoring plan:

监控计划应考虑到洁净度要求，关键位置以及那些影响安装性能的洁净房间或者洁净区域的性能属性。创建、执行和维护以下监控计划：

— use appropriate risk assessment tools to understand, evaluate and document the risk of adverse contamination events;

使用合适的风险评估工具，理解、评估和记录不良污染事件风险

— develop a written monitoring plan; 制定书面监测计划

— review and approve the plan; 审核和批准计划

— implement the plan by performing the monitoring; 执行监控实施计划

— analyse the data derived from the monitoring activity, undertake trend analysis where appropriate and report performance;

分析来自监控活动的数据，进行趋势分析，并适时的报告。

— implement and document actions or corrective actions required;

执行和记录操作或纠正措施

— undertake periodic review of the monitoring plan.

对监控计划进行定期评审

The concentration of airborne particles measured under a monitoring plan may be higher than the concentration observed during at-rest classification. The observed values may fluctuate considerably due to factors such as, but not limited to, the number of personnel present, the airflow rate, ventilation effectiveness, the operation of instruments or machinery, and activities in adjacent spaces.

按照监控计划测量的粒子浓度可能会高于在静态时观察到的粒子浓度。所观测到的值可能会波动相当大的原因可能是，但不限于此：人员数量、风速、通风效果、仪器或者器械操作、或者相邻区域的活动。

For processes that inherently produce particles as part of the process and where these particles are not a threat to the process or product, it may be appropriate to rely on periodic at-rest classification, or operational classification of simulated operations, rather than monitoring of airborne particles in operation. Other performance and cleanliness attributes may still be required to be monitored.

对于以上提到的作为工艺过程一部分产生的粒子，这些粒子不会对工艺或者产品产生威胁。它可能适用于定期的在静态或者模拟动态操作，而不是真正的操作中监控粒子。其他性能或者洁净级别属性可能仍然需要被监测。

4.2 Risk assessment 风险评估

Risk assessment is a systematic process of identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

风险评估是一个识别危害和分析评估危害相关风险的系统过程。

A risk assessment shall be undertaken in order to

风险评估应该被进行，以便：

— develop a monitoring plan by determining factors that may affect the ability to maintain the agreed air cleanliness by particle concentration of the cleanroom or clean zone, and

通过可能影响洁净房间或者洁净区域空气级别粒子浓度的决定因素来制定监控计划

— determine the monitoring requirements to provide evidence of performance.

确定监控要求，用于提供性能的证明

For guidance on what to consider when undertaking a risk assessment, see informative Annex A.

对于在进行风险评估过程中应该考虑什么的指导，见附录 A.

4.3 Monitoring plan 监控计划

4.3.1 The monitoring plan shall take into account the output from the risk assessment.

监控计划应该考虑风险评估结果

When developing the monitoring plan, the factors described in 4.3.2 to 4.3.13 shall be included as a minimum.

当制定的风险评估计划时，至少应该包括在 4.3.2 到 4.3.13 所描述的因素。

4.3.2 Listing and justification of all the parameters to be monitored, including those that may affect the airborne particle concentration.

被监测的所有参数的列表和理由，包括哪些所有可能影响空气粒子浓度的因素。

4.3.3 Description and justification of measurement methods. For further guidance on considerations when developing a monitoring plan, see informative Annex A.

测试方法的描述和理由，对于进一步制定的监测计划指导，见附录 A.

4.3.4 Accuracy, maintenance and calibration of monitoring instrumentation.

监控设备的精度、维护保养和校验。

4.3.5 Identification and justification of selected monitoring locations. Monitoring locations shall be defined in three dimensions.

识别和选择监测点的理由。监测位置应该在三维空间中定义。

4.3.6 Identification and justification of monitoring acceptance criteria or limits, including establishment of a single alarm level, or a dual alarm approach of alert and action levels. The minimum requirement is that a single alarm action level is established. Additionally, an alarm alert level can be established to provide early warning of performance deviation. For further guidance on setting alert and action levels, see informative Annex B.

监测接受标准或者限度的识别和判定。包括独立警戒限的建立，或者双警戒或者行动限的报警方法。最低要求是建立单一的警戒行动限，另外，警戒限警报水平的建立能够提供性能偏差预警，为进一步设定警报和行动水平提供指导，见***附件 B*** 内容。

4.3.7 Specification of the response required should the data fall outside the specified limits.

数据超出标准限之外的响应标准。

4.3.8 The need for and frequency of periodic cleanroom or clean zone air cleanliness classification by particle concentration in accordance with ISO 14644-1:2015, 5.1.

按照 ISO 14644-1:2015, 5.1.对洁净室或洁净区域的尘埃粒子浓度的定期检测。

4.3.9 The format for recording data.

记录数据格式

4.3.10 The methods, including statistical methods to be used for data trending or other appropriate analysis.

方法，包括用于统计分析数据趋势或者其他适当的分析方法。

4.3.11 The reporting requirements. 报告要求。

4.3.12 The policy and media to be used for record retention.

用于记录保存的策略和媒介。

4.3.13 The frequency of review of the monitoring plan.

监测计划的审核频次。

NOTE Monitoring plans are reviewed periodically; and based on the knowledge gained about the cleanroom or clean zone, the monitoring programme is revised.

备注 监测计划需根据洁净室和洁净区域所得知识定期审核，更新监测程序。

4.4 Calibration 校验

Instrumentation used for monitoring shall be adequate to perform the monitoring operations required, shall have a valid calibration certificate, and shall meet current accepted practices for the frequency and method of calibration.

用于检测用的仪器应该足以满足检测操作要求，应该有校验证书，校验频次和方法应该符合目前公认的做法。

In particular for airborne particle counters, the frequency and method of calibration should be based upon current accepted practice as specified in ISO 21501-4.

尤其是粒子计数器，校验的频率和方法应该根据当前通行的惯例 ISO 21501-4 规定要求。

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 monitoring plan.

注： 某些粒子计数器不能按照 ISO 21501-4 的所有要求进行校验，如果是这种情况，记录该决定至计数器的使用监控计划中。

4.5 Review and approval 审核和批准

The completed plan shall be reviewed and approved.

完成的计划需审核和批准。

4.6 Response to a deviation during monitoring 监控期间偏差响应。

If monitoring results exceed the specified limit(s), an investigation shall be conducted to determine cause, and remedial action taken as required.

如果监控结果超过标准限度，应该发起调查确定导致该事件的原因，并根据需要采取补救行动。

If the remedial action requires significant changes to the installation and/or its operation, then the classification test according to ISO 14644-1 shall be undertaken. The monitoring plan shall also be reviewed as a result of the changes to the installation and/or its operation.

如果补救行动，可能导致安装或者运行的显著变更，应根据 ISO 14644-1 分类测试进行级别测试，监控计划也应该审核所有安装或者运行变更后的结果

When the desired classification has been achieved, monitoring may be resumed.

当达到所需的级别，监控将被重新恢复。

5 Periodic classification of air clean liness by particle concentration

通过粒子浓度定期进行空气洁净度级别

Periodic classification testing shall be undertaken annually in accordance with ISO 14644-1. This frequency can be extended based on risk assessment, the extent of the monitoring system, and data that are consistently in compliance with acceptance limits or levels defined in the monitoring plan.

NOTE ISO 14644-3 specifies ancillary tests related to other aspects of cleanroom performance such as pressure different, airflow, etc

定期的洁净度测试应该按照 ISO14644-1 每年实施。该频次可基于分析评估进行扩展，监控系统的数据是始终符合监控计划中定义的接受限度和水平的。

备注：ISO 14644-3 定义的洁净室性能其他方面的相关测试方法，如压差，气流等。

Annex 附录 A

(informative)

（资料）

Matters to consider when developing a monitoring plan

制定环境监测计划时应考虑的因素

A.1 Risk assessment considerations

风险评估

A.1.1 Selection of an appropriate risk assessment tool

选择合适的风险评估工具

Risk assessment can be undertaken using a number of tools – separately or in combination – including

可以单独或组合使用风险评估工具，包括但不限于：

- HACCP
- FMEA/FMECA
- PHA
- FTA
- HAZOP

A.1.2 Definition of required performance and operating conditions that may need to be monitored 需要进行检测的工作条件

These can be factors such as：此类要素包括：

— Understanding the contamination sources and their impact on the activity in the cleanroom or clean zone at critical locations or at locations representative of the

general air cleanliness in a cleanroom or clean zone,

— Performance of the installation that might affect the cleanliness levels such as pressure differential, airflow uniformity, airflow volume, ventilation effectiveness, temperature, relative humidity,

— Normal and energy-saving set-back mode,

— At -rest or operational states, and

— Occupancy and level of activity, such as change of shift.

- 理解污染源，认识污染源对洁净室或关键点洁净区域内操作的影响，或污染源对洁净室或洁净区域内代表性点位的空气洁净度的影响；
- 可能影响洁净级别（例如，压差、气流均一性、风量、气流保护有效性、温度、相对湿度等因素）的安装行为；
- 正常条件或节能模式；
- 静态或动态条件；
- 活动范围和水平，例如换班。

A.2 General considerations 一般考虑因素

A.2.1 The general matters described in A.2.2 to A.2.21 should be considered when developing a monitoring plan.

在制定监测计划时，应当考虑 A.2.2 至 A.2.21 项中规定的通用要求。

A.2.2 The measurement technique, including the selection of manual and/or automated monitoring.

测量技术，包括人工和/或自动监测模式的选择。

A.2.3 The resolution, accuracy and calibration requirements of the measurement

system including, in the case of airborne particle counters, the efficiency and limitations of the collection system.

以空气悬浮粒子计数器为例，测量系统的分辨率、准确度和校准要求，包括粒子收集系统的效率和限度。

A.2.4 The location of monitoring system components, including requirements for access for maintenance and calibration.

监测系统部件的位置，包括维保和校准的权限要求。

A.2.5 Instrument or sample probe location, configuration and orientation.

设备或采用探头的位置、构造和方向。

A.2.6 Identification of frequency of measurement or sampling in order to detect deviation events.

确定测量或采样的频率，以便监测到偏差事件。

A.2.7 Consideration of issues that may influence the monitoring system or the results obtained, such as (but not limited to) temperature, humidity, cleaning procedures and agents, fumigation agents, product materials or process hazards and sources of potential convection currents in the air due to heated surfaces.

可能影响监测系统或监测结果的考虑因素，例如（包括但不限于）：温度、湿度、清洁程序和清洁剂、熏蒸剂、产品物料或工艺危害、由于热表面引起的对流气流等。

A.2.8 Consideration of any potential adverse impact of the sampling system on the process or the process environment (e.g. possible effects of the extraction of the air-sample volume required by a particle counter on small enclosed environments).

采样系统对工艺或工艺环境可能造成的潜在不良影响（例如，粒子计数器进行空气抽样时，可

能对小区域封闭环境造成的影响）。

A.2.9 The results of any airflow visualization studies such as "smoke studies," computer airflow modelling simulations or other studies.

对气流进行可视化研究，例如“发烟试验”、计算机气流模型模拟或其他研究。

A.2.10 Understanding the ventilation effectiveness in the cleanroom or clean zone, as might be affected by rate of air exchanges, recovery or clean-up time studies, or any other method to understand the potential rate of removal of airborne particles.

理解洁净室或洁净区域的通风效率。通风效率可能受换气次数、复原或净化时间研究影响，或通过其他方法理解空气悬浮粒子去除的潜在效率。

A.2.11 Extent and/or frequency of cleaning or maintenance procedures and their impact on airborne particle levels, both during execution and immediately after completion of the procedure.

清洁或维保程序的执行范围和/或频次，以及在清洁、维保过程中及完成后，清洁、维保操作对空气悬浮粒子水平的影响。

Consideration of process-related events that may affect environmental conditions at monitoring locations. Such events may include (but are not limited to) dismantling, cleaning and reassembly of equipment，whether as part of the process cycle or as an element of maintenance work.

NOTE It may be useful to include within the monitoring plan provisions for monitoring the recovery time at the conclusion of such refitting, prior to resuming normal operations.

关注可能影响监测点环境条件的工艺相关事件，此类事件可能包括但不限于设备拆解、清洁和

组装等，生产工艺和设备维保过程中的上述设备相关操作均包括在内。

注意：在完成上述设备安装工作后、恢复正常生产操作之前，应监测环境恢复时间。在环境监测计划中应考虑到这一点。

A.2.13 Typical positions and movements of personnel during the critical operational periods.

在关键操作过程中，操作人员的典型位置与活动。

A.2.14 Expectations for the number of personnel active in the cleanroom or clean zone, the nature of their occupation and the duration of their activities.

在洁净室或洁净区域活动的预期人数，人员活动的性质及活动时长。

A.2.15 Assessment of the impact of equipment-generated changes to airflow patterns.

评估设备运行对气流模式的影响。

A.2.16 Assessment of the potential for equipment-generated particle sources. Examples include particles generated from abrasion of surfaces on moving conveyor systems, and processes such as sealing of glass ampoules and radio frequency (RF) welding of tubing.

评估设备产生的潜在粒子源。例如，传送系统表面磨损产生的粒子，玻璃安瓿封口产生的粒子，以及管道射频焊接产生的粒子。

A.2.17 Data logging and data management, including data integrity, storage and retrieval

NOTE In some industries the storage and integrity of data are specifically regulated.

数据记录和数据管理，保留数据完整性、数据储存和检索。

注意：在某些行业中，需要对数据储存和数据完整性进行特殊规定。

A.2.18 Establishment of suitable techniques for the evaluation of raw data, assessment of trends, and production of reports.

建立合适的技术手段进行原始数据评估、趋势评估和生成报告。

A.2.19 Definition of acceptance criteria and establishment of a single alarm level, or a dual approach of alert and action levels.

确定可接受标准，并建立单侧警戒限水平，或双侧警戒限、行动限水平。

A.2.20 Requirements for commissioning and testing of the monitoring system(s).

监测系统试运行和测试要求。

A.2.21 Requirements for maintenance of the monitoring system(s).

监测系统维保要求。

A.3 Pressure differential monitoring 压差监测

A.3.1 The additional aspects described in A.3.2 to A.3.5 should be considered for specifying monitoring systems for differential pressures in cleanrooms or clean zones.

在对洁净室或洁净区域压差监测系统进行规定时，应当考虑 A.3.2 至 A.3.5 项中描述的内容。

A.3.2 The method of minimising or managing fluctuations caused by disturbances such as door openings or intermittent operation of local exhaust systems. A common method is the introduction of time delays on alarms.

最大限度降低或管理干扰因素（例如，开门或局部排风系统的间歇式运行）导致的压差波动的方法。引入延时报警系统，是一种常用的方法。

A.3.3 Selection of a pressure-measurement reference principle (measurement of differential pressure between rooms or spaces, or measurement of differential against

a common reference pressure).

选择压差测量的参考标准（测量房间或空间之间的压差，或者以一个常用参考压差为标准测量压差）。

A.3.4 Establishment of alert and action levels that are sensitive to normal pressure fluctuations due to factors such as wind effects on buildings, the opening and closing of doors and other factors.

建立对正常的压差波动敏感的警戒限和行动限水平。造成压差波动的因素包括风力对建筑物的影响、开门、关门以及其他因素等。

A.3.5 The pressure differential may be monitored by periodic observation or by automated instrumentation.

可以通过定期观察或自动化设备对压差进行监测。

A.4 Airborne particle monitoring system 空气悬浮粒子监测系统

A.4.1 The additional aspects described in A.4.2 to A.4.6 should be considered for specifying real-time airborne particle counting systems.

在设计实时空气悬浮粒子监测系统时，应当考虑 A.4.2 项至 A.4.6 项中描述的传统因素。

A.4.2 The configuration of the system based on evaluating the following system attributes:

系统的配置应当基于对如下系统属性的评估：

— airborne particle collection efficiency;

— suitability to monitor the selected particle size(s);

— accessibility for maintenance, calibration, and repair.

- 空气悬浮粒子的收集效率；
- 监测特定粒径粒子的适用性；
- 维保、校准和维修的便捷性。

NOTE 1 These considerations will influence the choice between using multiple local "point of use" particle counters or using a single particle counter with a multiplexing manifold and long sample transport tubes.

NOTE 2 The use of long sample transport tubes as required by multiplexing manifold systems is inappropriate for monitoring particle sizes ≥5 µm.

注意 1. 上述因素将影响粒子计数器类型的选择：是选择使用多台局部"使用点"粒子计数器，还是使用一台多路多头管系统、长样本输送管道粒子计数器。

注意 2. 多路多头管系统要求使用长样本输送管道，该系统不适用于粒径≥5µm 的粒子的监测。

A.4.3 Air sample flow rate and volume.

空气采样风速和采样量

A.4.4 The frequency and duration of the collection of each air sample (determined by the sampling rate).

每份空气样本采集的频率和采集时长（以采样速率测定）。

A.4.5 The sample probe configuration and orientation with respect to airflow (e.g. isokinetic or an-isokinetic).

NOTE It may not be appropriate to locate a sample probe directly under a supply air terminal High-Efficiency Particulate Air (HEPA) filter in a non-unidirectional airflow configuration because such a location may not be representative of the cleanroom or clean zone, and may prevent detection of contamination events in operation.

采样探头的构造以及相对于气流的方向（例如，同流态取样或非同流态取样）。

注意：在非单向流条件下，不能将采样探头直接至于高效空气过滤器终端进行采样，因为这一位置的空气不能够代表洁净室或洁净区域的空气质量，且有可能导致无法监测到操作过程中的污染事件。

A.4.6 Potential adverse impact of the sampling system on the process or the process environment (e.g. possible effects of the rate of the extraction of the sample volume in small volume environments).

采样系统可能对工艺或工艺环境造成的潜在不良影响（例如，在小范围环境下，空气采样频率可能对环境造成的影响）。

A.5 Airflow velocity and volume monitoring 风速风量监测

A.5.1 The additional aspects described in A.5.2 to A.5.3 should be considered for specifying airflow velocity or air volume monitoring systems.

在设计风速风量监测系统时，应当考虑 A.5.2 项至 A.5.3 项中描述的传统因素。

A.5.2 The selected airflow velocity or volume measurement technique.

选择风速或风量测量技术。

A.5.3 The location of the measurement device so that the measurement is representative of the system being monitored.

NOTE It may be necessary to evaluate locations to prove measurements are representative and not adversely influenced by airflow turbulence or uneven flow in ducts or other factors.

确定测量设备的位置，以保证测量结果在被测量的系统中具有代表性。

注意：可能需要对测量位置进行评估，证明测量结果具有代表性，且测量结果不会受到管道中气流湍流或不均匀气流以及其他因素的影响。

Annex B 附录B

(informative)

Considerations for setting alert and action levels

警戒限和行动限设定的考量

B.1 General basis for setting alert and action levels警戒限和行动限设定的常规基础

The establishment of alert- and action-level alarms requires careful consideration to ensure they provide an effective basis for initiating a response, such as further investigation or increased observation(known as an “alert level”), and trigger a remedial action response (designated as an “action level”). The following should be considered:

建立警戒限和行动限时要深思熟虑，以确保可以提供一个有效并且能及时触发响应，比如进一步调查或加强监测（被称为“警戒限”），并触发弥补措施响应（定义为“行动限”）。应考虑以下内容：

— the intent and purpose of monitoring;

监测的目的和意图；

— the importance and/or criticality of the monitored parameters;

监测参数的重要性和/或关键性；

— the selection of a single alarm action level or dual alarm alert and action levels;

行动限和单警戒限或警戒限选择；

— the risk from failing to react to the “alert” or “action” due to high frequency of alarms. This may occur from setting inappropriate alarm levels and may result in personnel not acting upon or muting alarms;

由于报警过于频繁，无法对“警戒”或“行动”做出响应。如果设定的警戒限标准不恰当，可导致操作人员不理会警报或者关闭警报；

— how normal acceptable fluctuations in monitored parameters are managed; for example, the rationale for time delays and the algorithms for rate of change prediction systems;

如何管理受监测参数的常规可接受波动，例如，时间延误合理性和更改预测系统速度的算法；

— frequency of sampling or measurement to enable assessment of the rate at which the next data point will be acquired;

取样或监测频率，以便将评估的结果在下一阶段进行获取数据点的速率成为支撑性的依据；

— when responding to an “alert,” the ability to respond, the nature of the response and the time allowed for the response before it is elevated to an “action.”

在对一个“警戒报警”做出反应时，响应的能力、响应的性质，以及在其升级为“行动报警”之前剩余的时间。

B.2 Setting alert and action levels for pressure differential monitoring

压差监测警戒限和行动限设定

B.2.1 Establishing the normal operational range for pressure differentials

压差正常运行范围的建立

In order to set alert and action levels for pressure differentials, it is necessary to establish the normal operating range, including, for example, fluctuations due to doors opening and equipment interactions.Deviations from this normal operating range can then be established in terms of either solely a value deviation or a value

and time of deviation.

为了设定压差警戒和行动限，需要建立正常的运行范围，包括，例如，由于开门和设备相互影响产生的波动。此正常运行范围之外的偏差才可以用以建立单值偏差或数值加时间偏差标准。

The initial observations should be repeated periodically and after maintenance or modification of a cleanroom or clean zone due to variations in performance and ageing of components of the installation.The approach given in B.2.1.1 and B.2.1.2 should be adopted to explore and document pressure fluctuations.

在首次观察获得正常运行范围后，还要定期重复此观察，并且要在对洁净区或洁净间由于性能变化而进行维护或改造之后，以及安装部件长期使用之后重复此观察。

B.2.1.1 The impact of operating airlock doors 开关缓冲门时的影响

Air locks are designed to help maintain pressure differentials as personnel or materials move from one cleanroom or clean zone to another. Air locks are designed or operated so that one opposing door set is always closed. However, unless the doors are equipped with inflatable seals, the leakage through the airlock is usually greater when one of the opposing door sets is open than when they are both closed.

缓冲是设计来帮助在人员或物料从一个洁净区或洁净间移动至另一个洁净区/间时维持压差。缓冲设计或操作应该让其中一边的门总是保持关闭。除非门采用了充气密封，否则当一边的门打开时，通过缓冲产生泄漏通常大于两边门都打开的情况。

It is necessary to test and document these normal variations to properly set alert and action levels for pressure alarms. Follow this procedure:

需要测试和记录这些常规变化，以便为压力报警设定适当的警戒和行动限。参照以下程序进行评估：

— close all doors and pass-through hatches, define the operational status of any equipment, and observe the steady-state pressure differentials between the selected rooms or zones noting the small, normal fluctuations that will occur due to wind and other dynamic effects;

关闭所有的门和传递窗，定义所有设备的运行状态，观察稳定状态下所选择的房间或区间的压差，注意由于风或其它动态影响产生的小的常规波动；

— for each airlock, pass-through hatch or transfer chamber, open all the doors, one set of opposing doors at a time, and note room- or zone-pressure variation. Close the doors and confirm that the pressure differentials return to their original values;

每个缓冲、传递窗或转移舱，打开所有的门，一次打开一边的门，注意房间或区间压力波动。关门，确认压差回到其原始值；

— leakage paths, such as those around doors, should be evaluated as part of a cleanroom design to ensure adequate allowance is made in the air balance for such leakages.

泄漏途径，例如门周边泄漏，应进行评估，作为洁净间设计的一部分，以确保为此泄漏做出了足够的空气平衡余量。

B.2.1.2 The impact of process equipment工艺设备的影响

Some process equipment have a small and acceptable effect on room or zone pressure differentials due to small changes in the air lost from pressurized spaces via the equipment when functioning in different operational states. Follow this procedure:

当设备处于不同运行状态时，通过设备可能会有空气从压力空间散失变化，这时会对房间或区

间压差有较小的可接受影响。参照以下程序进行评估：

— close all doors and pass-through hatches, set the equipment in a defined operational state, and observe the steady-state pressure differentials between the selected rooms or zones noting the small, normal fluctuations that occur due to wind and other dynamic effects;

关闭所有的门和传递窗，设定设备在定义的运行状态，观察所选择的房间或区间之间的稳定压差，注意由于风或其它动态影响产生的小的常规波动；

— repeat the test for each of the different operational states of the equipment. For each state, observe the steady-state pressure differentials between the selected rooms or zones noting the small normal fluctuations that occur due to wind and other dynamic effects.

将设备设定在不同的运行状态重复测试。对于每个状态，观察稳定状态下所选择的房间或区间之间的压差，注意由于风或其它动态影响产生的小的常规波动。

B.2.2 Setting alert and action levels 警戒限和行动限的设定

B.2.2.1 After observing and recording the normal operating ranges, it is recommended that a pressure setting for the warning pressure measurement device be selected a few Pascal below the lowest pressure observation for a positive-pressure configuration, or a few Pascal above in a negative-pressure configuration (guidance value 2 Pa to 3 Pa).

观察和记录正常操作范围之后，建议对报警压力装置设定一个压力报警范围值，以高低之间的范围来进行控制（建议数值的设定范围为2-3Pa）

B.2.2.2 It is often necessary to delay the alert or action alarm to allow for normal

activity in the cleanroom, such as the opening of doors to permit entry and exit of personnel. Careful observation of the duration of typical or expected normal deviation is necessary to determine appropriate time delay.Deviations that extend beyond the normal durations should activate warnings.

正常设定发生警戒或者行动报警过程中会存在有延时的设定，以此保证洁净间的常规活动，比如：开门允许人员的进出，在该过程中需仔细观察所执行的正常或预期的时间，以此确定报警的延时。若超过常规时间造成偏离系统将会激发报警。

B.2.2.3 Managing excessive pressure fluctuations or leakage by simply increasing the pressure differentials is not recommended because air leakage will be increased further with associated inefficiencies in the performance of the air-conditioning or ventilation system.

不建议仅仅通过增加压差来管理多余的压力波动或泄漏，因为空气泄漏会随着空调或通风系统性能效率下降而不断增长。

B.2.2.4 In regulated industries there is an expectation that root causes of problems will be identified and rectified rather than being accommodated by changes in operational limits. Failure to identify the root cause may lead to adverse regulatory action.

在受到行业或法规管辖要求中，需对问题的根因进行有效的识别进行调整而不是采用变更设置操作参数范围来进行，在此过程中未能进行有效识别找出根因可能受到法规的制裁。

B.2.3 Pressure differential instrumentation 压差仪表

B.2.3.1 When pressure switches are used, ensure that the action of the pressure switch is repeatable and that any switching hysteresis is accounted for and

accommodated by the setting of the alert or action level.

当使用压力开关时，需确保压力开关的操作过程是可以重复的，任何操作开关滞后可以通过设定警戒或行动限进行补偿。

B.2.3.2 To simplify calibration and avoid the need to remove instruments from the installation, especially when instrumentation is mounted in areas that are difficult to access, the instruments should be fitted with test ports and a method to isolate the instruments from the pressure source to enable the

为了简化校准的流程，避免从安装场所移除仪表，尤其是当仪表被装在一个难以进入的区域时，仪表应固定安装在某一个测试点位置.

B．3 Setting alert and action levels for airborne particle counts

设置尘埃粒子数的警报线和行动线

B.3.1 Gener al guidance 指导原则

B.3.1.1 The objective of particle concentration count monitoring in an operational cleanroom or clean zone is to provide evidence that the required level of cleanliness is achieved at critical control points. Risk assessment and evaluation of data from formal cleanroom or clean zone classification in accordance with ISO 14644-1 should be used to determine the monitoring locations (critical control points). The alert and action levels identified should provide effective information to allow management of performance changes and identification of deviations from defined acceptance criteria.

NOTE Statistical process control principles can be used to set alert and action levels based on analysis of historical data.

洁净室或洁净区操作是否符合所需的清洁水平，是依靠在关键控制点计数监测目标粒子浓度的原则来实现的。依照 ISO 14644-1，洁净室或洁净区按形式分类数据的风险评估来确定监控点（关键控制点）。警报和行动线确定应提供有效的信息，信息来源于以管理过程中变化的性能和偏差的识别。

注意：采用统计学原理，基于历史数据的分析，来设置警报线和行动线。

B.3.1.2 It is essential to establish appropriate methods to annunciate or indicate when the particle count values reach alert or action levels.

建立适当的方法，以通知或指示当颗粒计数值达到警报或行动水平是至关重要的。

B.3.1.3 When setting alert and action levels, it is important to be sensitive to the high variability of airborne particle concentrations with time and at different locations. In particular, special care shall be taken when considering alert and action levels for cleanliness classes ISO Class 5 and cleaner with low concentrations of particles. In these circumstances, the occurrence of "nuisance alarms" due to false counts and/or natural variability of particle concentration is more likely and should be avoided by careful selection of alert and action levels. Frequent "nuisance" alarms should be avoided as they can lead to alarms being ignored by users.

当设置警报和行动线时，识别尘埃粒子浓度随时间，以及在不同的敏感位置的高可变性是很重要的。尤其特别的关注清洁度等级为 ISO 5 级以及更洁净的环境中，低尘埃粒子浓度下的警报和操作线。在这种情况下，更可能发生因虚假计数和/或颗粒浓度的自然变化产生的 "误报"，

应谨慎选择警报和行动线来避免。应避免频繁出现“扰民”的报警，因为这种报警很可能会被用户忽略。

B.3.1.4 The consistency of the physical sampling position and the orientation of the sample probe can have a marked effect on the particle concentration measured. This is especially true when there is a need to compare the values from one sample period to the next. It is important that the position of the sample does not change substantially without due consideration of the impact on trending history and alert and action levels.

物理采样位置的一致性和采样探头的方向可以对测量的粒子浓度有明显的影响。这是特别真实的，当有需要地比较一个样本期的值从到下一个样本周期时。重要的是，基于历史趋势形成的警报和行动线的基本上不考虑样本的位置的影响。

B.3.2 Establishing normal operating range for particle counts

建立正常操作的粒子计数范围

B.3.2.1 Initially measure and record the particle concentration at the designated critical control points over a significant period of time, in both the “at rest” and “operational” occupancy states. The intended sampling time and sample size should be used. From this set of data, the expected normal performance of the cleanroom or clean zone can be determined and become the basis for establishment of the alert and action levels. It is anticipated that these normal values will be below the ISO cleanliness class limit or action level.

最初，测量并记录在指定的关键控制点的颗粒物浓度在一段显著时期，无论是“静态”和“动

态”的状态。应该执行预定的采样时间和采样量。从该组数据，该清洁室或清洁区域的预期的正常性能可被确定，并成为建立警报和操作水平的基础。预计，这些正常的数值将低于 ISO 清洁度等级限制或行动水平。

B.3.2.2 It may be necessary to conduct a subsequent period of observation when a major change occurs to the design or operation of the installation.

当在设计、安装或运行时发生一个主要的变化时，进行一个持续的观察期是必要的。

B.3.2.3 Particle count data have some unique characteristics that should be understood. The following are important:

粒子计数的数据有一些独特的特点。理解以下几条是必要的：

a) the particle concentration baseline in a space is highly dependent on the level of activity, the volume of the cleanroom or clean zone, and the ventilation mechanism and effectiveness;

b) it is good practice to investigate particle count readings that are consistently lower than the expected norms because this may be an indication of the malfunction of the particle counter, air sample acquisition system or data-logging apparatus;

c) the acceptable range of particle concentrations for the “at rest” state may be significantly lower than the “operational” state in non-unidirectional airflow systems;

d) warning values may need to be different for different sample points within the same room or zone;

e) normal activity in the room may create momentary increases in particle counts that may be acceptable.

A）在一个空间的粒子浓度的基线高度依赖于洁净室的活跃程度、体积和其通风换气设施的效果；

B）这是很好的做法，研究粒子数读数比预计的准则始终较低，因为这可能是粒子计数器，空气样品采集系统和数据记录仪的故障的指示;

C）在可接受的范围内的非单向气流系统中，“静态”状态的粒子浓度可能是显着低于“操作”的状态。；

D）在同一个房间或区域内，不同的点可能需要不同的警告值；

E）在房间的正常活动可能会造成颗粒计数暂时的增加，可能是可以接受的。

B.3.2.4 To ensure quality particle monitoring data, and to assist comparison of data from subsequent air samples, it is essential that the sampling position and probe orientation are consistent. The consistency of the physical sampling position and the orientation of the sample probe can have a substantial effect on the quality of the data, especially when there is a need to compare the values from one sample period to another. Changes to the sampling location or orientation can have an adverse effect on the trending history, alert and action alarm levels. An example of this occurs when a cleanroom or clean zone air supply passes through terminal HEPA or Ultra-Low Penetration Air (ULPA) filters that are adjacent to one another. In this situation, moving the sample position only a short distance, for example 0,5m, may lead to the air being sampled from a different filter than previously sampled, thus making it impossible to compare the cleanliness data with different samples. In most cases, a significant repositioning of the sample probe should be considered as the establishment of a new location, triggering a new series of observations to determine

appropriate alert and action alarm levels.

为了保证质量粒子监测数据，并协助从后续空气样本数据的比较，很重要的是在取样位置和探头取向是一致的。物理取样位置及试样探头的方向的一致性可以对数据的质量产生重大影响，特别是当有必要将值从一个样本周期比较到另一个。改变采样位置或取向可以对向的历史，警报和操作警报水平产生不利影响。这方面的一个例子发生在洁净室或洁净区空气通过彼此相邻的终端高效或超低渗透空气（ULPA）中，在这种情况下，移动样品的位置只有很短的距离，0.5 M 的例子，可能会导致被取样空气来自于和先前采样不同的过滤器，从而使其无法清洁数据不同样品的比较。在大多数情况下，取样探头的显著重新定位应被视为建立一个新的位置，引发了一系列观察来确定新的适当的警报和行动警报级别。

B.3.3 Setting alert and action alarm levels for particle counts 通过粒子浓度建立警报线和行动线

B.3.3.1 The principles described in B.3.3.2 to B.3.3.8 are important when setting alarm, alert and action level thresholds.

下面 B3.3.2 和 B3.3.3 描述了建立警报线和行动线阈值的原则。

B.3.3.2 Select either a single alarm action level or a dual approach of alert and action levels. In some industries or applications, two levels of alarm – termed alert and action – are employed as a quality control measure and response tool.

选择一个报警动作水平或警报和行动水平的两重数值。在某些行业或应用程序，报警的两个层次 - 称为警报线和行动线 ，被用作一个质量控制的评测工具。

B.3.3.3 Set the alarm, alert or action levels between the normal operating range and the cleanliness class limit.

洁净等级限制区域应设置正常的工作范围、警报和行动水平线。

B.3.3.4 It is important to set the alert alarm level correctly. This will ensure that the occurrence of a warning event will be more likely to generate corrective action rather than creating a spurious and annoying occurrence or “nuisance alarm”, which can often result in operators ignoring the warning.

正确地设置警报报警水平是很重要的。这将确保警告事件的发生将更有可能产生的纠正措施，而不是创建一个虚假和恼人的发生或“滋扰报警”，这往往会导致操作员无视警告。

B.3.3.5 In most cases, a significant repositioning of the sample probe should be considered as the establishment of a new location and should trigger a new series of observations to determine the appropriate normal operating range, alarm or alert and action levels at the new location.

在大多数情况下，改变取样头的位置应视为建立一个新的位置，并应触发新系列的观察，以确定在新的位置相应的正常操作范围，报警或警报和操作水平。

B.3.3.6 If it is important to trend the data set from a specific location, care must to be taken to ensure the levels of activity for each sample taken are similar. Data taken during quiet periods of low or no activity will typically have a different baseline and range of values in comparison with data obtained during periods of greater activity and/or when more people are present in a room or zone.

从特定位置设置的数据集很重要，必须小心以确保每一个样本的活动水平是相似的。在低或没有活动期间采样的数据，和在更大的活动期间获得的数据（或当更多的人是存在于一个房间或区域），通常因在不同的基线和范围内进行比较。

B.3.3.7 The duration of sample period needs to be considered in terms of allowable

risk. Setting a longer sample duration can smooth data and avoid potential "nuisance alarms" but may conceal an unacceptably high level of airborne particle concentration over a short period caused by an unusual contamination-generating event.

采样周期的持续时间应该在允许的风险程度范围内。设置较长的时间样本可以平滑数据并避免潜在的"误报"，但可能掩盖短期内空气中一个不寻常的污染导致的颗粒物浓度不可接受的上升事件。

B.3.3.8 The performance of the monitoring system, the data gathered, norms established and trends should be reviewed periodically. Revision of alert and action alarm levels (relaxation or tightening) should be considered based on performance evidence.

监测系统的性能，数据收集，规则确立和发展趋势应该定期审查。警报线和行动线（放松或紧缩）的修订应根据累计数据分析来考虑。

B.3.4 Possible alternate strategies for warning levels for particle counts 粒子计数警告线的替代策略

B.3.4.1 If two particle sizes are monitored simultaneously and samples are taken at one-minute intervals, setting alert and action alarm levels is more complex. B.3.4.2 and B.3.4.3 describe two strategies.

如果 2 个不同粒径大小的粒子同时取样和监测在一分钟的时间间隔内，设置警报和行动警报水平更复杂。b.3.4.2 和 b.3.4.3 描述这两种策略。

B.3.4.2 Al ternate strategy 1: A trigger threshold value based on a series of consecutive higher readings. The higher readings trigger a warning based upon the

occurrence of a higher level of counts being maintained over a period of time (for example, three consecutive 1-min readings all above a specified level).

备选策略 1 :基于一系列连续的高读数的触发阈值。较高的读数触发被保持一段时间(例如，三个连续 1 分钟在某特定区域的检测数据）后，依据数值仍然超过基线水平再触发警告。

B.3.4.3 Alternate strategy 2: A threshold value trigger based on a high frequency of elevated readings. Sometimes referred to as "x out of y", this strategy records readings that are above a specified threshold; if a sufficient number of readings in a series are above the specified values then an alert or action alarm is triggered. For example, if 3 out of the last 10 readings are above a threshold then an alert or action alarm will be triggered.

备选策略 2：频繁以超过基准的阈值触发。有时被称为 "X 超出 Y"，这种策略记录读数高于规定的阈值;在出现一系列，足够数量高于指定值的读数时，则发出警报或动作触发报警。例如，设置 10 个读数的是高于阈值都不会触发报警，如果 3 是第 11 超出阈值的读数，则触发警报或执行报警动作。

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