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GB/T 25915.14-2022 / ISO 14644-14:2016

Cleanrooms and associated controlled environments - Part

**14: Assessment of suitability for use of equipment by
airborne particle concentration**

(ISO 14644-14:2016, IDT)

洁净室及相关受控环境 第 14 部分:按粒子浓度评估设备适用性

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Table of Contents

Foreword	3
Introduction	5
1 Scope	7
2 Normative references	7
3 Terms and definitions	8
4 General outline of the assessment	9
5 Visual examination	10
6 Assessment of suitability by airborne particle concentration measurements	11
7 Record	18
8 Statement on cleanroom suitability	21
Annex A (Informative) Example for data processing deriving from measurements ..	22
Annex B (Informative) Additional optional tests	26
Bibliography	29

Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 *Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents*.

This document is Part 14 of GB/T 25915 *Cleanrooms and associated controlled environments*. The following parts have been issued for GB/T 25915:

- Part 1: Classification of air cleanliness by particle concentration;
- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration;
- Part 3: Test methods;
- Part 4: Design, construction and start-up;
- Part 5: Operations;
- Part 6: Vocabulary;
- Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments);
- Part 8: Classification of air cleanliness by chemical concentration (ACC);
- Part 9: Classification of surface cleanliness by particle concentration;
- Part 10: Classification of surface cleanliness by chemical concentration;
- Part 12: Specifications for monitoring of air cleanliness by nanoscale particle concentration;
- Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications;
- Part 14: Assessment of suitability for use of equipment by airborne particle concentration;
- Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration.

This document is identical to ISO 14644-14:2016 *Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration*.

Cleanrooms and associated controlled environments - Part

14: Assessment of suitability for use of equipment by

airborne particle concentration

1 Scope

This document applies to the assessment of the suitability of equipment (e.g., machinery, measuring equipment, process equipment, components and tools) for use in cleanrooms and associated controlled environments. As specified in GB/T 25915.1, airborne particle sizes range from 0.1 μm to equal to or larger than 5 μm .

The following items are not covered by this document:

- assessment of suitability with respect to biocontamination;
- testing for suitability of decontamination agents and techniques;
- cleanability of equipment and materials;
- requirements on design of equipment and selection of materials;
- physical properties of materials (e.g., electrostatic, thermal properties);
- optimizing performance of equipment for specific process applications;
- selection and use of statistical methods for testing;
- protocols and requirements for local safety regulations.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to its application. For dated references, only the version corresponding to that date is applicable to this document; for undated references, the latest version (including all amendments) is applicable to this document.

GB/T 25915.1-2021, Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015, MOD)

Note: There is no technical difference between the referenced content of GB/T 25915.1-2021 and the referenced content of ISO 14644-1:2015.

Note: Testing of equipment for ISO Class 1 suitability is accomplished in an ISO Class 1 environment.

The test environment shall not contain any other particle sources than the equipment to be assessed to avoid influencing the measurement results. This can be achieved using unidirectional airflow.

6.2.6 Approximate identification of HPC location(s)

For equipment with moving elements/components, there is frequently a significant variation in the concentration of particles generated between different zones of the equipment.

The intention of the cleanroom suitability methodology is to include those zones that contain HPC(s) within the suitability assessment measurements. It is essential that moving elements/components, utilities, interfaces, etc., are included in this assessment.

Note: The number of moving elements/components can influence the number of approximate HPC locations.

Although safe sampling can impose sampling position limitations, the objective is to vary the distance and/or position of the sampling probe in order to identify the HPC location(s).

The approximate identification shall be performed using a systematic scan of the equipment with a light scattering discrete airborne particle counter (LSAPC). The entire system including product spaces of the equipment should be scanned by the sampling probe. While the equipment is scanned using a sampling probe of the LSAPC, a correlation between its position and the HPC is acquired. Depending on the make/model of the LSAPC used, the feedback required to establish this correlation can use visual and/or acoustic means. The sample acquisition time shall be chosen to ensure that the location of the HPC(s) can be identified appropriately.

Previously identified contamination sources (output of any pre-tests) should be included in this part of the assessment.

The conclusions of the measurements undertaken for the approximate identification of particle sources are qualitative in nature.

6.2.7 Precise determination of HPC location(s)

Following the approximate identification, a precise determination of HPC location(s) is carried out using a LSAPC assessing at least 28.3 L/min of air with a probe having an openness limited to 20 cm². During this measurement stage, the geometrical position of the LSAPC sampling probe is adjusted to achieve the optimum sampling of the HPC location. Probe position shall be set and recorded. This is repeated for each HPC location identified under 6.2.6.

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