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(JACA/JSA)

**Cleanrooms and associated
controlled environments—Part 2:
Monitoring to provide evidence of
cleanroom performance related to
air cleanliness by particle
concentration**

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In the event of any doubts arising as to the contents,
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Foreword

This Japanese Industrial Standard has been established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by Japan Air Cleaning Association (JACA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

Consequently **JIS B 9920:2002** has been withdrawn and partially replaced with this Standard.

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Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public or utility model rights.

JIS B 9920 series consists of the following 2 parts under the general title *Cleanrooms and associated controlled environments*:

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

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

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 14644-2:2015**, Edition 2, without any modification in technical contents of the corresponding International Standard.

The dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard describes the monitoring to assure that a cleanroom or clean zone performs and maintains the required control of air cleanliness by particle concentration. Also, this Standard 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.

This Standard does not address condition monitoring of aspects such as vibration or general maintenance of the engineering systems. Also, this Standard does not cover the monitoring of ultrafine particles (particles smaller than 0.1 μm) that are outside the specified lower threshold particle-size range (0.1 μm to 5 μm).

NOTE The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

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* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standards and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS B 9920-1 *Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration*

NOTE Corresponding International Standard: ISO 14644-1:2015 *Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration*

JIS B 9921 Light scattering airborne particle counter for clean spaces

3 Terms and definitions

For the purpose of this Standard, the terms and definitions given in **JIS B 9920-1**, and the following apply.

3.1

test

procedure undertaken in accordance with a defined method to determine the performance of cleanroom or clean zone

3.2

monitoring

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

NOTE 1 Monitoring may be continuous, sequential or periodic; and if periodic, the frequency should be specified.

NOTE 2 This information may be used to detect trends in operational state and to provide process support.

3.3

action level

level of a parameter set by the user which, when exceeded, requires immediate intervention, including investigation of cause and corrective action

3.4

alert level

level of a parameter set by the user giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention or corrective action

4 Creating, implementing and maintaining a monitoring plan

4.1 Principle

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.

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:

- use appropriate risk assessment tools to understand, evaluate and document the risk of adverse contamination events;
- develop a written monitoring plan;
- review and approve the plan;

- implement the plan by performing the monitoring;
- analyse the data derived from the monitoring activity, undertake trend analysis where appropriate and report performance;
- implement and document actions or corrective actions required;
- undertake periodic review of the monitoring plan.

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.

4.2 Risk assessment

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

A risk assessment shall be undertaken in order to

- 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
- determine the monitoring requirements to provide evidence of performance.

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

4.3 Monitoring plan

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

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

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

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

4.3.4 Accuracy, maintenance and calibration of monitoring instrumentation.

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

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 Annex B.

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