Nederlandse norm

NEN-EN-ISO 14644-14

(en)

Schone ruimten en gelijksoortige beheerste omgevingen - Deel 14: Beoordeling van geschiktheid voor het gebruik van apparatuur voor deeltjesconcentratie in lucht (ISO 14644-14:2016,IDT)

Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016,IDT)

ICS 13.040.35

oktober 2016

Als Nederlandse norm is aanvaard:
- EN ISO 14644-14:2016,IDT
- ISO 14644-14:2016,IDT

Normcommissie 301003 "Cleanrooms and associated controlled environments"

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14644-14

October 2016

ICS 13.040.35

English Version

Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

Salles propres et environnements maîtrisés apparentés - Partie 14: Évaluation de l'aptitude à l'emploi des équipements par la détermination de la concentration de particules en suspension dans l'air (ISO 14644-14:2016)

Reinräume und zugehörige Reinraumbereiche - Teil 14: Bewertung der Reinraumtauglichkeit von Geräten durch Partikelkonzentration in der Luft (ISO 14644-14:2016)

This European Standard was approved by CEN on 13 August 2016.

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Ref. No. EN ISO 14644-14:2016 E

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European foreword

This document (EN ISO 14644-14:2016) has been prepared by Technical Committee ISO/TC 209 “Cleanrooms and associated controlled environments” in collaboration with Technical Committee CEN/TC 243 “Cleanroom technology” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

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The text of ISO 14644-14:2016 has been approved by CEN as EN ISO 14644-14:2016 without any modification.

INTERNATIONAL STANDARD

ISO 14644-14

First edition
2016-09-15

Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

Partie 14: Évaluation de l'aptitude à l'emploi des équipements par la détermination de la concentration de particules en suspension dans l'air

Reference number
ISO 14644-14:2016(E)

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Foreword

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.

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).

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

A list of all part in the ISO 14644 series, published under the general title *Cleanrooms and associated controlled environments*, can be found on the ISO website.

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear and life sciences (pharmaceuticals, medical devices, food and healthcare).

This part of ISO 14644 links the cleanroom classification of air cleanliness by particle concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

INTERNATIONAL STANDARD **ISO 14644-14:2016(E)**

Cleanrooms and associated controlled environments —

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

1 Scope

This part of ISO 14644 specifies a methodology to assess the suitability of equipment (e.g. machinery, measuring equipment, process equipment, components and tools) for use in cleanrooms and associated controlled environments, with respect to airborne particle cleanliness as specified in ISO 14644-1. Particle sizes range from 0,1 µm to equal to or larger than 5 µm (given in ISO 14644-1).

NOTE Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptation of the assessment methodology can be required.

The following items are not covered by this part of ISO 14644:

— 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 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.

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

3 Terms and definitions

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

3.1
cleanliness
condition not exceeding a specified level of contamination

3.2
cleanroom
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

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

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.

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

[SOURCE: ISO 14644-1:2015, 3.1.1]

3.3
cleanroom suitability
ability to maintain the critical control attributes or condition of any clean zone when used as intended

Note 1 to entry: For the purposes of this part of ISO 14644, the assessment is based on airborne particle concentration.

3.4
clean zone
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

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

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.

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.

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

[SOURCE: ISO 14644-1:2015, 3.1.2]

3.5
decontamination
reduction of unwanted matter to a defined level

[SOURCE: ISO 14644-7:2004, 3.7]

3.6
equipment
system designed for specific function(s), integrating materials, components and/or controls

EXAMPLE Testing and manufacturing equipment and machinery, equipment for transport and handling, storage units, tools, furniture, doors, ceilings, Information Technology (IT) hardware and handling robots.

3.7
test environment
space in which the test is carried out, described by a set of parameters

4 General outline of the assessment

Cleanroom suitability assessment has the following outline.

a) Before the assessment can be executed, the customer and supplier shall agree upon the particle size range(s), with reference to air cleanliness by particle concentration, designated by ISO Class *N* as given in ISO 14644-1 and item to be tested including the modes of operation(s). Each selected mode of operation shall be assessed separately.

b) A short description regarding how the equipment will be used in routine operation (with operating parameters) shall be given to promote setting the appropriate testing condition and parameters.

c) Visual inspection (see Clause 5).

d) The procedure described in Clause 6 shall be used in order to establish a link to the ISO 14644-1 classification system.

e) Execution of measurements (see 6.2).

f) The data gathered will be processed and the results linked to the ISO classification system (see 6.2.9 and 6.2.10).

g) The results obtained shall conclude the equipment's cleanroom suitability; the statement shall follow the defined designation (see Clause 8).

Additional optional tests (not linked to ISO class *N*), such as total emission of particles or operational life cycle test, are described in Annex B.

The method described in B.4 may be used to determine the average total emission of equipment and provides data that may be used to determine the particle load on a cleanroom.

5 Visual inspection

Visual inspection of the equipment shall be carried out before and after any measurement-based assessment.

The visual inspection shall ensure that all packaging has been removed and that the equipment is undamaged and that it is correctly assembled and appropriately connected to its required utilities.

Visual surface cleanliness shall be qualitatively assessed such that any subsequent quantifiable tests shall not be compromised. This part of the visual inspection can include assessment for particles, surface films or inappropriately located lubricants.

The objectives of this inspection are the following:

— identify contamination, such as particles and films originated from manufacturing, packaging, transportation or initial assembly;

— identify contamination that has withstood any prior decontamination process.

It is not intended that this inspection will provide a measurement of surface cleanliness.

Depending on the location of the contamination, the results from visual inspection shall be

— recorded and available for comparison with the post-test visual inspection of surface cleanliness, and

— used as basis to direct a repeat or improved decontamination process.

Detection efficiency of visible contamination on equipment will depend upon the following factors:

— the accessibility and orientation of the surface to be inspected;

— the materials used for equipment construction, their surface condition and treatment;

— the viewing parameters (e.g. illumination, field of view, vision magnification, viewing distance).

6 Assessment of suitability by airborne particle concentration measurements

6.1 General

The objective of Clause 6 is to describe a suitability methodology using measurement of airborne particle emissions at critical locations. By including measurement locations at, or close to, the locations of high particle concentration (HPC), the intended use of the application is reflected.

This assessment methodology enables a link to the classification system of ISO 14644-1, in one or more particle size ranges to be established.

In order to assess the cleanroom suitability of equipment, it is intended that the location(s) with HPC emitted by the equipment be identified and included in the final suitability measurement. Since the size distribution of the emitted particles is not known in advance, it is required that more than one particle size range is measured. Ideally, three widely spread particle size ranges should be selected.

Subsequently, the particle concentrations thus determined from equipment assessment are compared with the air cleanliness by particle concentration limits for ISO Class *N* as specified in ISO 14644-1.

For the equipment to be tested, it shall be ensured that cleanroom compliant design principles have been incorporated. These principles include, but are not limited to, the following:

— selection of appropriate materials and surface finishes;

— avoidance of static air zones;

— design principles for cleanability;

— considerations for maintenance.

This measurement methodology is not intended to determine overall emission rates for the equipment under test.

6.2 Assessment procedure

6.2.1 Overview

The flowchart in Figure 1 gives an overview of the necessary assessment steps.

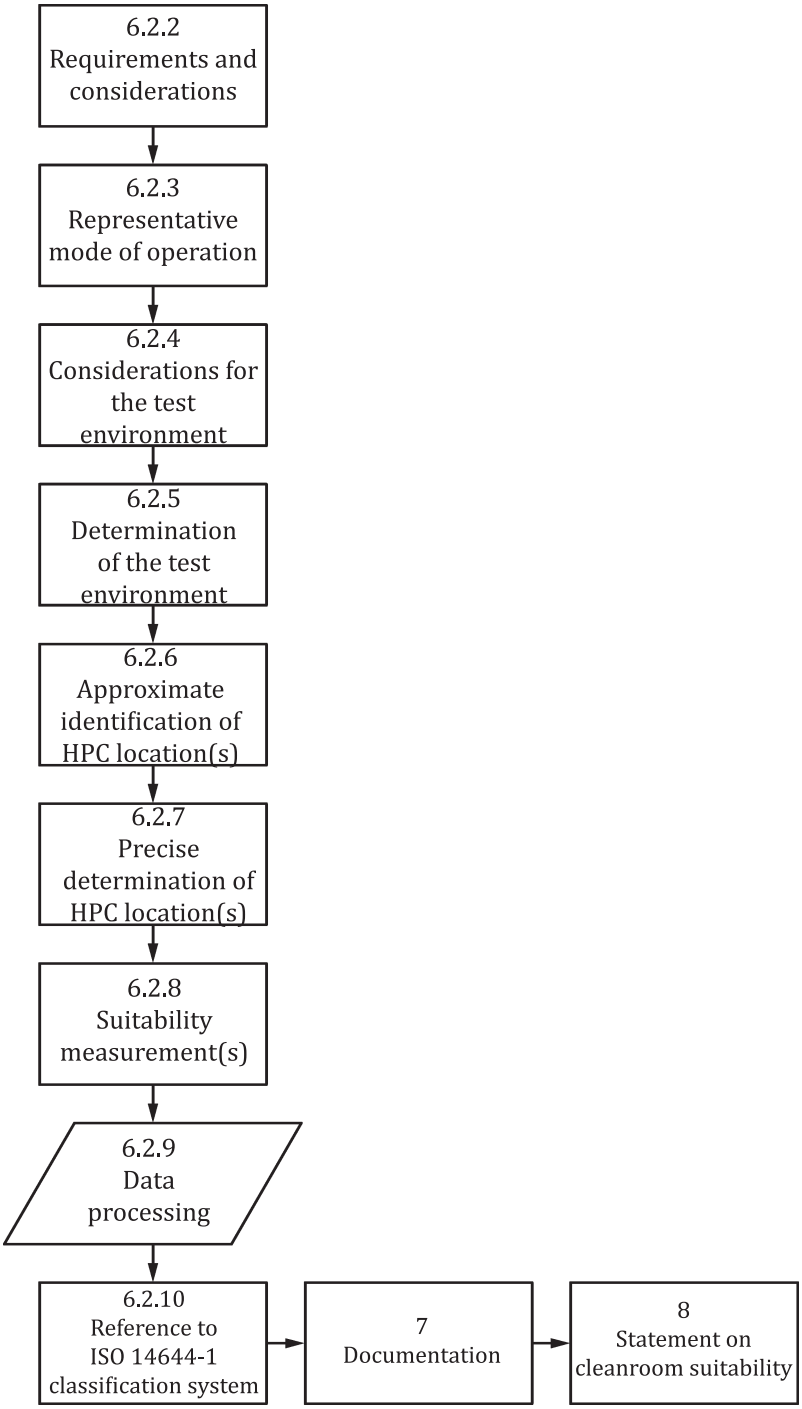

Figure 1 — Overview of the assessment procedure

6.2.2 Requirements and considerations

When defining the scope of the suitability assessment, aspects that could influence the assessment results shall be considered, for example (but not limited to):

— variability between the same type of equipment;

— pre-conditioning of the equipment to be tested (accumulated operating hours);

— running-in of equipment.

The test environment shall be agreed upon before testing (see 6.2.4 and 6.2.5).

6.2.3 Representative mode of operation

A representative mode of operation of equipment shall be defined, which ensures that particle emission sources are detected. The mode of operation shall reflect the intended use of the equipment. If the equipment can be operated in different modes of operation (e.g. with or without product), it shall be decided which of these different modes form part of the assessment. Equipment parameters of operation shall be defined and agreed upon before testing.

If standardized procedures exist, these procedures shall be taken into consideration. For non-standardized handling, the manner of handling chosen shall be documented, and reasons for this choice shall be given.

6.2.4 Considerations for the test environment

The objective of these tests is to characterize and select a test environment prior to installing the equipment that is to undergo assessment for cleanroom suitability.

Consideration should be given to whether all or some pre-tests are conducted at more than one measuring plane. An illustration of selected measurement plane(s) may be added.

Information on measurement test methods and equipment can be obtained from ISO 14644-1 and ISO 14644-3. The following shall be considered.

— Airborne particle concentration measurement: The aim is to confirm that the test environment is at least one ISO class *N* (as given in ISO 14644-1) cleaner than the cleanroom or clean zone within which the equipment is intended to be used.

— Airflow velocity measurement: Guidance range for vertical velocity should be in the range of 0,3 m/s to 0,5 m/s.

— Temperature: Guidance range should be 18 °C to 25 °C.

— Humidity: Guidance range should be 30 % RH to 70 % RH.

Additional informative pre-tests can include the following:

— airflow direction test and visualization;

— electrostatic and ion generator test;

— particle deposition test.

The results of the considerations shall be used for the determination of the test environment (see 6.2.5).

6.2.5 Determination of the test environment

The test environment shall provide a background level at least one ISO Class *N* (as given in ISO 14644-1) cleaner than the cleanroom or clean zone in which the equipment is intended to be used.

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.

The objective of this stage of the assessment is to determine the measuring locations of HPC(s) that shall be included in the subsequent final suitability measurement. 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 cm^2. 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.

NOTE The number of measuring locations will be influenced by the number of moving elements/components.

6.2.8 Suitability measurement(s)

The HPC location(s) with the highest particle concentration obtained in 6.2.7 shall be selected for the suitability measurement. Select at least one HPC location. Measurement locations of specific point of interest, e.g. associated with product handling, can be added.

Perform particle concentration measurement(s) at selected location(s) using a LSAPC as described in 6.2.7.

The following parameters, required for performing the suitability measurements, shall be specified and documented:

— modes of operation of the equipment;

— number of operating cycles of the equipment;

— positioning of the equipment to be tested;

— HPC location(s) derived from approximate identification and precise determination;

— additional measurement point(s) derived from a specific point of interest (e.g. product critical location);

— positioning of the measuring LSAPC sampling probe(s);

— particle size range(s) being assessed;

— sampling volume and time;

— number of consecutive independent readings at each individual measurement location. For statistical reasons this number shall be ≥100.

NOTE The acquired data from the LSAPC can be captured, processed and then analysed using suitable software in order to avoid transcription errors.

6.2.9 Data processing

6.2.9.1 General

The following data processing procedure shall be applied to the readings of particle concentrations obtained in 6.2.8.

The readings per specified particle size range obtained in 6.2.8 are subject to statistical analysis. In most cases of the measurements, where the expected value (mean value, $\bar{x}$) for the particle size under consideration is assumed to be larger than 10 particles per measurement, procedure a) (see 6.2.9.2) shall be applied. In case that the expected value of the measurements is 10 or below, procedure b) (see 6.2.9.3) shall be applied.

6.2.9.2 Procedure a)

The arithmetic mean of the particle numbers is calculated using Formula (1):

$$\bar{x} = \frac{\left(x_{i,1} + x_{i,2} + \ldots + x_{i,n}\right)}{n} \tag{1}$$

where

$\bar{x}$ is the mean value;

x_i is a single reading in the consecutive measuring of a particle size range i;

n is the number of readings.

For the calculation of the standard deviation, Formula (2) is used:

$$s = \sqrt{\frac{\left(x_{i,1} - \bar{x}\right)^2 + \left(x_{i,2} - \bar{x}\right)^2 + \ldots + \left(x_{i,n} - \bar{x}\right)^2}{\left(n-1\right)}} \tag{2}$$

where

s is the standard deviation;

x_i is a single reading in the consecutive measuring of a particle size range i;

$\bar{x}$ is the mean value;

n is the number of readings.

Formula (3) shall be used to calculate the upper confidence limit:

$$P_u = \bar{x} + 1,66 \times \frac{s}{\sqrt{n}} \quad (3)$$

where

P_u is the upper confidence limit for a confidence level of $(1 - \alpha) = 95$ %;

$\bar{x}$ is the mean value [according to Formula (1)];

s is the standard deviation [according to Formula (2)];

1,66 is the factor from Student's t distribution.

NOTE $t_{\alpha,v} = 1,66$ for the upper confidence limit for a confidence level of $(1 - \alpha) = 95$ % and 100 individual measured values.

Formula (4) shall be used to calculate the z-value:

$$z = \sqrt{n}\,\frac{G - P_u}{s} \quad (4)$$

If the calculated value of z according to Formula (4) is larger than 1,645, the class limit G will not be exceeded with a confidence level of 95 %.

The derived classification number N which corresponds to the class limit G (maximum permitted particles of the considered size range within the ISO class number N) will be used in 6.2.10 to establish reference to the ISO 14644-1 classification system.

NOTE A detailed example is given in Annex A.

6.2.9.3 Procedure b)

If the expected value (mean value, $\bar{x}$) of the measurement result is less than or equal to 10, Table 1, which is based on Poisson statistics, is used to determine the upper confidence limit.

The mean value is calculated using Formula (1).

Table 1 — Upper confidence limit for procedure b)

Mean value $\leq \bar{x}$	Upper confidence limit P_u
0,051 2	0
0,355	1
0,818	2
1,366	3
1,970	4
2,613	5
3,285	6
3,981	7
4,695	8
5,425	9
6,169	10
NOTE Table 1 is based on Poisson distribution for 95 % confidence limit.	

Table 1 *(continued)*

Mean value $\leq \overline{x}$	Upper confidence limit P_u
6,924	11
7,690	12
8,464	13
9,247	14
10,000	15
NOTE Table 1 is based on Poisson distribution for 95 % confidence limit.	

The derived P_u will be used in 6.2.10 to establish reference to ISO 14644-1 classification system.

NOTE A detailed example is given in Annex A.

6.2.10 Reference to ISO 14644-1 classification system

For each particle size range measured, a reference to the ISO 14644-1 classification system shall be made. For this purpose, ISO 14644-1:2015, Table 1 is used to identify the respective ISO class number *N*.

NOTE 1 ISO 14644-1:2015, Annex F provides calculation for intermediate class numbers and threshold particle sizes.

If a LSAPC is used that measures an air volume smaller or larger than one cubic meter per time interval, the class limits *G* (maximum permitted particles of the considered size range within the ISO class number *N*) shall be calculated to derive the corresponding figure for *G*.

If P_u (see 6.2.9) is less than or equal to *G*, the reference to the measured particle size range and respective ISO Class *N* is established.

If P_u is larger than *G*, then the next higher ISO class number *N* shall be used.

The comparison shall be done for each specified particle size range.

The highest ISO class number *N* (as given in ISO 14644-1) of the specified particle size ranges shall be chosen for the cleanroom suitability assessment (see Clause 8). If more than one HPC location has been taken into account, the highest number of the ISO Class *N* (as given in ISO 14644-1) shall be chosen for the cleanroom suitability assessment.

NOTE 2 A detailed example is given in Annex A.

7 Documentation

7.1 General

The documentation shall contain all information required to reproduce the test for suitability.

Where applicable, the items listed in subsequent sections are recommended as minimum information. Further relevant items may be added to the list.

7.2 Common documentation requirements

a) description of test

b) reference to standards and/or guidelines used

c) date

d) place where the assessment is carried out

e) person(s) performing the test

f) customer

g) description of piece of equipment including mode(s) of operation considered

h) marking/identification of test object

7.3 Documentation for visual inspection

In addition to common documentation requirements:

— observations of the equipment to be tested; general condition, damage and compatibility with the utilities and services connection.

— For visual inspection of surfaces:

  — description of the visual inspection approach (e.g. normal or magnified; additional light sources, etc.);

  — description of any "critical" surfaces selected for inspection (with justification). Diagrams and/or photographs to be included.

  — In addition, for each surface location of the equipment visually inspected:

    — vision magnification when used;

    — description of any additional light source used;

    — distance between inspector and the surface being examined;

    — description of contamination observed;

    — results from any assessment used to establish contamination mobility, including whether any contamination was removed during this assessment.

7.4 Documentation for assessment of test environment

In addition to the common documentation requirements, the type designations of each measuring instrument/apparatus used and their calibration status shall be required.

a) airborne particle concentration;

  1) measurements at the agreed size range(s),

  2) derived test environment classification,

  3) sampling probe description and orientation,

  4) location(s) of sampling,

b) airflow velocity measurement readings and their locations;

c) temperature measurement readings and their locations;

d) humidity measurement readings and their locations;

e) additional informative pre-tests;

  1) airflow direction and visualization, method description, results summary and reference to any audio-visual files,

2) electrostatic and ion generator tests; method descriptions and results summary,

3) particle deposition test; method descriptions and results summary.

7.5 Documentation for classification measurement

a) test setup photo (and drawing if applicable);

b) ambient conditions/installation conditions of the test environment;

1) temperature,

2) relative humidity,

3) mean air velocity,

4) ISO Class *N* in accordance with ISO 14644-1,

c) pre-tests that have been carried out and their results;

d) agreed representative mode of operation chosen for the assessment;

e) description of measuring probe location(s) and their justification;

f) description of operating parameters;

g) any extraordinary observations during the measurement(s);

h) serial number/working range of LSAPC used, including reference to calibration certificate;

i) type of probe;

j) duration of measurement;

k) number of measurements taken per location;

l) sampling volume and time;

m) particle size ranges under consideration and their results;

n) analysis of data;

o) result of visual inspection of the test object after the measurement.

8 Statement on cleanroom suitability

The cleanroom suitability of the equipment shall be stated in the following way:

a) *An assessment including an agreed upon representative mode of operation, according to ISO 14644-14 showed that:*

Equipment Z has cleanroom suitability for use within a cleanroom of ISO Class X (Y µm).

where

X is the ISO class number *N*, highest value according to 6.2.10;

Y is the particle size range measured;

Z is the designation of equipment and unique identification (e.g. type, serial number, manufacturer).

b) *The representative mode of operation is as stated in the documentation.*

The documentation according to Clause 7 (including results of visual inspection) is an integral part of the statement on cleanroom suitability and shall be attached.

Annex A
(informative)

Example for data processing deriving from measurements

A.1 General

The following facts are assumed:

— 0,1 µm, 0,2 µm and 5,0 µm are specified as particle size ranges;

— six particle size ranges were measured;

— a LSAPC was used with a sampling volume of 28,3 l/min (1 ft^3/min);

— 100 consecutive measurements for the suitability measurements were performed.

A.2 Measurement values at one single HPC

For this example, the following individual values in Table A.1 have been obtained during suitability measurement.

Table A.1 — Values measured per 28,3 l measuring air volume during classification measurements

Value number	≥0,1 µm	≥0,2 µm	≥0,3 µm	≥0,5 µm	≥1,0 µm	≥5,0 µm
1	1	0	0	0	0	0
2	33	11	3	3	1	1
3	27	13	13	10	9	3
…						
100	0	0	0	0	0	0

Applying Formula (1) and Formula (2) provides the most important data that are needed to assess the cleanroom suitability of the equipment (see Table A.2).

Table A.2 — Statistical data of the suitability measurement

	≥0,1 µm	**≥0,2 µm**	**≥0,3 µm**	**≥0.5 µm**	**≥1,0 µm**	**≥5,0 µm**
Number of measured values, n	100	100	100	100	100	100
Mean value, $\bar{x}$	16,33	7,39	5,88	4,19	2,87	0,90
Standard deviation, s	68,12	28,13	22,34	15,79	10,70	2,27
Maximum	586	216	166	116	74	10
Minimum	0	0	0	0	0	0

The readings per specified particle size range obtained in 6.2.8 are subject to statistical analysis. In most cases of the measurements, where the expected value (mean value) for the particle size under consideration is assumed to be larger than 10 particles per measurement, procedure a) (see 6.2.9.2) shall be applied. In case that the expected value of the measurements is 10 or below, procedure b) (see 6.2.9.3) shall be applied.

To determine which statistical procedure according 6.2.9 is to be used, the expected values (mean values) for the particle size under consideration are reviewed. Therefore, ≥0,1 µm particle size range is subjected to procedure a) (see 6.2.9.2), ≥0,2 µm and ≥5,0 µm particle size range are subjected to procedure b) (see 6.2.9.3).

For particle size range ≥0,1 µm, Formula (3) is used.

$$P_u = \bar{x} + 1,66 \times \frac{s}{\sqrt{n}} \tag{A.1}$$

$$P_u = 16,33 + 1,66 \times \frac{68,12}{10} = 27,64 \tag{A.2}$$

For ISO Class 3 and the particle size range ≥0,1 µm, the limit G is 28 particles per sampling volume of 28,3 l (see Table A.3).

$$z = 10\frac{\left(28 - 27,64\right)}{68,12} = 0,05 \tag{A.3}$$

As the calculated value z = 0,05 does not fulfil the demand of the confidence level (z has to be larger or equal to 1,645), the corresponding ISO class number N = 3 is not applicable (see ISO 14644-1).

For the ISO Class 4 and the particle size range ≥ 0,1 µm, the limit G is 283 particles per sampling volume of 28,3 l.

$$z = 10\frac{\left(283 - 27,64\right)}{68,12} = 37,49 \tag{A.4}$$

As the calculated value z = 37,49 fulfils the demand of the confidence level (z has to be larger or equal to 1,645), the corresponding ISO class number N = 4 is applicable (see ISO 14644-1).

For particle size range ≥0,2 µm

As in the previous measurement example, the assumed value (mean value) of the particle size range >0,2 µm has a value of 7,39, which is smaller than 10. The probability of not exceeding the given class limit values G has to be calculated with Table A.4, based on Poisson statistics.

Table A.4 leads to an upper confidence limit of P_u = 12.

In the above-mentioned example, P_u = 12 is smaller than the class limit G = 67 (see Table A.3) of the particle size ≥0,2 µm at ISO Class 4.

The calculations performed demonstrate cleanroom suitability for the equipment, as derived from the measurements, for the particle size range ≥0,2 µm for ISO Class 4 (0,2 µm), as the likelihood of not exceeding the limit is ≥95 %.

For particle size range ≥5,0 µm

As in the previous measurement example, the assumed value (mean value) of the particle size range >5,0 µm has a value of 0,90, which is smaller than 10. The probability of not exceeding the given class limit values G has to be calculated with Table A.4, based on Poisson statistics.

Table A.4 leads to an upper confidence limit of P_u = 3.

In the above-mentioned example, P_u = 3 is smaller than the class limit G = 8,28 (see Table A.3) of the particle size ≥5,0 µm at ISO Class 6.

The calculations performed demonstrate cleanroom suitability for the equipment, as derived from the measurements, for the particle size range ≥5,0 µm for ISO Class 6 (5,0 µm), as the likelihood of not exceeding the limit is ≥95 %.

Establishing reference to ISO 14644-1:2015, Table 1

For establishing reference to ISO 14644-1:2015, Table 1, the following has to be taken in consideration.

Sampling volume was 28,3 l, which is equivalent to 0,028 3 m^3. Multiplication of the respective figure of ISO 14644-1:2015, Table 1 leads to the corresponding figures for *G* in Table A.3.

Table A.3 — Calculated *G* figures

ISO class number *N*	Calculated class limit *G* for specified particle size ranges		
	≥0,1 µm	≥0,2 µm	≥5,0 µm
1	0,28	0,07	0,00
2	2,83	0,67	0,00
3	28	6,70	0,01
4	283	67	0,08
5	2 832	671	0,83
6	28 321	671 2	8,28
7	283 206	671 20	83
8	2 832 059	671 198	830
9	28 320 589	671 198 0	829 8

NOTE Grey areas indicate particle size ranges not intended for classification according to ISO 14644-1.

Table A.4 — Upper confidence limit for procedure b)

Mean value $\leq \overline{x}$	Upper confidence limit P_u
0,051 2	0
0,355	1
0,818	2
1,366	3
1,970	4
2,613	5
3,285	6
3,981	7
4,695	8
5,425	9
6,169	10
6,924	11
7,690	12
8,464	13
9,247	14
10,000	15

NOTE Table A.4 is based on Poisson distribution for 95 % confidence level.

A.3 Result

For the specified particle size ranges, the following ISO class numbers have been established.

≥0,1 µm ISO class number *N* equals 4

≥0,2 µm ISO class number *N* equals 4

≥5 µm ISO class number *N* equals 6

According to 6.2.10, the highest ISO class number has to be chosen for the cleanroom suitability assessment:

≥5 µm ISO class number *N* equals 6

The methodology, which is based on the measurement data and data processing of this example, leads to the equipment's overall assessment:

"An assessment including an agreed upon representative mode of operation, according to *ISO 14644-14* showed that:

Equipment Z has cleanroom suitability for use within a cleanroom of ISO Class 6 (≥ 5 µm)."

Annex B
(informative)

Additional optional tests

B.1 General

To obtain information about impact on processes and adjacent environment, additional tests can be performed as an option.

B.2 Assessment in different phases of equipment operational life cycle

The assessment of the cleanroom suitability is typically performed on new equipment that has undergone limited operational running.

The particle emission of equipment or single elements/components of it will vary over its operational life cycle. B.2 makes the following assumption in relation to particle generation over the equipment operational life cycle.

Particle emission, over time, can be described in three phases.

a) Run-in phase: When equipment with moving elements/components begins to operate, the particle emission changes over time; typically the emission decreases.

b) Steady-state phase: Particle emissions fluctuate in time, centred about a mean value that is characteristic of this phase.

c) Deterioration phase: Increased wear of the equipment or single elements/components typically leads to higher emission rates.

Carrying out measurements according to 6.2, either within differing phases of the equipment operational life cycle or for longer sampling durations, may provide data for trend analysis.

B.3 Particle deposition measurement method

A particle distribution deposition test makes use of one or more witness plates which can be inspected *in situ* or off line. The result is expressed in the change of surface cleanliness by particle concentrations (according to ISO 14644-9) on the witness plate before and after exposure. The result can be expressed by the number of particles larger than particle size D (µm) per unit surface area per unit of time.

B.4 Total emission measurement method

B.4.1 General

The total emission measurement methodology provides data that enable an assessment of the potential impact of the particle load, emitted by the equipment under test, on the cleanroom during operation.

NOTE This impact might be used during design of a cleanroom or when introducing new equipment into an existing cleanroom.

The total emission method is appropriate for non-unidirectional cleanrooms or clean zones with classification ISO Class 6 to 9.

The total emission measurement method does not identify local particle sources and the result represents the average of the total emission of particles over time including HPC locations. Variations of particle emissions will be averaged.

The concentration of totally emitted particles of the equipment under test per time and volume of air are compared with the particle concentration of supply air per time and volume of air.

A visual inspection of the equipment under test and the test environment (see Clause 5) should be executed prior to the measurement.

Similar requirements and considerations as in the HPC method should be observed (see 6.2.2).

NOTE Various total emission methods are described elsewhere (IEST-RP-CC026.2, JIS B 9926, VDI 2083–9.1). In this part of ISO 14644, the application for cleanroom suitability is addressed.

B.4.2 Establishment of test environment

The test environment should enclose the equipment to be tested completely and should be of the same magnitude of volume the equipment needs for operation.

The test environment should provide a unidirectional clean airflow (HEPA or ULPA filtered) or a background level at least one class better than the desired airborne cleanliness by particle concentration class in which the equipment will be used.

Since the test is meant for ISO Class 6 to 9, an air supply or environment at ISO Class 5 or better is recommended.

The test environment should not contain other particle sources which influence the measurement results.

The particle concentration of the air that exits the test environment should be measured. The intention is to measure as much air volume as possible. It should be ensured that the measured air sample is representative for the total load. Mixing of air and funnel type contraction might be necessary to achieve even distribution of contamination.

B.4.3 Total emission measurement set-up

In a total emission measurement, the tested equipment will increase the particle concentration of the air passing through the test environment. To measure this increase, the background concentration of the test set-up should be measured first. Therefore, the following pre-tests should be executed:

a) determine the air cleanliness of the test environment;

b) perform a measurement without equipment or with equipment at rest. Record the results of the background measurement (locations and concentrations);

c) non-airborne macro particles could be measured by particle deposition measurement (see B.3).

B.4.4 Total emission measurement of equipment

After the equipment is put into the test environment and set to operation or kept at rest, the particle concentration of the exiting air should be measured with the same particle counting system as in the pre-test.

B.4.5 Calculation of average total emission rate of equipment

The results of the total emission measurement (locations and concentrations) should be recorded. The results of the pre-test should be subtracted.

The average total particle emission of the equipment is determined using Formula (B.1):

$$P = \Delta C \times Q \tag{B.1}$$

where

P is the equipment emission rate in particles/time unit;

ΔC is the increase in particle concentration due to equipment presence/operation in particles/m^3;

Q is the air volume flow rate in m^3/time unit.

Second, minute or hour can be selected as the time unit.

B.4.6 Assessment of the impact of the total particle load

For the assessment of the impact of the total particle load, the emission rate and volume and air change rate of the intended operating environment should be taken into consideration.

Bibliography

[1] ISO 8573-8:2004, *Compressed air — Part 8: Test methods for solid particle content by mass concentration*

[2] ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

[3] ISO 14644-7:2004, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

[4] ISO 14644-9, *Cleanrooms and associated controlled environments — Part 9: Classification of surface cleanliness by particle concentration*

[5] AIR1167, *Environmental criteria and tests for aerospace ground equipment in support of space systems*

[6] IEST-RP-CC002.3, *Unidirectional — Flow clean-air devices*

[7] IEST-RP-CC013.3, *Calibration procedures and guidelines for select equipment used in testing cleanrooms and other controlled environments*

[8] IEST RP-CC026.2, *Cleanroom operations*

[9] IEST-RP-CC028.1, *Minienvironments*

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[11] SEMI E49-1104 (Reapproved 1211), *Guide for high purity and ultrahigh purity piping performance, subassemblies, and final assemblies*

[12] SEMI E137-0705 (Reapproved 1111), *Guide for final assembly, packaging, transportation, unpacking, and relocation of semiconductor manufacturing equipment*

[13] SEMI F28-1103 (Reapproved 0710), *Test method for measuring particle generation from process panels*

[14] SEMI F70-0611, *Test method for determination of particle contribution of gas delivery system*

[15] SEMI G67-0996 (Reapproved 0811), *Test method for the measurement of particle generation from sheet materials*

[16] VDI 2083-9.1, *Clean room technology — Compatibility with required cleanliness and surface cleanliness*

ISO 14644-14:2016(E)

ICS 13.040.35

Price based on 21 pages

Waarom betaalt u voor een norm?
Normen zijn afspraken voor en door de markt, zo ook deze norm. NEN begeleidt het gehele normalisatieproces. Van het bijeenbrengen van partijen, het maken en vastleggen van de afspraken en het bieden van hulp bij de toepassing van de normen. Om deze diensten te kunnen bekostigen betalen alle belanghebbende partijen die aan tafel zitten voor het normalisatieproces, en u als gebruiker voor normen en trainingen. NEN is een stichting en heeft geen winstoogmerk.

Wat is nu precies de toegevoegde waarde van normen?
Stelt u zich eens voor … u wilt in het buitenland geld pinnen, maar uw bankpas past niet. Of uw nieuwe telefoon herkent uw simkaart niet. De samenstelling van de benzine over de grens is anders waardoor u niet kunt tanken. Het dagelijks leven zou zonder goede afspraken over producten, processen en diensten een stuk complexer zijn.

Het maken en vastleggen van afspraken door belanghebbende partijen noemen we het normalisatieproces. Normalisatie had vanouds betrekking op techniek en producten. Nu worden steeds vaker normen voor diensten ontwikkeld. Zo zijn er afspraken op het gebied van gezondheidszorg, schuldhulpverlening, kennisintensieve dienstverlening, externe veiligheid en MVO.

Normen zorgen voor verbetering van producten, diensten en processen; qua veiligheid, gezondheid, efficiëntie, kwaliteit en duurzaamheid. Dit ziet u op de werkvloer, in de omgang met elkaar en in de samenleving als geheel. Organisaties die normalisatie onderdeel van hun strategie maken, vergroten hun professionaliteit, betrouwbaarheid en concurrentiekracht.

Wat doet NEN?
NEN ondersteunt in Nederland het normalisatieproces. Als een partij zich tot NEN richt met de vraag om een afspraak tot stand te brengen, gaan wij aan de slag. We onderzoeken in hoeverre normalisatie mogelijk is en er interesse voor bestaat. Wij nodigen vervolgens alle belanghebbende partijen uit om deel te nemen. Een breed draagvlak is een randvoorwaarde. De afspraken komen op basis van consensus tot stand en worden vastgelegd in een document. Dit is meestal een norm. Afspraken die in een NEN-norm zijn vastgelegd mogen niet conflicteren met andere geldige NEN-normen. NEN-normen vormen samen een coherent geheel. Een belanghebbende partij kan een producent, ondernemer, dienstverlener, gebruiker, maar ook de overheid of een consumenten- of onderzoeksorganisatie zijn. De vraag is niet altijd om een norm te ontwikkelen. Vanuit de overheid komt regelmatig het verzoek om te onderzoeken of er binnen een bepaalde sector of op een bepaald terrein normalisatie mogelijk is. NEN doet dan onderzoek en start afhankelijk van de uitkomsten een project. Deelname staat open voor alle belanghebbende partijen. NEN beheert ruim 30.000 normen. Dit zijn de in Nederland aanvaarde internationale (ISO, IEC), Europese (EN) en nationale normen (NEN). In totaal zijn er ruim 800 normcommissies actief met in totaal bijna 5.000 normcommissieleden. Een goed beheer van de omvangrijke normencollectie en de afstemming tussen nationale, Europese en internationale normcommissies vereisen dan ook een zeer goede infrastructuur.

Betalen kleine organisaties net zoveel als grote organisaties?
Het uitgangspunt is dat alle partijen die deelnemen aan het normalisatieproces een evenredig deel betalen. De normcommissieleden kunnen onderling andere afspraken maken. Zo worden er wel eens afspraken gemaakt dat de grote partijen een groter deel betalen dan de kleinere bedrijven. De prijzen voor normen zijn voor iedereen gelijk. De kosten voor licenties zijn afhankelijk van de omvang van een organisatie en het aantal gebruikers.

Voordelen van normalisatie en normen
Gegarandeerde kwaliteit | Veiligheid geborgd | Bevordert duurzaamheid | Opschalen en vermarkten van nieuwe innovatieve producten | Meer (internationale) handelsmogelijkheden | Verhoogde effectiviteit en efficiëntie | Onderscheidend in de markt.

Voordelen van deelname
Invloed op de (internationale en Europese) afspraken | Als eerste op de hoogte van veranderingen | Netwerk; ook op Europees en internationaal niveau | Kennisvergroting.