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Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up (ISO/DIS 14644-4:2021)

Reinräume und zugehörige Reinraumbereiche - Teil 4: Planung, Ausführung und Erst-Inbetriebnahme (ISO/DIS 14644-4:2021)

Salles propres et environnements maîtrisés apparentés - Partie 4 : Conception, construction et mise en fonctionnement (ISO/DIS 14644-4:2021)

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13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments

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Cleanrooms and associated controlled environments —

Part 4:
Design, construction and start-up

Salles propres et environnements maîtrisés apparentés —

Partie 4: Conception, construction et mise en fonctionnement

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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).

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

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

This second edition cancels and replaces the first edition (ISO 14644-4:2001), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Normative part is extended

— The process of gathering and defining requirements is included

— Scope is extended from classified cleanrooms to additional cleanliness attributes

— The text of the whole document has been revised or clarified to aid in application

A list of all parts in the ISO 14644 series and the ISO 14698 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination and, if relevant, other forms of contamination, to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food and research and development laboratories and some applications in healthcare.

Cleanrooms and associated controlled environments are classified for air cleanliness by particle concentration (ISO 14644-1). Cleanliness attributes relating to chemicals, nano-scale particles and viable particles (microorganisms) as well as cleanliness of surfaces can also be considered.

This part of ISO 14644 is one of the series of International Standards concerned with cleanrooms and associated controlled environments prepared by ISO/TC 209.

This part, Part 4, provides guidance for the design, construction and start-up of cleanrooms, both new and those undergoing modification or refurbishment. In this edition of Part 4, a more structured approach is provided with separate normative sections on requirements, design, construction and start-up, supported by four corresponding informative annexes.

For this edition, key recommendations and considerations include:

a) A structured approach with a logical sequential flow through the design, construction and start up stages. There will normally be reviews and iterations of the requirements, contamination control concepts, layouts and other considerations. The final design should be reviewed against the requirements before construction commences and when construction is complete. The operation and performance is verified against the requirements during start-up.

b) Inclusion of other cleanliness attributes. The ISO 14644 series has parts that deal with other cleanliness attributes, namely chemicals, nano-scale particles, macro-particles and, in ISO 14698, viable particles (microorganisms) as well as cleanliness of surfaces. These other attributes should be considered if relevant, bearing in mind that the primary requirement for a cleanroom or clean zone is that it meets a classification by airborne particle concentration according to ISO 14644-1.

c) Importance of a contamination risk assessment. Assessments should be carried out to better understand the contamination risk and its impact on the process and product and to identify the critical control points in the cleanroom or clean zone

d) A clear statement of requirements in terms of what users want to do and achieve along with acceptance criteria for performance parameters. This is critical and should be captured prior to the start of the design process.

e) Ventilation effectiveness. This revision focusses on the importance of ventilation effectiveness through control of air flow patterns and clean up recovery rates. Two measures are identified: air change effectiveness and contaminant removal effectiveness.

f) Using air supply rate for calculations of contaminant removal. This will make it possible to achieve energy-efficient cleanrooms whilst achieving the required level of contamination.

g) Energy efficiency and lifecycle considerations. Energy efficiency in cleanrooms is very important and is covered by ISO 14644 part 16.

h) A clean build protocol. This is included to minimise contamination during construction of the cleanroom.

An ISO standard is not a textbook. Therefore only directly relevant information to “Cleanrooms and associated controlled environments” is included in the informative annexes. Supporting information is given in the Bibliography.

Cleanrooms and associated controlled environments —

Part 4:
Design, construction and start-up

1 Scope

This part of ISO 14644 specifies the process for creating a cleanroom from requirements through to its design, construction and start-up. It applies to new and refurbished or modified cleanroom installations. It does not prescribe specific technological or contractual means of achieving these requirements. It is intended for use by users, specifiers, designers, purchasers, suppliers, builders and performance verifiers of cleanroom installations. The primary cleanliness consideration is airborne particle concentration. Detailed checklists are provided for the various stages including requirements, design, construction and start-up, which include important performance parameters to be considered. Energy management design approaches are identified, to support an energy efficient cleanroom design. Construction guidance is provided including requirements for start-up and verification. A basic element of this standard is consideration of aspects including maintenance that will ensure continued satisfactory operation for the entire lifecycle of the cleanroom.

NOTE Further guidance in respect of the above requirements is given in annexes A to D. Normative parts 1, 2, 8, 9, 10, 12 and 17 of ISO 14644 provide complementary information. ISO 14644-7 offers guidance on design, construction and requirements for Separative Devices (clean air hoods, glove boxes, isolators and mini-environments).

The following subjects are mentioned but not addressed in this standard:

— Specific operational activities, processes to be accommodated and process equipment in the cleanroom installation

— Fire and safety regulations. The appropriate national and local regulations shall be respected and addressed during the design as appropriate.

— On-going operation, cleaning and maintenance activities, which are covered by ISO14644-5

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14644. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

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

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

ISO 14644-16, *Cleanrooms and associated controlled environments — Part 16: Energy efficiency in cleanrooms and separative devices*

In case where there are air cleanliness requirements with respect to chemicals, nano scale particles or viable particles (microorganisms), or where there are particle deposition rate requirements, the associated document should be used as a normative reference:

ISO 14644-8, *Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)*

ISO 14644-12, *Cleanrooms and associated controlled environments — Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration*

ISO 14698-1, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

ISO 14698-2, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

In cases where there are surface cleanliness requirements with respect to particles or chemicals the following additional standards should be used as a normative reference:

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

ISO 14644-10, *Cleanrooms and associated controlled environments — Part 10: Classification of surface cleanliness by chemical concentration*

ISO 14644-17, *Cleanrooms and associated controlled environments — Part 17: Particle deposition rate applications*

3 Terms and definitions

For the purposes of this part of ISO 14644 the following terms and definitions apply:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
Air change effectiveness
ACE
ratio between the recovery rate at a location or locations in a *cleanroom* (3.1.4) and the overall recovery rate of the cleanroom after a contamination event

Note 1 to entry: The recovery rate is defined and measured in accordance with ISO 14644-3[1].

[SOURCE: ISO 14644-16:2019. 3.2.7]

3.1.2
classification
method of assessing level of cleanliness against a specification for a cleanroom or clean zone

Note 1 to entry: Levels should be expressed in terms of an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air.

[SOURCE: ISO 14644-1:2015, 3.1.4]

3.1.3
cleanliness
condition not exceeding a specified level of contamination

[SOURCE: 14644-15:2017, 3.5]

3.1.4
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]

3.1.5
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]

3.1.6
commissioning
planned and documented series of inspections, adjustments, measurements, tests and verifications carried out systematically to set the installation into correct technical operation as specified

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of testing other forms of determination such as performing alternative calculations or reviewing documents

3.1.7
contaminant
any particle, chemical or microorganism that adversely affects the product or process

3.1.8
contaminant removal effectiveness
CRE
ratio of particle concentration in the air leaving the cleanroom to the average of particle concentration in the working plane of the cleanroom, when particles entering from filtered supply air are ignored

Note 1 to entry: If the air leaves the cleanroom at more than one point then the weighted average of the particle concentrations based on the relative flowrates can be used

Note 2 to entry: The number and positioning of the sampling locations for determining the average particle concentration in the working plane of the cleanroom can be based on the method given in 14644-1:2015

Note 3 to entry: The local particle concentration is dependent on the airflow pattern in the cleanroom and may vary significantly in the cleanroom. CRE in a sub-area of interest in the cleanroom may be calculated by selecting a single sampling location considered to be representative of the characteristics of the sub-area of interest

Note 4 to entry: Particles may be replaced by another airborne contaminant

[SOURCE: ISO 14644-16:2019, 3.2.5, modified — definition revised and Notes 1 to 3 to entry added].

3.1.9
customer
person or organisation that could or does receive a product or a service that is intended for or required by this person or organisation

EXAMPLE Consumer, client, end-user, retailer, receiver of product or service from an internal process beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the organisation.

[SOURCE: ISO 9001-2015, 3.2.4]

3.1.10
non-unidirectional airflow
air distribution where the supply air entering the cleanroom or clean zone mixes with the internal air by means of induction

[SOURCE: ISO 14644-1:2015, 3.2.8]

3.1.11
particle
minute piece of matter with defined physical boundaries

[SOURCE: ISO 14644-1:2015, 3.2.1]

3.1.12
setting to work
activities to bring a system from a static state into correct operation

3.1.13
source strength
number of airborne particles or other airborne contaminants considered emitted per time unit expressed as a rate

Note 1 to entry: a source can be a person, equipment or an object.

Note 2 to entry: Each rate should be indicated with a specific particle size. Particles are often emitted in multiple sizes and each size may have a different rate.

3.1.14
start-up
period following the construction of an installation when the systems and installation are brought into active service, including all commissioning activities, training and handover to the customer

3.1.15
supplier
Organisation that provides a product or a service

EXAMPLE Producer, distributor, retailer or vendor of a product or a service.

Note 1 to entry: A supplier can be internal or external to the organisation.

Note 2 to entry: In a contractual situation, a supplier is sometimes called “contractor”.

[SOURCE: ISO 9001-2015, 3.2.5 provider]

3.1.16
unidirectional airflow
controlled airflow through the entire cross-section of a cleanroom or a clean zone with a steady velocity and airstreams that are considered to be parallel

Note 1 to entry: This type of airflow results in a directed transport of particles and other contaminants from the clean zone.

[SOURCE: ISO 14644-1:2015, 3.2.7]

3.1.17
ventilation effectiveness
VE
dimensionless index that relates to both the dilution and removal of indoor airborne contaminants as it determines how effectively the filtered supply air is distributed to the critical areas in the occupied space and the contamination removed by the air leaving the room

Note 1 to entry: Ventilation effectiveness can be expressed in terms of air change effectiveness (ACE) or contaminant removal effectiveness (CRE). In cleanrooms mostly ACE is used.

3.1.18
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection, testing or other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

3.2 Installation

3.2.1
air handling unit AHU
unit or plant, comprising fan, filtration, heating, cooling, humidification/de-humidification and mixing of fresh air and recirculated air, that provides conditioned air to a room or facility

3.2.2
air diffuser
device placed at the outlet of a room air supply terminal to improve distribution and mixing of supply air with room air

Note 1 to entry: A mesh grille or a perforated screen is not considered to be a diffuser.

3.2.3
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities

[SOURCE: ISO 14644-1:2015, 3.1.3]

3.2.4
filter system
assembly composed of filter, frame and other support mechanism or other housing

[SOURCE: ISO 14644-3:2019, 3.3.4]

3.2.5
final filter
last high efficiency filter in the system before the air enters the cleanroom or clean zone

Note 1 to entry: Terminal filter is a final filter located at the point where the air enters the cleanroom

[SOURCE: ISO 14644-3:2019, 3.3.5]

3.2.6
turn-down
controlled reduction of airflow velocity in unidirectional airflow cleanrooms and clean air devices or airflow rates in non-UDAF cleanrooms in order to save energy during periods when the cleanroom is not in operation

[SOURCE: ISO 14644-16:2019, 3.2.8]

4 Abbreviations

ACE	Air Change Effectiveness
AHU	Air Handling Unit
CRE	Contaminant Removal Effectiveness
ESD	Electro-Static Discharge
HEPA	High Efficiency Particulate Air
HVAC	Heating, Ventilation and Air Conditioning
MCP	Microbe-Carrying Particle
Non-UDAF	Non-Unidirectional Airflow
UDAF	Unidirectional Airflow
ULPA	Ultra Low Penetration Air
URS	User Requirement Specification

5 General

A cleanroom or clean-zone may be used to protect products and processes that are sensitive to airborne particles and other types of contaminants. A cleanroom installation may be new or the expansion or modification of an existing installation.

The lifecycle of the cleanroom shall be considered from the outset. This includes its design, construction, start up, occupation, operation, renovation, expansion, repair and demolition and consequent re-cycling or disposal.

An analysis of the need for a cleanroom and its justification shall be performed. This analysis shall address, but is not limited to:

a) Contamination risk to product, processes, people and environment (6.1);

b) Statutory requirements;

c) Relevant regulations;

d) Business related aspects (financial viability and resource capability);

e) Future needs.

The flowchart (figure 1) is used to guide the reader through this standard with a logical sequence of the work. The informative annexes are aligned with the clauses in the normative section (requirements, design, construction and start-up).

There should be a review after each step based on the requirements and previous steps. In a small project these steps may be simplified.

This document can also be used for non-classified clean controlled environment and controlled zones.