# INTERNATIONAL STANDARD

ISO 14644-16

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# Cleanrooms and associated controlled environments —

Part 16:

**Energy efficiency in cleanrooms and separative devices** 

Teh S T Salles propres et environnements maîtrisés apparentés —
Partie 16: Efficacité énergétique dans les salles propres et les dispositifs séparatifs

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#### Foreword

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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

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

## Introduction

Cleanrooms and associated controlled environments are widely used in many industries, such as life-sciences (including pharmaceutical, medical device), micro-electronics, aerospace, food processing, nuclear and hospitals. Operational size ranges from tens to thousands of square metres, most with unique design and operational characteristics based on their function. Their development has involved rapid expansion and progress for several decades, mirrored by an increasing energy demand. This document embraces the accumulated experiences and practices in cleanroom design, operation and maintenance, formulated to reduce their energy consumption and the global impact of this dramatic growth.

Users are also referred to ISO 50001 for energy management.

Although varying greatly in function and size, the energy consumption of cleanrooms can be over 10 times higher than that for offices of similar size. A considerable amount of energy is required to provide large amounts of filtered and conditioned air to achieve specific levels of air cleanliness. Air movement fans can account for 35 % to 50 % of the HVAC consumption of cleanrooms due to the power required to overcome the high pressure differentials needed to operate high-efficiency filters and other circulation components in the cleanroom system. Production of this type of high-quality air can consume up to 80 % of the total energy used in a typical manufacturing facility.

Additional energy is also used to achieve temperature and relative humidity control for processes in the cleanroom, for personnel comfort and to achieve the requisite pressurization of the cleanroom space. There is therefore significant potential for energy saving by diligent design in the installation of new cleanrooms, and by retrofit improvements and upgrades to existing facilities. This document sets out the measures that can be taken to introduce these techniques and applies to the full spectrum of "cleanroom technology", from cleanrooms to clean air devices, including isolators, glove boxes and minienvironments as described in ISO 14644-711 This document is based on actual experience, practice and tests supported by theoretical calculations for the purpose of clear and scientific description of the effects of energy saving.

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The energy saving methods and techniques used in this document are all general ones applicable to varied environments and situations. They are not process-specific and exclude related production processes such as water treatment, and oven, autoclave and stress cycling operations. Their specific application depends on the actual conditions of cleanroom operation as agreed between the customer, the supplier and the installation engineers.

At each stage in the cleanroom life cycle, opportunities exist to optimize system performance and reduce energy consumption. Energy saving measures implemented at the design stage achieve the most effective results for new cleanrooms, but similar energy savings can also be achieved for those currently in operation. Cleanrooms can be used singly or as a group, based on practical conditions on site.

During design, when information about the finished building and process is at its minimum, conservatism can dictate the oversizing of systems and the mandating of overly tight specifications. At this stage, challenging these specifications and design considerations is valuable for energy efficiency.

When setting the system to work and executing performance testing, there is an opportunity to adjust the system to accommodate the actual conditions as built to optimize the system performance and minimize energy usage.

During the operating life of the facility, analysis of monitoring data can and should be used to further optimize system performance and minimize energy usage.

# Cleanrooms and associated controlled environments —

# Part 16:

# Energy efficiency in cleanrooms and separative devices

## 1 Scope

This document gives guidance and recommendations for optimizing energy usage and maintaining energy efficiency in new and existing cleanrooms, clean zones and separative devices. It provides guidance for the design, construction, commissioning and operation of cleanrooms.

This document covers all cleanroom-specific features and can be used in different areas to optimize energy use in electronic, aerospace, nuclear, pharmaceutical, hospital, medical device, food industries and other clean air applications.

It also introduces the concept of benchmarking for the performance assessment and comparison of cleanroom energy efficiencies, while maintaining performance levels to ISO 14644 requirements[2][3].

# 2 Normative references TANDARD PREVIEW

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-16:2019

ISO 50001, Energy management systems log/Requirements with guidance for use dt84e2552827/iso-14644-16-2019

#### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 50001 and the following apply.

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

- ISO Online browsing platform: available at <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 3.1 General terms

#### 3.1.1

#### air-handling unit

#### **AHU**

unit or plant, comprising fan, filtration, heating, cooling and mixing of fresh air and recirculated air, that delivers conditioned air to a room or facility

#### 3.1.2

#### classification

method of assessing level of cleanliness against a specification for a *cleanroom* (3.1.4), *clean zone* (3.1.5), controlled zone or a defined location therein

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, modified — In the definition, the part after "clean zone" has been added.]

#### 3.1.3

#### clean air device

stand-alone equipment for treating and distributing clean air to achieve defined environmental

Note 1 to entry: Clean air devices include certain separative devices (3.1.7) as defined in ISO 14644-7[1], for example, clean air hoods, containment enclosures, gloveboxes, isolators and mini-environments.

[SOURCE: ISO 14644-4:2001, 3.2, modified — Note 1 to entry has been added.]

#### 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 are also specified and controlled subject to application.

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

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

### 3.1.5

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clean zone (standards.iteh.ai) 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 standards.iteh.ai/catalog/standards/sist/b18b7600-d2c0-4a06-908d-

Note 1 to entry: The class of airborne particle concentration is specified. 19

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 (3.1.4) or can be achieved by a separative device (3.1.7). Such a device can be located inside or outside a cleanroom.

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

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

#### 3.1.6

#### pre-filter

air filter fitted upstream of another filter to reduce the challenge on that filter

[SOURCE: ISO 14644-4:2001, 3.8]

#### 3.1.7

#### separative device

equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

Note 1 to entry: This equipment can be used as a *clean zone* (3.1.5).

Note 2 to entry: Some industry-specific examples of separative devices are clean air hoods, containment enclosures, glove boxes, isolators and mini-environments.

[SOURCE: ISO 14644-7:2004, 3.17, modified — Note 1 to entry has been replaced, and former Note 1 to entry has been renumbered accordingly.]

#### 3.2 Terms related to installation

#### 3.2.1

#### adaptive control

capability of the system to modify its own operation parameters automatically to achieve the best possible performances in various modes operations year-around

#### 3.2.2

#### air change rate

rate of air exchange expressed as number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the *cleanroom* (3.1.4) or *clean zone* (3.1.5)

[SOURCE: ISO 14644-3:2005, 3.4.1, modified — In the definition, "space" has been replaced by cleanroom or clean zone".]

#### 3.2.3

#### diffuser

device placed on inlet air supply terminal to improve distribution of incoming air with room air

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

#### 3.2.4

#### non-unidirectional airflow STANDARD PREVIEW non-UDAF

air distribution where the supply air entering the clean zone (3.1.5) mixes with the internal air by means of induction

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[SOURCE: ISO 14644-4:2001, 3.6] https://standards.iteh.ai/catalog/standards/sist/b18b7600-d2c0-4a06-908d-

df84e2552827/iso-14644-16-2019 3.2.5

#### contaminant removal effectiveness

#### CRE

ratio of particle concentration measured in the exhaust/return to the average of particle concentration in the room, when particles entering from filtered supply air are ignored

[SOURCE: REHVA Guidebook No. 2]

#### 3.2.6

### air volume flow rate

#### supply airflow rate

air volume supplied into an installation from final filters or air ducts in unit of time

[SOURCE: ISO 14644-3:2005, 3.4.5, modified — "air volume flow rate" has been added as main term.]

#### 3.2.7

#### 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[6].

#### 3.2.8

#### turn-down

controlled reduction of airflow velocity in *unidirectional airflow* (3.2.9) *cleanrooms* (3.1.4) and *clean air* devices (3.1.3) or airflow rates in non-UDAF (3.2.4) cleanrooms in order to save energy during periods when the cleanroom is not in operation

#### 3.2.9

#### unidirectional airflow

#### **UDAF**

controlled airflow through the entire cross-section of a *clean zone* (3.1.5) with a steady velocity and approximately parallel airstreams

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

[SOURCE: ISO 14644-4:2001, 3.11, modified — In the definition, "streamlines" has been replaced by "airstreams", and "to exit" has been added at the end of Note 1 to entry.]

#### 3.2.10

#### emission

amount of contaminants that is discharged from objects into the *cleanroom* (3.1.4) air

#### 3.2.11

#### source strength

rate describing the number of particles or colony-forming units emitted from an object per time unit

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

#### 3.2.12

#### microbe-carrying particle

particle on which a microorganism is carried, normally dispersed into room air by personnel as a skin cell, or fragment of skin cell, on which a skin microbe(s) is carried

# 3.3 Terms related to energy efficiency

# (standards.iteh.ai)

#### 3.3.1

#### benchmarking

comparative evaluation and/or analysis of similar operational practices

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## 3.3.2

#### energy cost

total financial cost of the energy consumed, related to the area being investigated

#### 3.3.3

#### power

time rate at which work is done or energy is transferred

Note 1 to entry: The SI unit of power is the watt (W) or joule per second (J/s).

#### 3.5 Abbreviated terms

CFD computational fluid dynamics

EMS environmental management system

FFU fan filter unit

HSE health, safety and environment

HVAC heating, ventilation and air conditioning

RH relative humidity

SFP specific fan power

URS user requirement specification

VE ventilation effectiveness

# 4 Energy reduction evaluation and implementation process

#### 4.1 General

The energy consumption of cleanrooms, clean zones and separative devices can be reduced in accordance with 4.2 to 4.13, following the process shown in Figure 1.

<u>Figure 1</u> summarizes the process that can be used for a typical cleanroom including its airflow system shown in <u>Figure 2</u>. It covers existing cleanrooms in operation, existing cleanrooms that are being modified and new build cleanrooms in the design phase.

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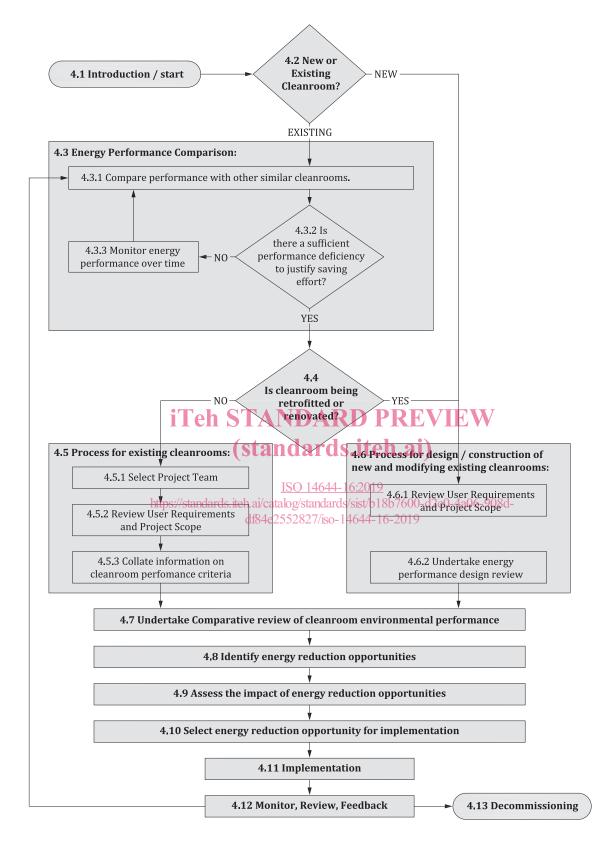


Figure 1 — Systematic approach to energy saving — Project work flow

### 4.2 New or existing cleanrooms

The process of reducing energy consumption of new and existing cleanrooms differ because the starting point and data available are different.

The recommendations of 4.5 and 4.6 should be followed if a new cleanroom is being designed or an existing cleanroom is being assessed for energy reduction purposes.

If an existing cleanroom is planned to be refurbished, then there might be other opportunities to reduce energy consumption that can be incorporated in the modifications.

### 4.3 Energy performance comparison

#### 4.3.1 General

The process of reducing energy consumption in existing cleanrooms can require the time involvement of many resources and there is a cost associated with this activity. For this reason, it is important to establish the cleanroom significant energy use (SEU) that justifies the reduction activity (see ISO 50001).

#### 4.3.2 Compare energy performance

Assess the current energy performance of the cleanroom and compare to a suitable comparator or benchmark. Example comparators can include another similar cleanroom facility, previous commissioning data where energy performance had previously been optimized, or a calculated comparator-based on previous experience. Guidance on benchmarking energy performance is given in Annex D.

# 4.3.3 Determine the business-case NDARD PREVIEW

Establish if the difference between the current cleanroom energy consumption and energy cost, and the comparator or benchmark is significant and would justify further investment of time and resources.

## **4.3.4 Monitor and review** ISO 14644-16:2019

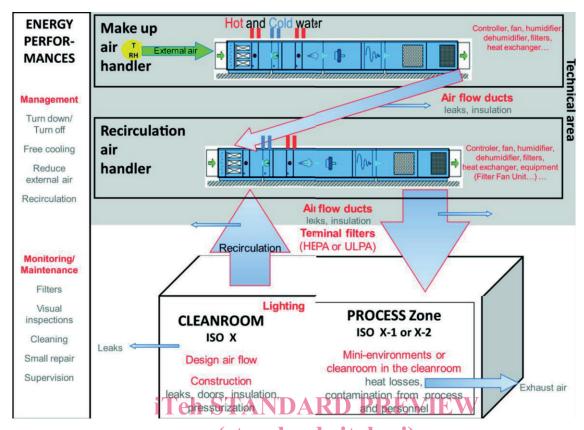
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If there is no justification at the **current point in time**; **con**tinue to monitor energy performance at regular intervals and reassess the energy performance in comparison to the benchmark. Over time, a number of variables can change which can change this assessment:

- cleanroom energy performance and efficiency can degrade;
- the unit cost of energy and project implementation costs can change, which will change the project economics; and
- new technologies can become available or more viable.

### 4.4 Existing cleanroom retrofit or renovation

The design of the cleanroom to be refurbished should be reviewed to ensure energy efficiency is considered in the design. The air handling and distribution system for a typical room is shown below.



SOURCE ASPEC-ADEME-EDF. Energy performance in clean zones (cleanrooms, controlled environments, contained areas)[5], reproduced with the permission of ASPEC France.

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Figure 2 — Illustration of typical cleanroom air handling and distribution df84e2552827/iso-14644-16-2019

The design should enable future regulation and optimization of cleanroom energy performance, for example, installation of variable speed drives for fan motors.

#### 4.5 Process for existing cleanrooms

#### 4.5.1 Select project team

Those selected for the project team should be sufficiently knowledgeable to provide expertise on the following aspects: engineering and maintenance of cleanroom equipment/utilities, cleanroom energy consumption, product quality, equipment/process validation, production operations, and health and safety.

The team can consist of any number of members.

#### 4.5.2 Review user requirements and project scope

The project team should understand the cleanroom operation and document the scope of the energy reduction project. This can include:

- overall objective of the cleanroom (its purpose);
- critical process parameters required to be maintained within the cleanroom.

EXAMPLE Temperature and relative humidity ranges, room cleanliness requirement, recovery time and pressure differentials between adjacent rooms of different classification.

#### 4.5.3 Collate information on cleanroom performance criteria

Documents, including drawings and specifications, and information that define the cleanroom performance criteria should be collated to:

- a) identify criteria that affect performance and consider the direct and indirect impacts of possible energy reduction actions;
- b) identify the cleanroom performance criteria to meet the requirements of the process, the products personnel safety and comfort;
- c) build a profile of energy use, covering lighting, air handling, comfort heating, cooling and any other significant energy use, or where this is not possible use professionally derived estimates;
- d) determine the current cleanliness performance (from classification and monitoring: particles, chemicals and microorganisms);
- e) establish airflow volume flow rate, airflow velocity and pressurization;
- f) identify practical issues related to onsite operations, e.g. reliability and control, layout, age, condition, function, maintenance;
- g) determine the results of any benchmarking exercise, which should compare the existing design with best practice energy use with respect to energy consumption and cost; and
- h) establish life cycle costs and optimization studies, if possible.

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# 4.6 Process for design/construction of new build or updating cleanrooms (Standards.iteh.al)

# 4.6.1 Review user requirements and project scope

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The cleanroom performance criteria to meet the trequirements of the process, the products and personnel comfort should be identified 552827/iso-14644-16-2019

NOTE See Clause 5.

#### 4.6.2 Undertake energy performance design review

The design of the cleanroom should be reviewed to ensure that the following energy performance aspects are considered:

- a) the design performance (in classification terms: particle concentration, and other cleanliness attributes;
- b) the results of any benchmarking exercise, which should confirm that the new design satisfies best practice energy use with respect to energy consumption and cost.

The design review should be specifically focused on energy performance of the cleanroom and the best estimates of projected energy use. This should cover lighting, air handling, heating, cooling and any other significant energy use, particularly for small mini environments.

#### 4.7 Comparative review of cleanroom environmental performance

A review should be undertaken to compare the environmental performance of the designed (new) cleanroom or redesigned (existing) cleanroom with the environmental performance requirements (of the process, the products and personnel comfort), to avoid overdesigning, e.g. specifying cleanliness classifications that are lower (cleaner) than necessary or clean spaces that are larger than necessary.