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Cleanrooms and associated controlled environments - Part 16: Code of practice for improving energy efficiency in cleanrooms and clean air devices (ISO/DIS 14644-16:2018)

Reinräume und zugehörige Reinraumbereiche - Teil 16: Leitfaden zur Verbesserung der Energieeffizienz von Reinräumen und Reinluftgeräten (ISO/DIS 14644-16:2018)

Salles propres et environnements maîtrisés apparentés - Partie 16: Code de bonnes pratiques pour améliorer l'efficacité énergétique dans les salles propres et les dispositifs à air épuré (ISO/DIS 14644-16:2018)

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Cleanrooms and associated controlled environments —

Part 16:
Code of practice for improving energy efficiency in cleanrooms and clean air devices

Salles propres et environnements maîtrisés apparentés —

Partie 16: Code de bonnes pratiques pour améliorer l'efficacité énergétique dans les salles propres et les dispositifs à air épuré

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14644-16 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

A list of all parts 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 are widely used in many industries, such as life-sciences (including pharmaceutical, medical device and hospital), micro-electronics, aerospace, food processing and nuclear. Where applicable, regulation can override some recommendations. Operational size ranges from decades to thousands of square meters, 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 part of ISO 14644 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[1] 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 part of 14644 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 mini-environments as described in ISO 14644-7.[2] The standard 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.

The energy saving methods and techniques used in the text 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 upon 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 might 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: Code of practice for improving energy efficiency in cleanrooms and clean air devices

1 Scope

This part of ISO 14644 gives guidance and recommendations for optimizing energy usage and maintaining energy efficiency in new and existing cleanrooms, clean zones and separative devices. The standard provides guidance for the design, construction, commissioning and operation of cleanrooms. It 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.

2 Normative references

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 14644-2, *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 14644-4, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

ISO 14644-5, *Cleanrooms and associated controlled environments — Part 5: Operations*

3 Terms and definitions

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

3.1 General

3.1.1
air-handling unit
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, clean zone, controlled zone or a defined location therein

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

Note 1 to entry: Levels are expressed in terms of an ISO class, which represents maximum allowable concentrations of contaminants in a unit volume of air.

3.1.3
clean air device
stand-alone equipment for treating and distributing clean air to achieve defined environmental conditions

[SOURCE: ISO 14644-4:2001, 3.2]

Note 1 to entry: Clean air devices include certain separative devices as defined in ISO 14644-7,[2] for example, clean air hoods, containment enclosures, gloveboxes, isolators and mini-environments.

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, airflow, 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, airflow, vibration and electrostatic.

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

3.1.6
controlled environment
defined zone in which sources of contamination are controlled by specified means

[SOURCE: ISO 14644-6:2007, 2.45]

3.1.7
final filter
last high-efficiency filter in the system before the air enters the cleanroom or clean zone

[SOURCE: ISO 14644-3:2005, 3.3.5]

3.1.8
filter system
system composed of filter, frame and other support system or other housing

[SOURCE: ISO 14644-3:2005, 3.3.4]

3.1.9
pre-filter
air filter fitted upstream of another filter to reduce the challenge on that filter

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

3.1.10
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.

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]

3.2 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 or clean zone

[SOURCE: ISO 14644-3:2005, 3.4.1]

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

[SOURCE: ISO 14644-4:2001, 3.6]

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
supply air volume flow rate
air volume supplied into a cleanroom through final filters or diffusers in unit of time

[SOURCE: ISO 14644-3:2005, 3.4.4]

3.2.7
terminal filter
air filter located at the point where the air enters the cleanroom

3.2.8
total air volume flow rate
air volume that passes through a section of a cleanroom in unit of time

[SOURCE: ISO 14644-3:2005, 3.4.5]

3.2.9
turn-down
controlled reduction of airflow velocity in unidirectional airflow (UDAF) 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

3.2.10
turn-off
controlled switching off of a part of an air-handling unit and/or clean air devices in cleanrooms in order to save energy during periods when the cleanroom is not in operation

3.2.11
unidirectional airflow (UDAF)
controlled airflow through the entire cross section of a clean zone 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]

3.3 Emission

3.3.1
emission
contaminants that are discharged from objects into the cleanroom indoor environment

[SOURCE: ISO 2889:2010, 3.30]

Note 1 to entry: For the purposes of this International Standard only particle and microorganism emission is considered.

3.3.2
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.

3.3.3
colony forming units (CFUs)
single microorganism or a single small mass of microorganisms that when deposited on a microbiological growth medium grows to form a single visible colony that can be counted

Note 1 to entry: One colony-forming unit is expressed as 1 CFU.

3.3.4
microbe-carrying particle (MCP)
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

3.4 Energy efficiency

3.4.1
benchmarking
comparative evaluation and/or analysis of similar operational practices

3.4.2
energy
electricity, fuels, steam, heat, compressed air, and other like media

Note 1 to entry: For the purposes of this International Standard, energy refers to the various forms of energy, including renewable, which can be purchased, stored, treated, used in equipment or in a process, or recovered.

Note 2 to entry: Energy can be defined as the capacity of a system to produce external activity or perform work.

[SOURCE: ISO 50001:2011, 3.5]

3.4.3
energy consumption
quantity of energy applied

[SOURCE: ISO 50001:2011, 3.7]

3.4.4
energy cost
total financial cost of the energy consumed, related to the area being investigated

3.4.5
energy efficiency
ratio or other quantitative relationship between an output of performance, service, goods or energy, and an input energy

EXAMPLE Conversion efficiency; energy required/energy used; output/input; theoretical energy used to operate/energy used to operate.

[SOURCE: ISO 50001:2011, 3.8]

3.4.6
energy use
manner or kind of application of energy

EXAMPLE Ventilation; lighting; heating; cooling; transportation; processes; production lines.

[SOURCE: ISO 50001:2011, 3.18]

3.4.7
energy performance
measurable results related to **energy efficiency (3.4.5)**, **energy use** (**3.4.6**) and **energy consumption** (**3.4.3**)

[SOURCE: ISO 50001:2011, 3.12]

3.4.8
energy performance indicator (EnPI)
quantitative value or measure of energy performance, as defined by the organization

Note 1 to entry: EnPIs could be expressed as a simple metric, ratio or a more complex model.