
Cleanrooms and associated controlled environments —

**Part 16:
Energy efficiency in cleanrooms and
separative devices**

Salles propres et environnements maîtrisés apparentés —

*Partie 16: Efficacité énergétique dans les salles propres et les
dispositifs séparatifs*



STANDARDSISO.COM : Click to view the full PDF of ISO 14644-16:2019



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 General terms	1
3.2 Terms related to installation	3
3.3 Terms related to energy efficiency	4
3.5 Abbreviated terms	4
4 Energy reduction evaluation and implementation process	5
4.1 General	5
4.2 New or existing cleanrooms	6
4.3 Energy performance comparison	7
4.3.1 General	7
4.3.2 Compare energy performance	7
4.3.3 Determine the business case	7
4.3.4 Monitor and review	7
4.4 Existing cleanroom retrofit or renovation	7
4.5 Process for existing cleanrooms	8
4.5.1 Select project team	8
4.5.2 Review user requirements and project scope	8
4.5.3 Collate information on cleanroom performance criteria	9
4.6 Process for design/construction of new build or updating cleanrooms	9
4.6.1 Review user requirements and project scope	9
4.6.2 Undertake energy performance design review	9
4.7 Comparative review of cleanroom environmental performance	9
4.8 Identify energy reduction opportunities	10
4.9 Assess the impact of energy reduction opportunities	10
4.10 Select energy reduction opportunities for implementation	10
4.11 Implementation	10
4.12 Monitor, review and feedback	11
4.13 Decommissioning	11
5 Impact of user requirement specification (URS) on energy consumption	11
5.1 Principle	11
5.2 Garment levels	11
6 Airflow volume and compensating factors	12
6.1 Fresh air supply	12
6.2 Airflow volume rate	12
6.3 Source strength and airflow rate calculation for non-unidirectional rooms	12
6.3.1 Determining air volume flow rate	12
6.3.2 Ventilation effectiveness index	13
6.3.3 Compensation factors (C_f)	13
6.4 Flexible procedure for airflow rate estimation in non-UDAF rooms	14
6.4.1 General	14
6.4.2 Design stage	14
6.4.3 Testing stage	15
6.4.4 Operational stage	15
6.5 Air velocity reduction for unidirectional air flow systems	15
7 Power management: turn-down, turn-off and recovery	15
7.1 Turn-down	15
7.2 Turn-off	16

8	Adaptive control	16
9	Heating and cooling loads	17
10	Fan and filter selection	17
10.1	Air movement fans	17
10.2	Selection of air filters	17
11	Lighting levels	18
12	Training	18
13	Operation	18
14	Maintenance	19
15	Decommissioning	20
Annex A (informative)	Source strength: Air volume and worked example	21
Annex B (informative)	Energy saving opportunities	26
Annex C (informative)	Impact assessment	32
Annex D (informative)	Benchmarking: Energy performance indicators for cleanrooms	33
Annex E (informative)	Useful measures to minimize excess heating and cooling losses or gains	38
Annex F (informative)	Critical area reduction example	40
Bibliography		42

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*.

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.

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 mini-environments as described in ISO 14644-7[1]. 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.

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

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 50001, *Energy management systems — Requirements with guidance for use*

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 <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

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 conditions

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

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* (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

non-UDAF

air distribution where the supply air entering the *clean zone* (3.1.5) 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

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

3.3.1

benchmarking

comparative evaluation and/or analysis of similar operational practices

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

<i>SFP</i>	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](#).

[Figure 1](#) summarizes the process that can be used for a typical cleanroom including its airflow system shown in [Figure 2](#). It covers existing cleanrooms in operation, existing cleanrooms that are being modified and new build cleanrooms in the design phase.

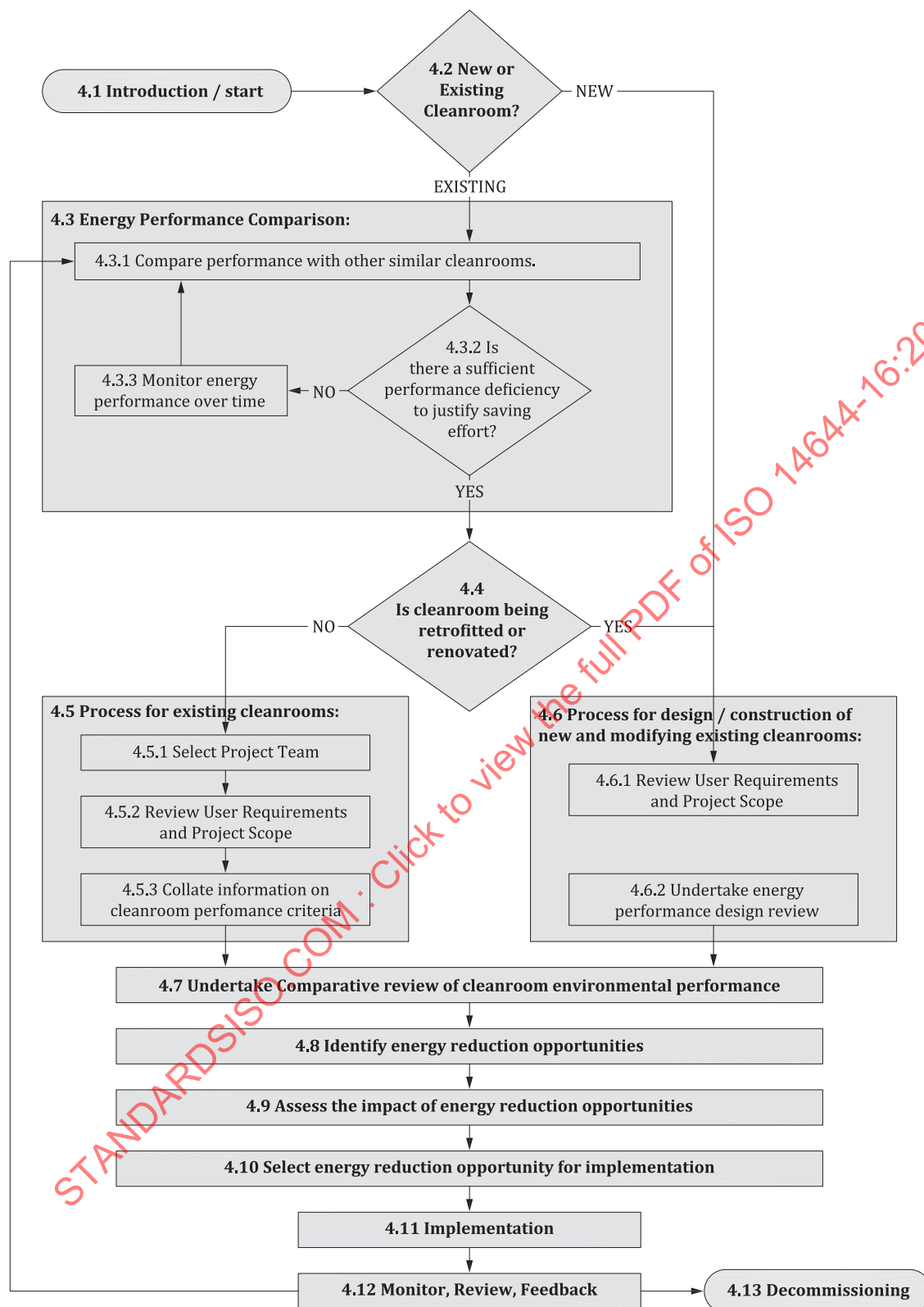


Figure 1 — Systematic approach to energy saving — Project work flow

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

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.

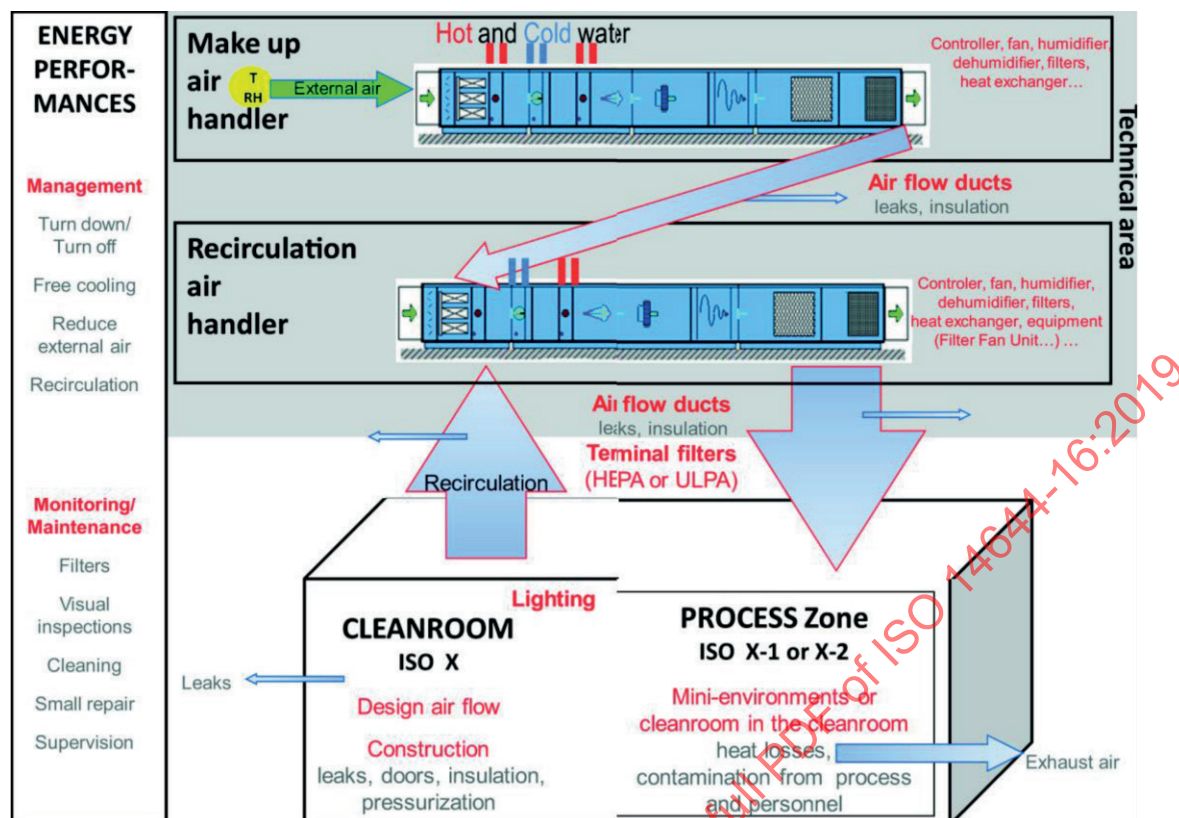
4.3.4 Monitor and review

If there is no justification at the current point in time, continue 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.

Figure 2 — Illustration of typical cleanroom air handling and distribution

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.

4.6 Process for design/construction of new build or updating cleanrooms

4.6.1 Review user requirements and project scope

The cleanroom performance criteria to meet the requirements of the process, the products and personnel comfort should be identified.

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.

4.8 Identify energy reduction opportunities

The project team should analyse the results of the comparative review, identify potential energy reduction opportunities and carry out a preliminary selection. This can be done using the checklist given in [Annex B](#).

Once the preliminary selection has been made the selection should be assessed and documented as part of the decision-making process, and the reasons why an opportunity is chosen, or not, should be recorded.

Life cycle cost of energy reduction opportunities should be evaluated and considered in the analysis.

4.9 Assess the impact of energy reduction opportunities

Once the potential energy saving opportunities have been identified (using, for example, the table in [Annex B](#)), a preliminary selection should be carried out. A detailed impact assessment report should be produced, covering all of the potential opportunities identified and taking into account any corresponding recommendations given in [Annex B](#), as well as the following business requirements:

- feasibility;
- process compatibility and product quality requirements;
- safety and regulations;
- cost;
- return on investment;
- incentives (e.g. government initiatives);
- implementation timeline/programme;
- implementation resources; and
- business continuity.

4.10 Select energy reduction opportunities for implementation

The energy reduction opportunities identified by the impact assessment report ([4.9](#)) as having become less viable or more challenging should be reprioritized behind those that can be easily and effectively delivered. A final prioritization and implementation programme should then be prepared.

Specifications and scopes of work should be defined for those opportunities that are to be implemented. Where industries have standards or guidelines that specify performance requirements, all the situations where one or more performance requirements are in conflict with a particular proposed energy reduction measure should be identified.

NOTE Such performance requirements can include air quality (in terms of particle and other cleanliness attributes), filter efficiency, unidirectional airflow velocity, supply air volume flow rate, recovery time, temperature, humidity and pressure differentials between adjacent rooms of different grades.

When these situations have been identified, a detailed justification should be prepared to demonstrate that product quality is not affected by the proposed measure. Agreement should then be obtained from the client prior to implementation.

4.11 Implementation

A detailed implementation plan should be prepared, and the work undertaken. The implementation plan should include the expected outcomes for all the selected elements.

4.12 Monitor, review and feedback

On completion of the project and thereafter at regular intervals, for each selected element the expected outcome defined in the implementation plan should be monitored and reviewed to ensure that the changes remain effective. The associated energy reductions should be monitored, recorded and analysed. The information gathered should be used as feedback for continuous improvement.

4.13 Decommissioning

When a cleanroom has reached the end of life and is no longer required, an impact assessment should be undertaken to determine if the cleanroom should be placed into an idle state, prior to dismantling to minimize the energy consumed. The impact on adjacent or associated rooms should be assessed. Idle state can include turn-down and turn-off actions.

5 Impact of user requirement specification (URS) on energy consumption

5.1 Principle

The user requirements specification (URS) is a key part of a cleanroom project's documentation. It sets the base requirements for the new or renovated facility at the earliest stage, so the information entered into the document should be carefully considered.

The science and understanding of cleanrooms have developed significantly to allow requirements to go beyond a simple specification of an air change rate for a specific cleanroom class.

The URS should indicate the usual and maximum number of people expected to be present in the cleanroom at one time plus the expected heat load of the process equipment. The acceptable range of the internal temperature and humidity requirements in relation to the expected outside conditions, particularly at specific times of the year, has a significant effect on the overall energy consumption of the facility. They should be carefully considered, taking into consideration personnel needs and comfort. An indication of the expected range of external temperatures and humidity levels should also be researched for the area where possible, to include the effects of future climate change.

Consideration of the overall footprint of the facility is also important. If a layout has not yet been prepared, or a site not yet identified, a request to minimize the overall footprint of the facility, taking account of standard spatial requirements, or the intention to use barrier technology where appropriate, should be included as requirements.

Additional requirements can also be added, including the as-expected source strength, insulation requirements, minimum fan efficiencies or other specific energy saving equipment or methods.

Flexibility of the design should be provided to allow future modifications to be made, to either improve energy efficiency further or improve product quality.

Use of information contained in [Annexes A](#) to [F](#) provides further energy reduction opportunities that can be added to the URS.

5.2 Garment levels

The required cleanroom garment levels should also be specified in the URS since they play a vital role in controlling particulate contamination. Personnel particle dispersion levels vary enormously between the different types of garment, depending on the amount of clothing and skin that is covered, the use of face masks, shoe covers and glove type. Where a reduction in airflow volume is to be considered, these garment levels should be critically reviewed, together with the nature, quality and laundry frequency of the gowns to be used. Enhancing garments can also help to reduce the required airflow supply rate (see [Annex A](#)). When this is to be practised, it is vital to establish a comfortable balance between the temperature and humidity of the room for the work force.

6 Airflow volume and compensating factors

6.1 Fresh air supply

Fresh air supply should be considered as conditioning. Fresh air is often more intensive than conditioning return air. The contamination level of the external conditions should be considered.

6.2 Airflow volume rate

The volume of airflow rate is a significant contributor to the energy consumption of a cleanroom. Therefore, a reduction of the air volume flow rate has a significant impact on the overall energy use. It is well understood that higher airflow rates in the form of volume for non-unidirectional flow (dilution) and velocity for unidirectional flow (displacement) lead to a lower airborne contamination level [see a) and b) below]. The volume of air that moves through a unidirectional cleanroom is significantly higher than for a non-unidirectional cleanroom of the same size. Regulations and expected practice for both cleanroom types have specified airflow rates that in some cases are excessive. A better understanding of cleanroom design and the way contamination is generated in a cleanroom now provides an opportunity to reduce the airflow rate while still maintaining an acceptable particle concentration.

a) Displacement of particles

Using unidirectional filtered airflow, particles are swept away from the critical zones when used for class ISO 5 and cleaner, and are velocity-dependent. The ceiling then has an effectively complete coverage of HEPA or ULPA filters for supply air, and room air is extracted from raised-floor perforated panels or low sidewall grilles.

Airflow direction can be vertically downwards or horizontal.

b) Dilution of particles

Using turbulent mixing, particles are diluted with filtered air and removed from the critical zone, used for class ISO 6 and less clean areas. Often air is extracted from low sidewall grilles to improve air change effectiveness. For these cleanrooms, the supply air rate, and correspondingly the air change rate, only need to be sufficient to effectively dilute the particles generated, known as the source strength, to an acceptable concentration.

For both displacement and dilution designs, consideration should also be given to the air supply requirements for both operational and at-rest states. Significant energy savings can be achieved through turn down during periods of cleanroom inactivity (see [Clause 7](#)).

6.3 Source strength and airflow rate calculation for non-unidirectional rooms

6.3.1 Determining air volume flow rate

The emission data given in [7], [8], [9] may be used to estimate the contamination source strength, D , dependent on the number of personnel, the clothing to be used and the process equipment. [Formula \(A.1\)](#) can then be used to estimate the minimum supply air volume flow rate required. The calculations should only be used as a guide and should include any required compensating factors. The designer should determine the current airborne contamination levels for existing cleanrooms and estimate all potential emissions likely to endanger the process for new cleanroom builds. Sufficient adjustability should be built into the design to allow progressive airflow tuning to take place as shown in [Figure 3](#).

The data produced should not be used to replace contractual volume or change rate figures agreed or demanded by the cleanroom client.

NOTE [Formula \(A.2\)](#) calculates air change rate if contractually required. There is no direct and independent correlation between air change rate (*ACR*) and space classification to ISO 14644-1[2]. That is, the amount of air required for a particular cleanroom is not dependent on the volume of the room, but rather on the nature of the activities within the room and the design of the air distribution system. *ACR* is a useful and important factor but is only one of many.

The *ACR* should not be used as a primary independent acceptance criterion for cleanrooms as it does not account for the rate of particle generation and other control factors. For example, for two rooms housing the same type of operations and the same number of personnel, but with one having a ceiling height 2 times that of the other, the particle emission rate is similar in both rooms. Therefore, similar airflow rates are required in both, regardless of volume.

6.3.2 Ventilation effectiveness index

Calculations for the supply air volume rate should include a suitable contaminant removal effectiveness index (*CRE*) or air change effectiveness (*ACE*), to ensure that the cleanroom will maintain the required particulate conditions during most of the anticipated variations of the source strength. These are explained in [Annex A](#) and used in the example in [Figure 3](#) [shown as ϵ in [Formula \(A.1\)](#)].

Computational fluid dynamics (CFD) is a suitable tool for varying this factor while predicting the effectiveness of different cleanroom designs. If used, it should be in addition to the standard calculations, and consideration should be given to the suitability of the computer model used.

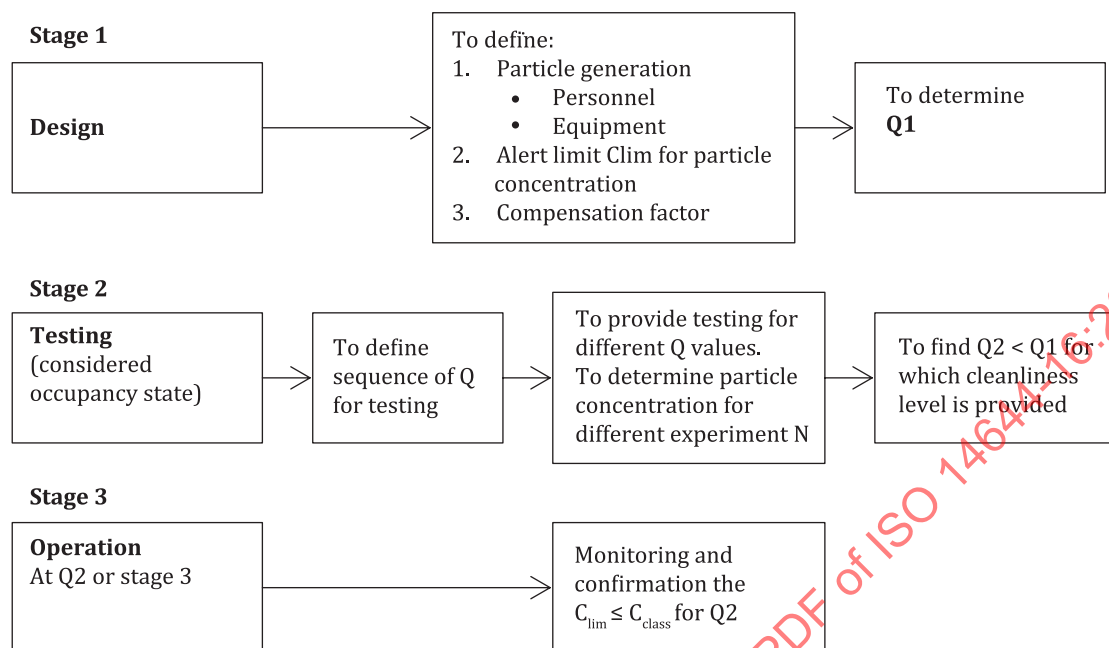
6.3.3 Compensation factors (C_f)

Compensation factors allow the inclusion of variable redundancy elements into the calculated air volume flow rate at the design stage. Note that they serve as a supporting instrument only to the calculations. They are arbitrary and should be estimated for each application by a professional cleanroom engineer.

Generally, compensation factors can be expressed in the following ways to compensate for the uncertainty of the data:

- a) as a margin for particle concentration limit alert levels, for example, ISO 7 class limit, C_{class} , is 352 000 particles/m³ for particles $\geq 0,5 \mu\text{m}$, but, for process reasons, its alert level, C_{lim} , can be chosen as 100 000 particles/m³, or even 50 000 particles/m³; and
- b) as a margin for particle removal effectiveness by lowering the predicted *CRE* or *ACE* to values less than 1,0 if air distribution is deemed to be not good enough.

Design – Testing – Operation



NOTE Q = airflow volume in cubic metres per second.

Figure 3 — Sequence of actions to determine air volume flow rates while controlling particle concentration

6.4 Flexible procedure for airflow rate estimation in non-UDAF rooms

6.4.1 General

The procedure set out in 6.4.2 to 6.4.4 should be followed (based on the principles developed by Fedotov A, in his work detailed in Bibliographic reference [10]).

The procedure recommended in 6.4 for air volume flow rate estimation is flexible, since only approximate data on particle generation are available at the design stage. The procedure allows incremental improvement of the accuracy of estimation by moving incrementally through the flow chain chart shown in Figure 3. As each stage is completed, more data become available.

6.4.2 Design stage

Specify an alert level, C_{lim} , for particle concentration that is less than the cleanroom class limit, C_{class} , using initial data from the user requirement specification concerning:

- cleanliness class required;
- cleanroom volume (where air change rate is a client requirement); and
- number of personnel, type of equipment and type of cleanroom clothing.

Estimate particle generation in the cleanroom, in D particles per second (see 6.3.1).

Agree a predicted *CRE* or *ACE* effectiveness index from the design study, ε (see 6.3.2).

Agree a suitable compensating factor, C_{lim} , in accordance with 6.3.3.

Calculate airflow rate, Q_1 , using [Formula \(A.1\)](#), in cubic metres per second.

Test the predicted airflow rate in the design in accordance with [6.4.3](#).

6.4.3 Testing stage

The purpose of the energy saving test is to determine the suitability of Q_1 and to find a more accurate AFR value, where Q_2 is less than Q_1 .

This test should be carried out in addition to testing in accordance with ISO 14644-1[2], ISO 14644-2[3], and ISO 14644-3[6], to confirm the ability of the cleanroom to operate within required cleanliness requirements, using the reduced flow rate of Q_2 , at a lower particle alarm rate, $C_{lim} < C_{class}$.

Tests with different flow rates can be done for “at-rest” and/or “operational” occupancy states, as specified. More than one test is needed to progress.

Reduction of air volume flow rate should not compromise cleanroom performance requirements such as particle concentration, pressure, temperature and humidity, or other control attributes.

6.4.4 Operational stage

Q_2 should at this stage be introduced to the operation, together with the requirements for operation at reduced air volume, covering training, operation and maintenance, set out in [Clauses 12](#) to [14](#).

A typical worked example from this procedure is shown in [Annex A](#), to demonstrate how these formulae and data can be used in quantifying and evaluating the effectiveness of airflow rate optimizations. See also Bibliographic reference [\[10\]](#).

Statistical methods for contamination control, such as process capability analysis, can also be used to confirm the flow rates.

6.5 Air velocity reduction for unidirectional air flow systems.

The calculation methods in [6.4](#) are not applicable to unidirectional airflow systems. Efforts in energy reduction should be made by careful consideration of the parameters identified in [A.5](#). Energy reduction should be made by careful consideration of the velocity and related items discussed in [A.5](#). It has been shown that where regulations allow, velocities as low as 0,35 m/s provide low concentrations of airborne contamination in normal levels of occupancy and activity for this type of room.

7 Power management: turn-down, turn-off and recovery.

7.1 Turn-down

An essential technique that should be assessed for energy saving is to turn down the airflow volume flow rate and allow the range of temperature and relative humidity (RH) to widen accordingly when the cleanroom or clean air device is in the “at-rest” or “unoccupied” state. Where possible, variable speed fans should be used to control the air velocity and reduce the energy load.

NOTE 1 Generally, air volume is proportional to the cube of the fan power, and to the cube of the airflow rate, so that a halving of the air volume can reduce the fan power by a factor of eight, subject to correct duct sizing.

All new installations should be capable of having their supply air velocity for UDAF and supply airflow rate for non-UDAF controlled down to a predefined level during non-operational periods. Motorized dampers should be fitted to the main branches of the ductwork which, in conjunction with the fan

motor inverter, facilitates turn-down during non-operational hours and lower pressure differentials during periods when the facility is not occupied.

NOTE 2 Under turn-down conditions, i.e. unmanned and not in operation, the contamination source strength and heat gains in the controlled space are substantially less than during operational conditions. Under these circumstances, a turn-down condition can be estimated at the design stage, and confirmed during commissioning or qualification.

When turning down performance parameters, segregation including physical barriers, or a positive cleanroom pressure, should be maintained to prevent ingress of contamination from the surrounding area into the cleanroom or clean zone. Appropriate visible notices that the zone is in a turn-down situation should be displayed and all personnel, including maintenance and janitorial staff, should be correctly trained with respect to their activity and movement during turn-down.

Access and entry points should be closed during turn-down to prevent unauthorized entry that can introduce contamination. Filter units should not be switched to maximum when the zone is reactivated, but allowed to ramp up gradually. When reactivating from a turn down state, air handling systems should be ramped up gradually using a controlled procedure.

The specified operating conditions should be re-established prior to commencing or recommencing normal operations. All turn-downs should be measured and controlled with the duration of the turn down time previously agreed and validated during commissioning.

In addition to all the standard tests, including particle counting, airflow visualization can also be useful during the validation process.

7.2 Turn-off

When systems are planned to be turned off as part of an agreed energy management programme, a detailed process impact assessment should be documented as detailed in the organization standard operating procedure.

NOTE The configuration of the cleanroom has a major impact on systems that can be turned off, for example: turning off a unidirectional airflow clean air device located within a less clean cleanroom, or turning off some of the fan filter modules within a large cleanroom using multiple modules. This can include heating and cooling systems while maintaining the normal or turned down airflow.

In order to assess whether turn-off is acceptable to product quality, the following risks should be taken into account:

- a) ingress of airborne contamination due to loss of pressurization in the classified space;
- b) depositions of contamination shaken from the clean side of terminal high-efficiency air filters; and
- c) the ability to restore the required cleanliness conditions upon restarting the system within a determined recovery time related to the emission risk and period of turn off.

Access and entry points should be sealed during these procedures.

8 Adaptive control

The active control of room airflow and/or fresh air is based on feedback from sensors or analytical instruments within the cleanroom space in real time. This approach represents one of the most energy-efficient control schemes possible and involves the airflow within a room being adjusted proportionally to the real-time sensed or measured concentration of particles within the cleanroom. Filtering and averaging of particle count signals are possibly required in order to provide an acceptably stable signal for control of the cleanroom. The level of savings achieved is affected by the variability of the particulate source within the room. Rooms which experience short periods of high particulate generation benefit most from this approach.

Typical adaptive control schemes utilize particle count information from representative locations within the cleanroom as feedback to the control system. However, other schemes are available which look at temperature, humidity, gaseous contaminants or other parameters to be controlled.

In life science industries and health care, the need to address airborne viable particulate as well as total particulate to meet regulatory requirement and expectations can influence the applicability of this control approach. Adequate verification showing the reliable and repeatable control of airborne viable particulate via adaptive control schemes is key to implementing this approach.

9 Heating and cooling loads

The temperature and relative humidity specifications within the cleanroom are established to provide operator comfort, control electrostatic build-up and meet process requirements. They have a great effect on energy consumption and should not be controlled within a tighter range than is necessary.

In situations where there is no specific requirement for tightly-controlled temperature and relative humidity conditions, the temperature should be allowed to vary according to personnel comfort. Relative humidity (RH) should be allowed to float according to ambient conditions within the range 30 % to 70 % subject to operator comfort.

[Annex E](#) lists some of the ways to limit excess heating and cooling losses or gains.

10 Fan and filter selection

10.1 Air movement fans

Air movement fans should be selected to achieve the best balance between energy and air delivery, taking into account fan efficiency, drive efficiency and fan characteristics to deal with increased filter loading. Their efficiencies have a wide range, and those operating at high efficiency should be selected as a major means of reducing energy usage.

Direct-drive fans with integral motor are the most energy-efficient and the latest generation of direct-drive fans can achieve higher than 80 % efficiency. The payback time for such fans should be considered.

An existing fan system with a motor separate from the fan should be considered for a belt upgrade, or be replaced by a direct-drive fan with a high-efficiency motor, since the belt drive between the motor and the fan can consume 10 % to 15 % of the motor energy before it reaches the fan.

The use of low-friction belts and toothed belts can minimize energy losses where belts must be used. Direct-drive fans with an integral motor should be considered for all new builds.

Generally motors should include inverters allowing variable speed drive (VSD) to give efficient control and flexibility. The fan manufacturer should be consulted in order to select a fan that is quiet in operation with the required static pressure at the duty point and with the lowest energy consumption.

10.2 Selection of air filters

The particulate removal efficiency of the final filters should be not more than is required to give the specified cleanliness level in the cleanroom. Filtration design should minimize the pressure drop of the filtration system in order to minimize the energy requirement of the fans. Final filters should be selected with the minimum pressure drop for the required particle removal efficiency. Those with a greater amount of filter media have a lower pressure drop than those with a lower amount. For example, by increasing the media pack depth of a high-efficiency air filter panel from 66 mm to 110 mm, pressure drop can be reduced by approximately 40 % and life increased by 2,5 times.

The final filters should be protected against frequent renewal by using adequate pre-filters. A robust cleaning or replacement protocol should be adopted for pre-filters in the return or recirculated air to

ensure that they do not become overloaded, causing excessive pressure drops in the system and a risk of particle release into the cleanroom. Energy-efficient pre-filters should be chosen with the assistance of an energy classification method, such as given in Eurovent 4/11^[11] and other charts. A life cycle costing (LCC) model should be used at the design stage to obtain an informed selection of air filters, filter purchase, energy use and the cost of installation, maintenance and disposal, e.g. the Eurovent chart^[11].

11 Lighting levels

The lighting within the cleanroom should be within operator control or governed by demand control devices so that the lights are turned off when the room is not occupied. Local LED lighting should be considered for intricate work, allowing the background lighting to be reduced. Work station lighting should be designed to facilitate work while reducing fatigue.

12 Training

Training should be provided to staff where necessary on the identification of energy-saving opportunities.

To assist with this process, the company's operational constraints should be agreed and understood.

As part of this training, staff should be briefed on the following:

- a) current standards, regulations, guidelines and codes of practice for cleanrooms specific to the organization;
- b) specific equipment and processes that are particularly energy-intensive;
- c) heating and ventilating as a specific consumer of energy in a cleanroom;
- d) sources of particle generation in cleanrooms; and
- e) air volume supply rates and their effect on cleanroom energy consumption.

It should be reinforced that the general objectives of hygiene, behaviour, and health and safety are not to be compromised when looking for energy savings.

If an energy saving programme is implemented within an organization, specific training should be provided on how to operate the facility in different HVAC modes, how to monitor the cleanroom in different states, and what to do in the event of a nonconformity.

General cleanroom courses should include a section on cleanroom energy savings.

13 Operation

13.1 The feasibility of working with reduced airflow volumes should be confirmed on a real-time scale while performing processes with the correct number of personnel specified. The correct type of clothing should be properly worn, and cleaning regimes reviewed and improved (see ISO 14644-5^[12]).

13.2 Energy-saving methods are focused on discovering realistic parameters for airflow volume or circulation rates, cleanroom recovery times and reliable operation. The following three tasks should be adopted to achieve this:

- maintain design redundancy for air volume rate;
- follow operational requirements for personnel, cleaning and maintenance; and
- define additional opportunities for energy saving, if relevant.

13.3 Instructions should be approved for the following:

- correct HVAC operation;
- room testing/monitoring; and
- data recording.

13.4 Actions to be taken where the specified particle concentration and other parameters, such as temperature and humidity, are exceeded should include:

- cleanroom designation;
- number of air-handling units (AHU) supplying the cleanroom;
- confirmation of designed airflow rate by testing and acceptance for operation, where this is a mandatory requirement;
- periodic or continuous control of particle concentration;
- checking alert and alarm limits for all parameters;
- table or chart recording of particle concentrations and airflow volume and velocity; and
- reporting increased particle concentration above alert or alarm limits.

13.5 The following should be understood in the case of a particulate increase:

- who to report to if necessary;
- actions to be taken to understand the deviations and responsibility for implementation; and
- decisions to improve cleaning, to increase air volume rates or to continue observation.

14 Maintenance

Cleanrooms should be subject to general maintenance in accordance with ISO 14644-5^[12], with the inspection frequency determined by the age of the installation.

Reduced airflow volumes for energy saving purposes can require the following additional precautions to prevent increase of particle concentration:

- adjust monitoring programmes in accordance with ISO 14644-2^[3]; and
- additional maintenance operations in accordance with the manufacturer's instructions, to support the reliable operation of HVAC systems.

Tighter requirements can be specified by facility maintenance instructions, which should include regular inspection for drive-belt slippage and pre-filter blockage.

Generally, more frequent control or checks should be used to compensate for the possible influence of reduced airflow volume.

Maintenance requirements can be simplified if the cleanroom operates extensively for long periods, for example the test intervals can be increased. Where an interactive building management system (BMS) is in use, the manual inspection frequency may be reduced.

The influence of seasonal (winter/summer) or outside particle generation factors, such as pollen generation in spring, should also be taken into account.

15 Decommissioning

When a cleanroom is planned to be out of use for a very long period, or is obsolescent and/or has a low efficiency, decommissioning is an option to be considered. Possible adverse impact on adjacent rooms, such as difficulties in maintaining required environmental parameters, should be evaluated and risk mitigation strategies put in place.

STANDARDSISO.COM : Click to view the full PDF of ISO 14644-16:2019

Annex A (informative)

Source strength: Air volume and worked example

A.1 Calculating air supply rate in non-unidirectional cleanrooms

The greatest effect on the particle concentration in non-unidirectional airflow cleanrooms is from the air supply rate, and emission rates from personnel and equipment. Air filters also have a large influence, but using the types normally fitted in cleanrooms ensures there is an insignificant contribution, so a good estimate of the concentration of airborne particles can be calculated with [Formula \(A.1\)](#):

$$Q = \frac{D}{\varepsilon \cdot C} \quad (\text{A.1})$$

where

- C is the required airborne particle concentration (counts/m³) in the considered location.
- D is the total particle emission rate from personnel and equipment (counts/s);
- Q is the supply air (flow rate) (m³/s);
- ε is the ventilation effectiveness (dimensionless);

NOTE 1 [Formula \(A.1\)](#) is based on the condition of particle “perfect mixing” with room air which rarely occurs in actual cleanrooms. Therefore, the ventilation removal effectiveness, ε , is used to include the factors of “actual mixing” condition and the effectiveness of various airflow patterns. The ventilation effectiveness can be obtained in terms of air change effectiveness (ACE) or contamination removal efficiency (CRE). The selection depends on the application, and the data that is available or can be acquired. See also Bibliographic references [7], [8], [9], [13] and [14].

Both C and D should refer to the same occupancy state, and to the specified particle size under consideration. In an existing cleanroom, a number of parameters can be measured and the emission rate from contamination sources can be determined. The acquired data can be used to optimize the required supply air.

If an air change rate is required, it can be calculated from the cleanroom’s physical volume as per [Formula \(A.2\)](#):

$$ACR = \frac{3\,600 \cdot D}{\varepsilon \cdot C \cdot V} \quad (\text{A.2})$$

where

- ACR is the air change rate per hour;
- C is the required airborne particle concentration (counts/m³) in the considered location.
- D is the total particle emission rate from personnel and equipment (counts/s);
- V is the cleanroom volume (m³).

NOTE 2 The airborne concentration in a cleanroom depends on the air supply rate and not the air change rate.

A.2 Ventilation effectiveness

A.2.1 Ventilation effectiveness indexes

Two types of ventilation effectiveness index, ε , can be used in [Formula \(A.1\)](#). These are air change effectiveness, ACE , and contamination removal effectiveness, CRE ^[4]. Traditionally, the measurement of ventilation effectiveness is determined by tracer gasses. However, in cleanrooms, tracer gas concentrations are influenced by gas re-entering the cleanroom, and air samplers are readily available to measure particle concentrations and, therefore, particles can be used. See also the work done by Whyte and colleagues^[18].

A.2.2 Air change effectiveness (ACE)

The air change effectiveness, ACE , index is determined in ANSI/ASHRAE 129-1997 (RA 2002)^[15] as the relationship between the nominal time constant and age of air at a location. However, Whyte et al.^[18] have shown that when the contamination and the air are fully mixed at the start of the recovery test for a cleanroom, the overall recovery rate for the cleanroom is the same as the air change rate. Therefore, ACE can be calculated in cleanrooms with [Formula \(A.3\)](#), which shows how much clean air a location receives, compared to the average in the cleanroom.

$$ACE = \frac{ACR_m}{ACR_{tot}} \quad (A.3)$$

where

ACR_m is the air change rate of cleanroom air in the space around the measuring location in air changes per hour;

ACR_{tot} is the total air change rate of all the cleanroom air in that room, in air changes per hour

The air change rate of cleanroom air in the space around recovery rate at the measuring location is determined by measuring the decay of test contaminant at the location in a similar manner to that used for determining the recovery rate according to ISO 14644-3. The overall air change rate can be obtained from the air supply rate and the cleanroom's volume as in [A.2](#).

If the air mixing in the cleanroom is perfect, the ACE index is 1. If less clean air than average reaches the measuring location, the ACE index is below 1, and if more air reaches the location it is above 1. Lower values of the ACE index can be used with [Formula \(A.1\)](#) to compensate for poorer ventilation.

The value of the ACE indices in existing cleanrooms is influenced by the air inlet and extracts. If diffusers are efficient in mixing supply and room air and if the correct design rating, are used with low-level extracts, then the ACE index is likely to be between 0,7 and 1,3 (see Lenegan^[16]).

It should be noted that the ACE index can be measured at one or more locations. Using one location is satisfactory if airborne contamination occurs mainly at that location, but if contamination occurs at several locations, it can be necessary to determine the lowest ACE index.

In the majority of cleanrooms, the main contamination problem is caused by personnel who move freely about the room. In that situation, the aim should be to ensure that sufficient contamination-free air reaches the critical location(s) to ensure the required concentration of contamination.

A.2.3 Contaminant removal effectiveness (*CRE*)

An alternative ventilation effectiveness data contributor is the contamination removal effectiveness (*CRE*) number. This measures the effectiveness of removal of particle contamination and is shown in [Formula \(A.4\)](#).

$$CRE = \frac{C}{C_{avg}} \quad (A.4)$$

where

C is the total number of 0,5 micrometre or larger particles measured at the cleanroom exhaust duct per cubic metre;

C_{avg} is the average number of 0,5 micrometre or larger particles measured in the cleanroom per cubic metre.

The *CRE* number is the effectiveness of the cleanroom's air supply in diluting contamination in the cleanroom, and can be used to calculate the extra air required to compensate for rooms with a poorer clean air supply (see Bibliographic reference [4]). It ranges between 0,3 and 1,0, depending on the application.

A.3 Emission rate of particles in cleanrooms

A.3.1 General

To calculate the air supply volume required for a cleanroom, the emission rate of particles in the cleanroom is required. Particles are normally emitted from personnel, and equipment, and the emission rates from these two sources should be added together.

A.3.2 Emission rate of particles from personnel in a cleanroom

The emission of particles from personnel is usually the most important source in the cleanroom. To determine the exact value of the emission rate is difficult, as the rate of particle emission is dependent on each person, the design of the cleanroom garments, the occlusive nature of the fabrics used to manufacture garments, and the activity of personnel. Clothing should be viewed as an air filter against contamination emitted from a person's skin and clothing, and the best garments are those that fully cover personnel and use fabrics that emit the minimum of particles and prevent particles passing through them, e.g. closely-woven polyester. Gowns (smocks) give a poorer performance than coveralls as the particles emitted from personnel are able to pass under the garment. High activity of personnel gives much higher emission than lower activity.

Typical emission rates are shown in Bibliographic references [7] and [8]. However, emission rates can vary from these values, so, if possible, the actual rates should be obtained from measurements made in a cleanroom using the method given in [A.4](#).

A.3.3 Emission rate of particles generated by equipment

Emission rates of particles from equipment vary according to type, and it is best to obtain information of the rates from the manufacturer of the equipment. Alternatively, the total emission rate can be obtained experimentally using the method outlined in ISO 14644-14[17].

Use [Formula \(A.5\)](#) for the approximation of emission rate:

$$E = C \times Q \quad (A.5)$$

where

E is the emission rate of particles in number per second;

C is average room particle count per cubic metre;

Q is the air volume supply in cubic metres per second.

This method can also be used to include personnel operating the equipment, and the total emission rate of all sources in the cleanroom obtained.

A.4 Example of basic calculation for air supply rate in a non-unidirectional cleanroom

A non-unidirectional cleanroom of dimensions 10 m × 10 m × 3 m high (volume of 300 m³) has been designed to operate at ISO class 7 in operation. For this facility, the concentrations for particles larger than 0,5 µm and larger than 5,0 µm are of importance.

The facility has a high supply airflow rate of 3,3 m³/s (40 changes per hour), the room regularly exceeds its classification and is very expensive to run. A maximum of four personnel work in the cleanroom. Process equipment operates in the room.

Following a CFD simulation and review, an experienced cleanroom engineer recommended the following changes:

- swirl diffusers to be installed on the supply filters, in place of perforated screens;
- gowning practices to be improved, with staff wearing full coveralls, hood, face mask and gloves; and
- cleaning practices to be improved.

After these changes were implemented, the cleanroom was tested with significantly improved results. Using the CFD data a monitoring plan was implemented over a period of 2 weeks (a typical example of this application is shown in Figure 5.1 of *Energy performance in clean zones (cleanrooms, controlled environments, contained areas)* [5]).

The monitoring data were analysed to estimate the source strength of the personnel and the equipment in the cleanroom.

The estimated data are as follows:

- particles at and above 0,5 µm = 150 000/sec; and
- particles at and above 5 µm = 3 000/sec.

These figures are considered to be the maximum emission rate during normal operations, but will be increased by a suitable compensation factor to allow sequential testing adjustment as explained in Figure 3 and 6.4.

Based on the changes made to the facility and the CFD predictions, an ε based on an ACE of 0,7 is used in [Formula \(A.1\)](#) and a compensation factor of 1,5 is agreed.

Applying [Formula \(A.1\)](#) to the source strength for each particle size and using $C = 352\ 000$ for particles larger than 0,5 µm and $C = 2\ 930$ for particles larger than 5,0 µm indicates the following:

- $Q = 0,61$ for the 0,5 µm particles and 1,46 for the 5 µm particles, multiplying these by the compensation factor of 1,5 indicates that the following can be used in the progressive tests;
- 0,93 m³/s (11 AC/hr) can be used for the room for particles larger than 0,5 µm; and
- 2,2 m³/s (26 AC/hr) can be used for the room for particles larger than 5,0 µm.

Therefore, based on the higher flow requirement, the airflow for the application can be reduced from 3,3 m³/s to 2,2 m³/s (a reduction of 1,1 m³/s) for the first of the adjustments in procedure 6.4. Progressive adjustment of the compensation factor is made to ensure an optimum result and an impact assessment made before final acceptance.

A.5 Calculations of airflow in unidirectional cleanrooms

The cleanliness of a unidirectional airflow cleanroom is dependent on the air velocity and not on the air supply rate, or air change rate. However, to reduce the airflow supply volume, and thus the energy consumption, a decision should be made on whether low concentrations of contamination obtained by unidirectional airflow systems are really required or whether a non-unidirectional system would be adequate. Where unidirectional airflow is required, the size of the unidirectional area should be minimized to cover only the critical areas (the process core). This can be obtained by using clean air devices. The air velocity should be reduced while the specified particle or microbe-carrying particle concentration limits are maintained at the same time. In general, the higher the air velocity, the lower the concentration of airborne contamination.

The following variables should be taken into account:

- a) the amount of contamination emitted by people;
- b) emissions from equipment;
- c) other sources of airborne contamination;

Personnel management should consider the following when seeking a lower velocity:

- a) minimize the number of personnel present;
- b) minimize the proportion of their bodies under the unidirectional airflow;
- c) minimize the proportion of time they are within the unidirectional airflow; and
- d) increase personnel distance from the exposed product and provide product protection during product movement.

Disturbance of the airflow by personnel and equipment increases the contamination concentration in the critical area and should also be evaluated. Personnel movement should be taken into account, and equipment movement, thermal emission and obstruction to airflow should be taken into account.

During periods of little or no activity, airflow velocity may be reduced to between 0,2 m/s and 0,3 m/s with prior agreement from Product quality concerning the verification of this reduced air velocity. Control and removal of particle ingress should be confirmed by particle counting during operation and by airflow visualization (see ISO 14644-3)[6].

Annex B
(informative)

Energy saving opportunities

STANDARDSISO.COM : Click to view the full PDF of ISO 14644-16:2019

Table B.1 — Energy saving opportunities checklist

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
Source strength evaluation	Contamination sources	Avoid over-designing	Identify all relevant contamination sources and evaluate their strength to optimize airflow	Errors in evaluating sources and/or their strength	Enhance study of process; literature, design of experiments	Annex A
	Performance requirements	Avoid over-specifying	Specify correct operational parameters for the process (i.e. cleanliness class, recovery time, room pressure-T/RH, lighting levels, occupancy levels, etc.)	Loss in flexibility for possible changes in process	Set a small, reasonable margin, differentiate parameters for different criticalities	5.1, 6, 9
	Facility size requirements	Avoid oversizing	Specify correct dimensions of process areas, correct occupancy levels, etc.	Loss in flexibility for possible changes in process	Set a small, reasonable margin, allow for modular expansion of the areas and HVAC systems	5.2, 6, Annex F
	Occupancy levels	Optimize occupancy	Optimize people number in order to save space and reduce contamination by particles and MCPs	Operations can be more complicated	Enhanced procedures and control	5.2, 13
	Garment requirements	Minimize people emissions	Specify correct kind of garments based on process requirements	Increased cost and personnel discomfort		5.2
	Process equipment loads	Reduce the heat and humidity loads of process equipment	Consider reducing heat and humidity load values in process equipment selection	None	—	5.1, 9
	Process equipment suitability	Reduce contamination from process equipment	Specify process equipment suitability for cleanroom use (ISO 14644-14[17])	None	—	
	Use of barrier technologies	Minimize high classification areas	Consider possibility of using barrier technology concepts at specification stage to minimize high classification areas	Loss in flexibility, process can be more complicated	—	5.1, Annex F
	Airflow: UDAF	Reduce air velocity	Consider possibility of air velocity reduction while maintaining displacement effectiveness in UDAF-protected areas	Increased ingress of particles, reduced particle removal	Use of CFD in design. Provide a small, reasonable margin.	6, 7, 8, Annex A
					Validation by smoke studies and subsequent monitoring of contamination levels and environmental data.	

Table B.1 (continued)

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
Design, redesign, construction	Airflow: non-UDAF	Reduce airflow volume flow rate	Consider possibility of airflow volume reduction by evaluating contamination sources/strength, ventilation effectiveness and heat loads	Insufficient particle dilution, presence of dead spots and poor room temperature control. High value of recovery time	Use of CFD in design. Provide a small, reasonable margin. Validation and subsequent monitoring of contamination levels and environmental data	6, 7.1
	Make-up air	Reduce make-up air use	Consider possibility of make-up air optimization by careful evaluation of HSE needs, process needs (exhaust offset), room air leakages	Poor HSE conditions, poor pressure control	Provide a small, reasonable margin. Verification and subsequent monitoring of room pressure and HSE data	6, 10
	Extract airflow rate	Reduce extract airflow rate from process equipment	Consider possibility of extract airflow rate optimization by suitable design; consequent reduction in make-up air requirement.	Poor HSE conditions	—	6, 10
	Lighting systems	Select high-efficiency lighting systems	Design high efficiency lighting systems (LED, HF fluorescent); control system based on occupancy sensors, daylight compensation, dimmers	None	—	11
	Centralized AHUs vs FFUs	Maximize ventilation efficiency	Depending on application, select correct air recirculation system in order to reduce ventilation energy consumption	Maximize fan energy and/or minimize its consumption	—	6, Annex A, Annex E
	Turn-down/set back capability	Reduce airflow rate during idle hours	Consider possibility of including turn down/set back capability in HVAC design to allow for idle-hours operation at reduced airflow rate	Increased complexity of HVAC and control system; increased risk of failure	Use of CFD in design. Provide a small, reasonable margin. Validation and subsequent monitoring of contamination levels and environmental data	6, 7.1

Table B.1 (continued)

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
	Air-handling units and HVAC components	Use high-efficiency components and optimize performance	Optimize performance of AHUs and HVAC components to reduce energy consumption: select high-efficiency fans, electric motors and variable speed drives; specify low values of pressure losses through coils, filters and AHU's sections. Specify target <i>SFP</i> values	Increase in cost of construction. Increase of AHU's dimensions. Change in chiller performance	Optimize sizing according to existing specific fan power (<i>SFP</i>) reference tables [Example: non-domestic building services compliance guide (NBS), UK]	10
	Air filters	Lower initial pressure drop	Optimize performance of filters by selection of pre-filters and final filters according to "air filter life cycle costing model"	None	Select appropriate quality filters; follow manufacturer's guidelines for installation	10
	HVAC distribution systems	Optimize pressure drop by design	Design low-pressure drop, self-balanced ducting systems in order to reduce ventilation energy consumption (all branches on index runs)	None	Ensure instruments are calibrated	10, 14
	Building management system (BMS)	Optimize and improve energy management	Specify correct BMS sequences to avoid conflicting energy demands between heating/cooling, humidifying/ dehumidifying	None	Ensure instruments are calibrated and control loops are tuned.	14
	Environmental management systems (EMS, PMS, MMS)	Monitor environmental parameters to support energy reduction measures	Specify environmental monitoring systems for T/RH/P (EMS), airborne particles concentration (PMS) and airborne microbial particles concentration (MMS) to support energy reduction measures	Cost of construction	Optimize number/location of sensors by means of risk assessment and CFD studies	13 14
Testing	Adaptive control	Reduce airflow volume flow rate according to contamination demand	Consider possibility of providing adaptive control systems to implement on-demand energy reduction measures	Failure in local control of contamination levels and environmental parameters	Select number/location of sensors by means of risk assessment	8
	Commissioning, validation	Verify energy reduction measures by commissioning and/or validation	Use outcomes of commissioning/validation to verify effectiveness of energy reduction measures	None		12, 6

Table B.1 (continued)

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
Operation and maintenance	Periodic testing	Verify energy reduction measures by periodic testing	Use outcomes of periodic testing over long periods to verify effectiveness of energy reduction measures and detect possible residual margins	None	—	12 , 4.12
	Operator competence (training)	Enhance training of personnel to reduce contamination strength	Operator competence helps reduce airborne contamination strength in clean room	None	—	12
	Monitoring	Monitor environmental parameters to verify energy reduction measures	Environmental monitoring systems for T/RH/P (EMS), airborne particles concentration (PMS) and airborne microbial particles concentration (MMS) helps verify on a continuous or frequent basis the effectiveness of energy reduction measures	None	—	13 , 14
	Turn-down/set back Programmes	Run HVAC at reduced rate when not in operation	HVAC can be operated with reduced airflow rate in at-rest, unmanned condition	Unauthorized room entry	Enhance training of personnel, especially maintenance and cleaning teams Implement effective access control and alarm systems	7.1
	Switch-off	Documented switch-off of HVAC when cleanroom not operational	HVAC can be switched off when non-operational and unmanned for a long period	Unauthorized room entry Risk of overall contamination, particulate displacement from filters on restart and dew point increase	Enhance training of personnel, especially maintenance and cleaning teams Implement effective access control and alarm systems Impact assessments required, take great care on start-up	7.2

Table B.1 (continued)

Stage of implementation	Element	Opportunity	Consideration	Possible adverse impact	Risk mitigation strategies/tools	Ref.
	Clean room Air leakage	Ensure pressure tightness over time	Ensuring pressure tightness over time helps avoid increase of make-up air	Possible instability of pressure control under a minimum leakage airflow rate	Promote a minimum, controlled leakage airflow rate (i.e. provide relief dampers)	14
	Maintenance programmes	Preserve energy efficiency of HVAC systems by setting proper maintenance programmes	Proper maintenance programmes help minimize filters' pressure drop and maximize efficiency of HVAC components	None	—	14
	Cleaning and housekeeping	Reduce contamination load on CR by setting appropriate cleaning and housekeeping programmes	Appropriate cleaning and housekeeping programmes help reduce the contamination load in cleanroom and can support energy reduction strategies	None	—	14
Cleanroom disposal (decommissioning)	Decommissioning	Stop operating an obsolescent cleanroom and/or a cleanroom with low efficiency	Energy saving resulting by decommissioning an obsolescent and/or low efficient cleanroom Need to assess the impact on adjacent or associated rooms	Difficulties in maintaining required parameters (temperature, humidity, pressure) in adjacent rooms	Ensure appropriate design or modify accordingly	15

Annex C **(informative)**

Impact assessment

[Annex B](#) gives a check list of things to consider as opportunities for energy optimization, along with possible adverse impacts and tools to minimise the impact of any change.

Changes can include modifications to the HVAC facilities production layouts and process flows, operational modes, cleaning and maintenance. Changes should be documented to ensure that the intended specification is met and any proposed change to a cleanroom design should not affect this.

A careful assessment of the impact and consequences of any proposed energy optimization change should be carefully addressed in the context of the fundamental principles of "establish control" and then "demonstrate control".

Assessment factors should include:

- 1) contaminants;
- 2) people variability and uncertainty:
 - people are a highly variable source strength of contamination; and
 - people density, gowning, and cleaning are significant factors to consider;
- 3) process variability.

Tools for identifying the critical control points for contamination control within a cleanroom environment are given in Bibliographic references [\[19\]](#), [\[20\]](#) and [\[28\]](#).

Any proposed change should be communicated clearly to the customer and any changes agreed in advance.

Annex D (informative)

Benchmarking: Energy performance indicators for cleanrooms

D.1 Metrics — General

Cleanrooms are amongst the most energy-intensive facility types due, at least in part, to high airflow rates, high filtration requirements and the use of ventilation air for pressurization. There is a wide range of energy efficiency in cleanroom facilities within and across industries. It is possible that facility managers in low-efficiency facilities do not possess a means to gauge the energy efficiency of the contamination removal in their cleanroom facility or, more specifically, to identify the energy costs for removing contamination from their cleanrooms by means of the air-handling system. [Annex D](#) describes a system for comparing the performance of cleanroom facilities over time or relative to other, similar facilities with the same cleanliness requirements.

[Annex D](#) proposes a scale for comparison of energy consumption between air-handling systems in clean environments with similar requirements. The energy performance indicators (EnPI) identified are intended to provide an effective means to compare one facility to another and to assess, track and manage the level of energy efficiency of a given facility over time; or to set targets for new construction. This annex addresses only those issues which are unique to cleanrooms, namely contamination removal, leaving overall mechanical heating, cooling and humidification/dehumidification to more general HVAC standards and their EnPIs.

The EnPIs proposed are adapted from those identified by Lawrence Berkeley National Laboratory and published in the ASHRAE Journal v. 53, issue 10^[21], VDI 2083-4.2^[22], BS 8568^[23], and as described in ISO 50006^[24].

D.2 Scope of metrics

The metrics are applicable to all clean manufacturing spaces addressed within the ISO 14644 series.

Spaces considered and evaluated under this system include ISO classified rooms, areas and equipment enclosures (e.g. isolators, RABS, clean work benches, downflow booths, “unidirectional” flow booths and workstations).

Excluded are offices, toilets, amenities, warehouses, workshops, public corridors and other non-clean manufacturing or research spaces, even if such spaces are within classified zones.

D.3 Performance indicator metrics and baselines

The system is split into three main metrics or energy performance indicators (EnPI):

- 1) Power intensity for contamination removal (*PICR*): gives the instantaneous power consumption per square metre of floor surface for the air-handling system to remove contamination. This is the power input to the fan system, in operational state (including efficiency losses for electrical components), divided by the floor area of the cleanroom. This metric is the product of two sub-metrics: specific fan power and normalized airflow rate (a more detailed description of the calculation method is provided in [D.4](#)). The overall *PICR* is the total of the *PICR* for all systems, or portions of systems, serving the area under consideration.
- 2) Energy intensity for contamination removal (*EICR*): gives the energy use which is required per square metre floor surface, on an annual basis, to remove contamination by the air handling

system. This metric takes into account set-backs, turndowns and advanced control strategies (a more detailed description of the calculation method is provided in [D.4](#)).

- 3) Energy intensity of the facility (EI): gives the energy use which is required per square metre of floor area, on an annual basis, including heating, cooling, humidification, dehumidification, lighting, etc. This metric includes the efficiency of generation systems, impact of energy recovery, as well as the impacts of building shell construction, siting and outside air pre-treatment. This metric is as described for all facility types in ISO 50006[24]. However, for this use the metric includes only the energy employed for the cleanrooms and is organized by cleanroom classification.

For monitoring a facility, a reference or energy baseline (EnB) should be determined. This is the value of EnPI at a specific point in time in the past for the facility. From this EnB, a periodic check can be made to determine change, and new targets set for energy reduction.

D.4 Power intensity for contamination removal (*PICR*)

PICR should be determined for all air-handling units serving the cleanroom, clean zone, clean enclosure, etc. This includes but is not limited to the make-up air units, recirculation air units and exhaust air units.

To determine this metric for a specific part of the system the electrical power consumption of the fans and the floor surface area of the cleanroom are required. Dividing the total fan power by the area, results in the power intensity for contamination removal [see [Formula \(D.1\)](#)].

$$PICR = \frac{\sum P_e}{A} \quad (D.1)$$

where

A is the floor surface area of the cleanroom (m^2).

$PICR$ is the electrical fan power for contaminant removal (kW/m^2);

$\sum P_e$ is the sum of the electrical power of the fans (kW);

This metric can also be determined via two sub-metrics: specific fan power, *SFP*, and normalized airflow rate, Q_N . The advantage of these sub-metrics is that it shows the efficiency and effectiveness separately. The efficiency is shown by the amount of energy required to move a cubic metre of air through the air handling system. The effectiveness is shown in the amount of air which is required to remove the contaminants from a square metre of cleanroom floor. For both metrics, a lower value indicates lower energy consumption.

a) Specific fan power (*SFP*)

The *SFP* should be determined for all air-handling units serving the cleanroom, clean zone, clean enclosure, etc. This includes (but is not limited to) the make-up air units, recirculation air units and exhaust air units. *SFP* is determined by measuring the airflow rate and electrical input of each unit in operational conditions.

Flow should be measured by a consistent and proven method to ensure comparable results. For example, measurement can be via a pitot tube and differential pressure instrument, thermo-anemometer (hotwire) or pressure differential instrument measurements at the fan using a *K*-factor selected by reference to the specific fan curve.

Measurement of input power can be made directly via a current meter and volt meter to determine the power consumption. Taking into account the ratio between active and reactive power, $\cos \varphi$, which is shown on the drive motor label for nominal power. When the motor load is lower than 70 % to 80 % of nominal power, $\cos \varphi$ should be measured specifically. Where the fan is equipped with a variable speed drive (VSD), power can be read directly from the display on the VSD or this reading can be recorded on the building energy management system.