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This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.

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European foreword

This document (EN ISO 14644-16:2019) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2019, and conflicting national standards shall be withdrawn at the latest by December 2019.

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Endorsement notice

The text of ISO 14644-16:2019 has been approved by CEN as EN ISO 14644-16:2019 without any modification.
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO’s adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

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

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.]