KLEANLABS

THE COMPLETE GUIDE

ISO 14644

CLEAN ROOM STANDARD

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The Revised Cleanroom ISO 14644

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 organizations, 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.

What exactly do I get for free?

We need to stress the importance that all ISO standards are the intellectual property of the ISO organization, therefore, spreading these across the internet free of charge would be illegal. Not to mention that the detailed specifications of these standards usually cost several thousand euros/dollars and giving them away for free would cause a competitive disadvantage for the companies who buy it. This is why you're unlikely to find the package on the internet. However, we have created an informative guide that will lead you to the exact place on the official ISO website where you can purchase what you need. Our goal was to provide information on the various parts of the standard so that you will know which parts you need and which parts to purchase.

For reference, the full set of ISO 14644 parts is listed below

ISO 14644-1:2015 – PART 1
Classification of air cleanliness

ISO 14644-2:2015 – PART 2
Specifications for testing and monitoring to prove continued compliance with ISO 14644

ISO 14644-3:2005 – PART 3
Test methods

ISO 14644-4:2001 – PART 4
Design, construction and start-up

ISO 14644-5:2004 – PART 5
Operations

ISO 14644-6:2004 – PART 6
Vocabulary

ISO 14644-7:2004 – PART 7
Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

ISO 14644-8:2013 – PART 8
Classification of air cleanliness by chemical concentration (ACC)

ISO 14644-9:2012 – PART 9
Classification of surface cleanliness by particle concentration

ISO 14644-10:2013 – PART 10
Classification of surface cleanliness by chemical concentration

NO PART 11
in draft

ISO 14644-12: DRAFT – PART 12
Classification of air cleanliness by nanoscale particle concentration

ISO 14644-13: DRAFT – PART 13
Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications

ISO 14644-14: DRAFT – PART 14
Assessment of suitability for use of equipment by airborne particle concentration

ISO 14644 Series Cleanroom Standards

Importantly, ISO 14644 is NOT a GMP standard. Parts of the standard have been adopted by GMP systems, such as the reference to ISO classes in the 2004 FDA Guidance on Aseptic Processing and the requirement to use the standard to classify cleanrooms in Annex 1 of EU GMP. Not all parts of the standard are applicable to GMP environments, for example, Part 12 is intended for the nanotechnology industry. Revisions to ISO 14644 In December 2015, of ISO 14644 were revised. The more substantial changes relate to Part 1. As part of the change process, the title of the second part of the standard was altered to “Specifications for testing and monitoring to prove continued compliance by ACP” (with ACP representing ‘airborne particulate contamination’).This main part of the article considers the key changes, beginning with Part 1.

LIST OF

ISO 14644

CLEANROOM STANDARDS PUBLISHED

Document	Title	Status	Description
ISO 14644-1	Classification of air cleanliness by particle concentration	ANSI Standard 2015	Covers the classification of air cleanliness in cleanrooms and associated controlled environments.
ISO 14644-2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	ANSI Standard 2015	Specifies requirements for monitoring and periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1.
ISO/ANS 14644-3	Test methods	ANSI Standard 2005	Specifies test methods for designated classification of airborne particle cleanliness for characterizing the performance of cleanrooms and clean zones.
ISO 14644-3	Test methods	ISO Standard 2019	This ISO Standard has not been approved as an American National Standard, and does not replace ANSI/IEST/ISO 14644-3:2005.
ISO 14644-4	Design, construction, and start-up	ANSI Standard 2001	Specifies requirements for the design and construction of cleanroom installations.
ISO 14644-5	Operations	ANSI Standard Aug. 2004	Specifies basic requirements for cleanroom operations.
ISO 14644-7	Separative devices (clean air hoods, gloveboxes, isolators, minienvironments)	ANSI Standard Nov. 2004	Specifies the minimum requirements for the design, construction, installation, testing and approval of separative devices.
ISO 14644-8	Classification of air cleanliness by chemical concentration (ACC)	ANSI Standard 2013	Covers the classification of airborne molecular contamination (AMC) in cleanrooms and associated controlled environments.
ISO 14644-9	Classification of surface particle cleanliness	ANSI Standard 2012	Establishes the classification of cleanliness levels on solid surfaces by particle concentration in cleanrooms and associated controlled environments.
ISO 14644-10	Classification of surface cleanliness by chemical concentrations	ISO Standard 2013	Defines the classification system for cleanliness of surfaces in cleanrooms with regard to the presence of chemical compounds or elements.
ISO 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	ANSI Standard 2018	Covers the monitoring of air cleanliness by particles in terms of concentration of airborne nanoscale particles.
ISO 14644-13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	ISO Standard 2017	Addresses the cleaning to a specified degree on cleanroom surfaces, surfaces of equipment in a cleanroom and surfaces of materials in a cleanroom.
ISO 14644-14	Assessment of suitability for use of equipment by airborne particle concentration	ISO Standard 2016	Specifies a methodology to assess the suitability of equipment for use in cleanrooms and associated controlled environments.
ISO 14644-15	Assessment of suitability for use of equipment and materials by airborne chemical concentration	ISO Standard 2017	Provides requirements and guidance for assessing the chemical airborne cleanliness of equipment and materials, which are foreseen to be used in cleanrooms and associated controlled environments.
ISO 14644-16	Code of practice for improving energy efficiency in cleanrooms and clean air devices	ANSI Standard 2019	Provides guidance and recommendations for optimizing energy usage and maintaining energy efficiency in new and existing cleanrooms, clean zones and separative devices.
ISO/DIS 14644-17	Particle deposition rate applications	DIS October 2019	Provides guidance on the interpretation and application of the results of the measurement of Particle Deposition Rate (PDR) on one, or more vulnerable surfaces in a cleanroom as part of a contamination control program.

How is ISO 14644-1:2015 different from ISO 14644-1:1999

What makes it substantially different? Let us guide you through it in the following table.

	ISO 14644-1:2015	ISO 14644-1:1999
UCL 95%	If the number of sampling locations was between 1 and 10, standard deviation and UCL 95% was calculated. It is this figure that must be within a certain range for the specific class of clean room.	Completely removed the standard deviation and UCL 95%. The clean room has met its classification requirements if the average particle concentrations at each sample location are within specification.
Equipment Calibration	The instrument shall have a valid calibration certificate, the frequency and method of calibration should be based on current accepted practice.	The particle counter shall have a valid calibration certificate: the frequency and method of calibration should be based upon current accepted practice as specified in ISO 21501-4
Ultra and Micro(u, M) Descriptors	Smaller than 0.1 microns defined as u, larger than 0.5 microns defined as M.	Smaller than 0.1-micron particles will no longer exist in ISO 14644-1. This issue will address in ISO 14644-12

What do you need to know about Kleanlabs?

Kleanlabs is the subsidiary of an established clean room manufacturer on the Central European market with quarter of a century history. Although the Kleanlabs brand might be young, our experience in the industry has helped us to be able to manufacture products with an outstanding quality. Today we manufacture 5000 items a year that are used all over the world.
Our unique selling point has always been a competitive price. We believe that cost efficiency should never be related to low quality. Kleanlabs systems meet all clean room requirements such as ISO14644-1 and GMP and feature a user-friendly design, meaning easy installation and maintenance. We offer world-leading quality at much more affordable prices that you might be familiar with.

Get to know our product line

Capitalizing on our several decades of experience in the industry, we have designed a product line that withstands extreme mechanical stress, yet is pleasing to the eye. Our product family focuses on clean room doors and pass boxes that can be installed into any already-existing clean room.

Kleanlabs clean room doors

All our clean room doors are independent systems and easy to mount. We offer both hinged and sliding models. The 60mm thick, completely flat aluminum door panels are outstandingly resilient to bending and are extremely long lasting. They feature a high level of airtightness that will comply with any standard. We market our doors with safety glazing, antistatic surfaces and premium hardware.

Kleanlabs pass boxes

We offer static, semi-active and active pass boxes, depending on the application. All our products are easy to clean thanks to their flat surfaces and easy to integrate into any wall structure. Similarly to our clean room door product line, Kleanlabs clean room pass boxes feature robust, 60 mm thick door panels that are extremely durable. Also equipped with safety glazing, antistatic surfaces and premium hardware, our clean room pass boxes will be an ideal addition to any clean room.

Kleanlabs clean room cabinets

As a version of Kleanlabs pass boxes, we have designed the Kleanlabs clean room cabinet especially for operating rooms. These cabinets are equipped with the same features as the above-mentioned products but are completely see-through and can be customized to fit a hospital environment perfectly.

Kleanlabs mobile clean room container

Should you need a certified clean room on the move, the Kleanlabs mobile clean room container might be the right solution for you. These portable clean rooms that are built into standard 20' and 40' containers can be taken to any remote location. Given its standardized measurements, easy shipping is guaranteed and can be done by boat or on the road. Only an adequate source of power is required to work the mobile clean room.

Kleanlabs clean room doors

Kleanlabs pass boxes

Kleanlabs clean room cabinets

Products

All our products are highly customizable with card opening, mechanical locking, electronic locking system etc. For more information, please visit our website:

https://kleanlabs.com/