How to use the international cleanroom standards

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Introduction

Cleanroom standards are documents to be used to improve the communication between customers and suppliers. Standards are not a textbook but an overview of terms and definitions, basic agreements and topics to be agreed and to consider. Historically the first standards focussed on cleanrooms and nowadays the focus is more on contamination control with respect to nanoparticles, airborne particles, macroparticles, microorganisms and chemicals and the application of cleanrooms. This approach has led to many standards and therefore it has become more difficult to select the standards to be used. There are various ways to select the right standards to be used. The starting point is the process(es) to be controlled. An impact or risk assessment can be executed to determine the required control topics.

ISO Standards

The ISO Technical Committee 209 has developed 18 standards. 15 standards are still in use. These are ISO 14644-part 1, 2, 3, 4, 5, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17 and 18. ISO 14644-6 and ISO 14698-1, 2 are not in use anymore. 2 new standards, ISO 14644-19 and ISO 14644-20, are in development. To support part 1 and 2 a Technical Report ISO TR 14644-21 is published.

The titles of the mentioned standard numbers are given in an overview in the annex.

ISO standards are reviewed every 5 years and are revised when necessary. A standard can be referred to with or without the year of publication. In case the year of publication is not given the latest published document should be used.

The standards can be grouped per type of contaminant to be controlled, cleanroom/separative device or cleaning. Per group relevant topics are shown in the table below:

Topic	Airborne particles	Macro-particles	Micro-organisms	Chemicals	Nano-particles
Air cleanliness	1, 2	17	20	8	12
Surface cleanliness	9	9, 17	20	10	
Measurement	1, 9	3, 21	20	8,10	12
Sources	14, 18	14, 18		15, 18	

The standards on cleanliness with respect to a contaminant contain ways to set limits and to measure cleanliness levels. An exception is part 17 on particle deposition rate of macro particles.

Topics	Cleanrooms	Separative devices	Cleaning
Design	4, 16	7, 16	13
Construction	4, 16	7, 16	13
Start up	4, 16	7, 16	13
Measurement	1, 3	1, 3	9, 10
Operation	5	5	5
Monitoring	2, 8, 12, 14698	2, 8, 12, 14698	9, 10, 14698

Cleanrooms, clean zones and separate devices can be classified with respect to the cumulative airborne particle concentration limit at a particular state of occupancy and a particle size between ≥0,1 µm and ≥5 µm using the method described in ISO 14644-1. At critical locations the air cleanliness can be monitored for one or more of the five contaminants. In ISO 14644-2 the way to set up a monitoring program is described and how to demonstrate a cleanroom is still functioning within its ISO class.

Contamination control

Products or processes that are sensitive to contamination by particles, microorganisms and/or chemicals need special measures to limit the likelihood of deposition and transfer of contaminants onto vulnerable surfaces. These measures include removing contamination by cleaning and prevention of contamination by the use of cleanrooms and/or separative devices.

To achieve a contamination control solution three steps can be identified:

1. Risk or impact assessment
2. Establish control
3. Demonstrate control

These three steps can be used to determine the standard that can be used.

Risk or impact assessment

The starting point is an assessment to determine which contaminants and how much of these contaminants can harm the assesses product or process. In case these contaminants cannot be removed, contamination needs to be prevented. Then it is important to determine the location(s) the product or process is at risk. At these critical locations contamination can deposit from the air and/or be transferred during contact. The difference between the initial surface cleanliness of the vulnerable surface before entering the critical location and the prescribed final surface cleanliness limit after entering the critical location determines the maximum acceptable amount of contamination.

To be able to do this exercise the surface cleanliness standards of the contaminants of interest must be used (ISO 14644-9 or ISO 14644-10). For microorganisms there is no quantitative standard. Since microorganisms are carried by particles, ISO 14644-9 could be used.

The contamination depends on the air cleanliness at the critical location and the surface cleanliness of potential contact surfaces. The required air cleanliness depends on the maximum acceptable deposition rate (ISO 14644-2, 14644-8 or ISO 14644-12). For particles this depends

on the particle size and mass and their concentration. The smaller the particle size, the lower the deposition velocity. The ventilation efficiency at the critical location determines the likelihood of deposition. This increases with particle size. Deposition depends on surface area of critical surface and time of exposure. For chemicals there no standard on deposition. For macro-particles see ISO 14644-17. The air cleanliness requirements can be determined by a worst case analysis.

In general the surface cleanliness of contact surfaces should be of the same order as the vulnerable surface. Here the exposure and cleaning program are important. Cleaning methods can be selected using ISO 14644-13.

The determined required cleanliness levels are input for the next step. In case it is not possible to perform a quantitative analysis, benchmarks can be made to determine the required cleanliness levels.

Establish control

To establish control a clean facility, cleanroom or associated controlled environment and a set of proper operational procedures has to be realised. The program of requirements will contain the required cleanliness levels at the critical location. The cleanroom class determines the overall limit of the critical locations inside the clean facility. See ISO 14644-1. The realisation involves design, construction and start-up of the clean facility. Standards that can be used are ISO 14644-4 and ISO 14644-7. For energy efficiency aspects ISO 14644-16 can be used. It is recommended to establish a tuneable installation to be able to reduce energy consumption when possible.

In the design of a clean facility the source strength of people, equipment, tools and materials determines the ventilation volume to reach the required air cleanliness level. Guidance can be found in ISO 14644-14, ISO 14644-15 and the future ISO 14644-18 and source data from suppliers.

For verification with respect to the required cleanliness levels the standards used during the risk assessment should be used.

For the development of the operational procedures ISO 14644-5 can be used. Training of personnel is an important part of the start-up.

Demonstrate control

During operation the relevant parameters are monitored to demonstrate control. In ISO 14644-2 the method of setting up a monitoring program is described. For the monitoring of the relevant cleanliness levels the documents used during the risk assessment can be used.

In ISO 14644-5 also the monitoring of personnel and retraining is addressed.

From the 3 contamination control steps the following overview of the relevant standards can be made:

Topic	Airborne particles	Macro-particles	Micro-organisms	Chemicals	Nano-particles
Risk assessment	1, 2, 9	2, 9, 17	14698-1,2	8, 10	12
Establish control	+ 3, 4, 5[1], 7, 14, 16	+ 1, 3, 4, 5, 7, 14, 16	+ 1, 3, 4, 5, 7, 16	+ 1, 3, 4, 5, 7, 15, 16	+ 1, 3, 4, 5, 7, 14, 16
Demonstrate control	+ 13, 18, 21	+ 5, 13, 18, 21	+ 5, 13	+ 5, 13, 18	+ 5, 13

Conclusion

ISO TC209 standards can be used by customers and suppliers. Depending on their task and the type of contaminants of concern the standards to be used can be selected. Three ways of ordering of the standards are demonstrated:

1. Type of contaminant,
2. Type of goal,
3. Contamination control approach.

Historically the standards focussed on setting up a cleanroom and classifying air cleanliness with respect to airborne particles. Later the design, construction and start-up of cleanrooms and measurement methods associated with the cleanroom environment, as well as operations. Then there was a focus on other contaminants, such as microorganisms, outgassing chemicals and nano particles. This was followed by surface cleanliness as while particles can be entrained in an airstream they can also settle on surfaces. A number of the original standards have gone through a systematic review and have been updated. In recent times there has been a wider focus on contamination control including materials, consumables and lifecycle considerations, such as energy efficiency.

[1] ISO 14644-5:2004 does not address chemicals, but this will be included after revision.

Annex

Overview of ISO TC 209 standards: "Cleanrooms and associated controlled environments":

ISO 14644

Part	Title	Year
1	Classification of air cleanliness by particle concentration	2015
2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015
3	Test methods	2019
4	Design, construction and start-up	2021
5	Cleanroom operations	2004[2]
7	Separative devices (clean air hoods, glove boxes, isolators and minienvironments)	2004[2]
8	Classification of air cleanliness by chemical concentration	2022
9	Classification of surface cleanliness by particle concentration	2022
10	Classification of surface cleanliness by chemicals concentration	2022
12	Specifications for monitoring air cleanliness by nanoscale particle concentration	2018
13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical concentrations	2017
14	Assessment of suitability for use of equipment by airborne particle concentration	2016
15	Assessment of suitability for use of equipment and material by airborne chemical and surface chemical concentration	2017
16	Energy efficiency in cleanrooms and separative devices	2019
17	Particle deposition rate applications	2021
18	Assessment of suitability of consumables	2023
20	Microorganisms[3]	In preparation
21	Airborne particle sampling techniques	2023

ISO 14968[4]

Part	Title	Year
1	Biocontamination control - General principles	2003
2	Biocontamination control - Evaluation & Interpretation of Biocontamination Data	2004

[2] In revision

[3] Title will be determined by ISO TC209 WG2

[4] Both parts are not in use and will be replaced by ISO 14644-20 that will be based on EN 17141 Cleanrooms and associated controlled environments - Biocontamination