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Contamination control – Cleanliness-controlled workshop environment

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Contents

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Foreword

This issue replaces the first issue of the standard, which was confirmed in 1995. The main difference from edition 1 is that the reference to the current ISO work has been changed after the publication of SS-EN ISO 14644-1, SS-EN ISO 14644-2 and SS-EN ISO 14644-4.

In this standard, the requirements from the standards in the SS-EN ISO 14644 series – Cleanrooms and associated controlled environments have been specified in one standard. It also gives concrete examples on the applications within the field, e.g. clothing for work in cleanrooms and tables with comparisons to other foreign national standards.

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Introduction

Cleanliness-controlled workshop environment has been developed during the last 50 years, starting in the USA. At an early stage, the miniaturization of components demanded a clean environment and increased requirements on reliability and service life. The requirements first came from the precision-engineering production and service (miniature ball bearings, gyro, etc.) for aeroplanes, optics and space research in the first place. At the same time, the cleanroom environment within the pharmaceuticals industry was developed and, at a later stage, the semi-conductor industry developed a very advanced cleanliness-controlled environment.

In order to achieve a cleanliness-controlled workshop environment, premises of appropriate design are required which are easy to keep clean and have a supply of filtered air. The personnel shall wear clothes which do not give off harmful dust and which prevent damage to products by the normal shedding of flakes of skin and hair, etc.

A basic consideration is for the personnel to receive training in contamination control and for their skills to be maintained, if the material resources are to produce good results

As far as the properties of the room/zone air are concerned, this standard is based on the classification applied by the Swedish defence industry since the 1960s with respect to air temperature, air humidity, air filter, air overpressure/underpressure and air exchanges.

For airborne particles in rooms/zones, there are both international and national room classes in use since the 1960s. Generally, Federal Standard 209 (USA) from 1963 has been used as a basis. However, this standard has been withdrawn in connection with the publication of ISO 14644-1 and ISO 14644-2. In Sweden, FMV (the Defence Material Administration) drew up standards at an early stage. ISO is currently preparing standards on room layout and inspection.

Concerning requirements on the building from a contamination-control point of view, there are general rules in Europe within the pharmaceutical field, EC GMP (European Community – Good Manufacturing Practice). To a certain extent, these rules can be applied. In this standard, documentation from FMV (the Defence Material Administration) has principally been used.

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1 Scope

This standard specifies requirements for achieving a cleanliness-controlled workshop environment for various kinds of production and service: for example the production, assembly and maintenance of hydraulic components, precision engineering, electronics, optics, when bonding, painting, etc.

The standard specifies:

— the requirements for cleanliness classes 10, 9, 8,5, 8 and 7 in the form of particle content/particle size in air, air temperature and humidity;

— how to plan, design and build rooms/zones with defined cleanliness requirements. Special emphasis is placed on those requirements which must be established between the purchaser/constructor and the seller/contractor in order to reduce later faults in production;

— various forms of premises maintenance and how it is performed to maintain the intended cleanliness class;

— various types of protective clothing for different cleanliness classes, including underclothes, specifications and the washing and care of protective clothing;

— how to carry out training for personnel who work in a cleanliness-controlled workshop environment.

The conception “cleanroom” is complex, and a number of designations and definitions are internationally used. A “cleanroom” may have a highly variable level of cleanliness, which may include the whole room or parts of the room, so-called zones. The room can also be combined with clean-air zones.

Depending on the context, different expressions may be applicable. The following concepts have been used in this standard (see also clause 3 Terminology):

— cleanrooms or clean rooms/zones (the shortest general designation)

— controlled rooms/zones (as above, but designates a considerably lower cleanliness level)

— cleanliness-controlled area/cleanliness-controlled space (a part of the room is mainly referred to)

— classified space (other factors than cleanliness, e.g. air humidity, are of great importance)

— cleanliness-controlled environment (a number of different environmental factors are relevant).

2 Normative references

The following referenced documents are indispensable for the application 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.

SS-EN 779, *Particulate air filters for general ventilation – Determination of the filtration performance*

SS-EN 1822-1, *High efficiency air filters (HEPA and ULPA) – Part 1: Classification, performance testing, marking*

SS-ISO 8573-1, *Compressed air – Part 1: Contaminants and purity classes*

SS-EN ISO 9237, *Textiles – Determination of permeability of fabrics to air (ISO 9237:1995)*

SS-EN ISO 14644-1, *Cleanrooms and associated controlled environments – Part 1: Classification of airborn particulates (ISO 14644-1:1999)*

SS-EN ISO 14644-2, *Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000)*

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SS-EN ISO 14644-4, *Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up (ISO 14644-4:2001)*

IEST-RP-CC-003.2, *Garment system considerations for cleanrooms and controlled environments*

3 Terms and definitions

For the purpose of this standard, the following definitions apply.

3.1
operating condition
(in this context) three conditions for cleanrooms/clean zones:

— finished cleanroom/clean zone without equipment (as-built)

— finished cleanroom/clean zone with all equipment, but without production (at-rest)

— finished cleanroom/clean zone with all equipment, and with production in progress (in-operation)

3.2
filter class
classification of filters

NOTE Classification of filters in accordance with SS-EN 779 or EUROVENT 4/5 (including basic and fine filters). SS-EN 1822-1 for HEPA filters and micro filters.

3.3
humidity class
classification of humidity within specified limits

3.4
damp mopping
wiping with the use of a damped mop (usually wiper)

NOTE A damped mop is a dry mop sprayed with liquid/water, while a wrought out mop has been immersed in liquid/water and then wrought out.

3.5
damp swabbing
wiping with the use of a damp swab

NOTE The swab is usually made of cotton threads, fibres or strips).

3.6
contaminant
material or physical factors that obstruct or prevent the achievement of the specified function or service life of a system and its medium

3.7
HEPA filter
filter with a ≥ 99,97 % degree of separation of particles ≥ 0,3 µm

NOTE HEPA stands for High Efficiency Particulate Air.

3.8
classified area
see “cleanliness-controlled area”, ”cleanliness-controlled space”

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3.9
inspection method
method for determining the level of air cleanliness and surface cleanliness, temperature, humidity, noise, etc

3.10
LAF bench
workbench with a horizontal or vertical airflow, which flows in a parallel pattern and with a uniform velocity

NOTE The airflow is usually 0,4 ± 0,1 m/s.

3.11
air shower
device for cleaning people and goods using filtered air flow

NOTE 1 Air showers are positioned direct adjacent to the entrance to and exit from a cleanliness-controlled zone/cleanliness-controlled space.

NOTE 2 See also “air lock”.

3.12
membrane filter
thin filter with a defined pore size

3.13
particle size
(at optical reading) the greatest linear extension of a particle

(when measured with an SPC instrument, “single-particle counting light-scattering instrument”) stated as the diameter of a sphere with an optically equivalent response (size, form, light reflection, etc.) compared with the measured particle

NOTE The definition of particle size depends on the method of measurement.

3.14
clean zone
delimited area where the concentration of airborne particles are checked (verified) against specified tolerances

NOTE 1 A clean zone may be in an LAF bench or an area under an LAF ceiling.

NOTE 2 UDF, (unidirectional flow) is a more correct denomination than LAF, (laminar flow).

3.15
cleanroom, clean room
room in which the number of airborne particles is checked against specified tolerances.

NOTE 1 This concept is applied primarily to rooms and zones with high requirements for cleanliness, e.g. in the electronics and pharmaceutical industries.

NOTE 2 Cleanroom concerns classified rooms. Clean room concern un-classified rooms.

3.16
cleanliness
characteristics of a component or system which indicate the presence of contaminants

3.17
cleanliness-controlled area/cleanliness-controlled space
room or zone in which the number of airborne particles is checked against specified tolerance

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3.18
cleanliness-controlled environment
surroundings in which quantified requirements apply to airborne particles, positive air pressure, negative air pressure, change of air, surface cleanliness, temperature, humidity, noise, vibrations and ESD (electrostatic discharges)

NOTE This standard does not specify all these requirements.

3.19
cleanliness class
cleanliness level indicated for any one or combination of the room/zone classes, air treatment, structural engineering requirements, work regulations, premises maintenance and protective clothing.

NOTE 1 In this standard cleanliness class is indicated in accordance with SS-EN ISO 14 644-1.

NOTE 2 Cleanliness requirement can vary depending on the type of contaminant.

3.20
cleanliness level
quantified requirement as to cleanliness

3.21
cleanliness technique
technique with the aim of preventing material or physical contaminants from damaging products

3.22
protective clothing
clothing, the principal purpose of which is to protect the product or activity from contamination by men

3.23
air lock
device for separating one room from another in some specific respect, and yet permitting passage into rooms or between rooms

NOTE 1 An air lock may be intended, for example, to keep airborne particle concentration, temperature and/or air humidity separate.

NOTE 2 See also “air shower”.

NOTE 3 This may be a goods air lock or a personnel air lock.

3.24
cleaning programme
written instructions on activities that take place in connection with premises maintenance

3.25
temperature class
classification of the temperature within specified limits

3.26
viper
cloth (with a woven or non-woven structure) with good absorption characteristics and a low tendency to give off fibres or fragments

3.27
dry mopping
wiping with a dry mop, which attracts dust

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3.28
wet mopping
wiping with a mop, which is wetted and wrung out

3.29
wet drying
wiping with a wiper, which is wetted and wrung out

3.30
surface contaminant
(in this context) particulate contaminant on a surface.

4 Cleanliness-controlled workshop environment

4.1 General

This standard specifies five essential elements in a cleanliness-controlled workshop environment:

— quality characteristics of the room/zone air: Air temperature and air humidity, particle content, air filter and other ventilation factors (see clauses 4.2 – 4.4 and Annex A);

— structural engineering requirements, including design (see clasue 4.5 and Annex B);

— maintenance of workshop premises (see clause 4.6 and Annex C);

— protective clothing (see clause 4.7 and Annex D);

— training (see Annex E).

In this standard the room classes have been designated in accordance with SS-EN ISO 14644-1. For comparison purposes table 1 lists these room classes together with room class designations according to other national standards.

4.2 Room/zone requirements

4.2.1 Room classes

Air quality is determined with respect to the particle content, temperature and relative humidity. This is expressed as a classification according to 4.2.3 - 4.2.5. Air quality can also be stated as an air quality code in accordance with 4.2.2.

Other factors that may influence the quality characteristics of the room/zone include noise, vibrations and electrostatic discharges (ESD). These factors are not classified in this standard

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4.2.2 Air quality code for a cleanliness-controlled workshop environment

The air quality code in accordance with this clause is a summarized description of the quality requirements associated with the nature of the activity and the use of the room/zone.

Two examples of air quality codes:

Position	1	2	3
Air quality SS 2680	8	3	3
Air quality SS 2680	8,5	5 (18-22)	6 (40-50)

The code shall be preceded by the text "Air quality SS 2680" and the code itself shall be separated from the text by an oblique stroke. The positions, separated by dashes, have the following meaning:

1 **Cleanliness class with respect to airborne particles**, see clause 4.2.3

2 **Temperature class**, see clause 4.2.4

3 **Humidity class**, see clause 4.2.5

The first example above has the following meaning:

8 cleanliness class 8, denoting max. 3 520 000 particles of ≥ 0,5 µm/m^3 and max 29 300 particles of ≥ 5 µm/m^3

3 temperature class 3, denoting a selected temperature of 22 ^{o}C with a tolerance of ± 3 °C

3 humidity class 3, denoting a selected humidity of max. 60 % RH.

Additional details or explanations can be added after the code, separated by an oblique stroke.