SLOVENSKI STANDARD
SIST ENV 1631:2000

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Cleanroom technology - Design, construction and operation of cleanrooms and clean air devices

Cleanroom technology - Design, construction and operation of cleanrooms and clean air devices

Reinraumtechnik - Planung, Ausführung und Betrieb von Reinräumen und Reinraumgeräten

Technologies des salles propres - Conception , construction et gestion du fonctionnement des salles propres et de dispositifs de l'air propre

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13.040.30	Kakovost zraka na delovnem mestu	Workplace atmospheres

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Descriptors: clean rooms, purity, controlled atmospheres, design, installation, equipment, specifications, qualification, tests, maintenance, inspection, contamination

English version

Cleanroom technology - Design, construction and operation of cleanrooms and clean air devices

Technology des salles propres - Conception, construction et gestion du fonctionnement des salles propres et de dispositifs de l'air propre

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This European Prestandard (ENV) was approved by CEN on 1996-03-20 as a prospective standard for provisional application. The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into an European Standard (EN).

CEN members are required to announce the existance of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents

Foreword

This European Prestandard has been approved by Technical Committee CEN/TC 243 'Cleanroom technology', the secretariat of which is held by BSI. It precedes the issue of a series of standards concerned with cleanrooms and associated technology, which are in preparation jointly by CEN/TC 243 and its international counterpart ISO/TC 209. With the transfer of drafting responsibilities to the ISO technical committee, the publication of this European Prestandard was considered an appropriate interim measure allowing the short term use of the document in a commercial environment.

European Prestandards are subject to enquiry, based on the experience gained by their use, after a period of two years. However, it is expected that the standard drafted by ISO/TC 209 corresponding to this European Prestandard will, on publication as an ISO standard, be implemented as an identical European Standard. In this circumstance, ENV 1631 would be withdrawn immediately.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A to K to this European Prestandard are informative.

1 Scope

This European Prestandard specifies requirements for cleanroom and clean air device installations. It applies where cleanroom technology is called for and is intended for use by purchasers, suppliers and designers, providing a check list of important performance requirements. Construction and installation guidance is given, including requirements for commissioning and qualification. Basic requirements to ensure continued satisfactory operation are identified through the consideration of operation and maintenance; further guidance in respect of these requirements is given in Annexes A to K.

In applying this European Prestandard the following shall be considered:

- User requirements are represented by purchaser or specifier.
- Specific applications of cleanroom or clean air devices to particular industrial or public sectors are not defined.
- Specific processes to be accommodated in the controlled environment are not considered.
- Fire and safety regulations are not considered specifically.
- Details for the construction of clean air devices or safety cabinets are not provided.
- Process media or utilities are not specified, only the consideration of principles of how to bring them into and out of the cleanroom or clean air device.
- External building envelope considerations are not covered.
- Regarding operation and maintenance only cleanroom specific requirements are considered.

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any

of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

EN 60651:1994	Sound level meters (IEC 651 : 1979, including Amendment 1 : 1993)
EN 779:1993 + AC:1994	Particulate air filters for general ventilation - Requirements, testing, marking
ISO 1940-1:1986	Mechanical vibration - Balance quality requirements of rigid rotors - Part 1 : Determination of permissible residual unbalance
ISO 10816-1 : 1995	Mechanical vibration - Evaluation of machine vibration by measurements on non-rotating parts - Part 1: General guidelines
prEN 1822-1	High efficiency particulate air filters (HEPA and ULPA) - Part 1: Requirements, testing, marking

3 Definitions

For the purposes of this European Prestandard, the following definitions apply:

3.1 General terms

cleanroom: Room in which the number concentration of airborne particles is controlled; constructed and used in a manner to minimize the introduction, generation and retention of particles inside the room and in which relevant clean processing parameters, e. g. temperature, humidity and pressure, are controlled as necessary.

clean air controlled space: Dedicated zone in which the number concentration of airborne particles is controlled.

NOTE: The zone may be open or enclosed and may be located within a cleanroom.

clean air device: Small enclosure with individual filtered air, or gas, supply and which may be located within another clean air controlled space.

materiel: All items which can be taken into a clean air controlled space.

fluid: Liquid or gas, other than ambient air, used in, or supplied to, a clean air controlled space.

cleanliness: Condition of a product, surface, device, gas, fluid, etc. with a defined level of particulate and/or non-particulate contamination.

cleaning (of a surface): Reduction of contamination, such as biological, organic/inorganic contamination, by a process which considers the condition of a treated surface and which takes into account chemical action, mechanical action, temperature and time of exposure.

prefilter: Air filter fitted upstream of another filter to reduce the challenge on that filter.

final filter: Last filter between the air supply and a clean air controlled space.

leak: Point in a final filter, a filter frame and/or a sealant, at which the local efficiency exceeds a given limit value.

3.2 Design, construction and operation terms

design: Generation of a concept followed by production of all of the necessary drawings and specifications to enable an installation to be procured.

installation: Cleanroom or clean air controlled space with all associated structures, air treatment systems, services and utilities.

construction: Assembling and building of a cleanroom or clean air controlled space.

changing room: Room where personnel using a cleanroom may change into, or out of, cleanroom apparel.

as-built: Condition where the installation is complete with all services connected and functioning but with no production equipment, materiel or personnel present.

at rest: Condition where the installation is complete with production equipment installed and operating in the manner agreed between the purchaser and supplier, but with no personnel present.

operational: Condition where the installation is functioning in the defined operating mode with the specified number of personnel present and working in the manner agreed.

supplier: Organization responsible for the provision of an installation to a purchaser's specification.

purchaser: Organization responsible for ordering and paying, or authorizing payment, for an installation.

user: Organization responsible for the operation of an installation.

4 Specification of requirements

NOTE: This clause specifies the information to be agreed between purchaser/user and designer/supplier of a system to provide a contamination controlled installation. The information required is summarised in table 1 and amplified in Annexes A to K.

4.1 Essential information

The information listed in 4.1.1 to 4.1.13 shall be defined and agreed between purchaser/user and designer/supplier:

4.1.1 The number and date of this standard.

4.1.2 The general purpose for which the controlled space is to be used, the operations to be carried out therein and any constraint imposed by the operating criteria.

4.1.3 The contamination control concept to be used to achieve the required cleanliness level (see Annex A).

4.1.4 The required classes or demands for cleanliness in accordance with relevant standards (see Annex B).

4.1.5 The environmental parameters to be measured to ensure compliance together with the measuring methods to be used.

4.1.6 The materiel and personnel flow.

4.1.7 The occupancy state under which the required conditions shall be achieved and maintained including variations with time, and the methods of control of occupants including e. g. gowning, sanitation techniques, personnel flow and access control to all clean areas (see Annex C).

NOTE: Annex C illustrates the relation between occupancy states and qualification stages. See Annex K for information on qualification testing.

4.1.8 The layout of the installation (see Annex D).

4.1.9 All critical dimensions and weight restrictions, including those related to available space.

4.1.10 The process equipment to be installed in the controlled spaces including usage, method of gaining access for construction and maintenance, emissions, size and weight, and utilitary requirements.

4.1.11 The maintenance requirements of the system components creating the controlled space (see Annex E).

4.1.12 The definition of all responsibilities for design, construction, qualification and commissioning, including the performance and witnessing of tests and final validation.

4.1.13 The identification and evaluation of external environmental influences, such as chemical and particulate contamination, noise and vibration.

The tests to be carried out, and in what sequence, to prove conformity to the required conditions under the defined occupancy state (see 4.1.7), shall be defined and agreed between user and supplier (see clause 7 hereafter).

4.2 Additional information

Depending upon the particular application, the following additional information may be required to be defined and agreed between purchaser/user and designer/supplier:

4.2.1 Any special requirements concerning design.

4.2.2 Any special requirements concerning construction materials, surfaces and the construction method (see Annex F).

4.2.3 Any additional requirements for determining compliance with cleanliness classes defined in relevant standards, and applied under 4.1.3.

4.2.4 Any additional requirements in respect of periodic or continuous in-use performance monitoring, including alarms and status recording.

4.2.5 Definition of specific requirements for the following environmental parameters (see Annex G):

a) Temperature and humidity required to satisfy the needs of the occupants or processes;

b) Lighting levels and glare, including requirements for emergency and security lighting;

c) Noise and vibration;

d) Ventilation and air change rate (see Annex H);

e) Recovery time after contamination;

f) Safety equipment (e.g. fire extinguisher systems, special breathing apparatus, toxic material control).

4.2.6 Any special air filtration requirements (see Annex J).

4.2.7 Any special consideration determined by the activity in, or use of the controlled space such as:

a) Chemical contamination;

b) Microbiological contamination;

c) Ionising radiation;

d) Optical radiation;

e) Other electromagnetic radiation;

f) Static electricity;

g) Others.

Table 1: Summary of information required

Information required	Clause(s)
Essential information:	
number of standard	4.1.1
purpose of contamination control installation	4.1.2
contamination control concept	4.1.3
cleanliness classes	4.1.4
other environmental parameters	4.1.13, 4.2.5
materiel flow, personnel flow	4.1.6, 8.2
occupancy states	4.1.7, Annex C
layout	4.1.8, Annex D
critical dimension and weight	4.1.9
specification of process equipment	4.1.10
maintenance requirements	4.1.11, Annex E
responsibilities	4.1.12
specification of external environmental influences	4.1.13
Additional information:	
special requirements for design	4.2.1, 5
special requirements for construction materials, surfaces	4.2.2, 8, Annex F
additional requirements for compliance	4.2.3, Annexes G and K
performance monitoring and alarming	4.2.4, A.3, Annex K
environmental parameters:	4.2.5, Annex G
- temperature, humidity	4.2.5 a), G.2

Information required	Clause(s)
- lighting	4.2.5 b), G.3
- noise and vibration	4.2.5 c), G.4
- ventilation and air exchange rate	4.2.5 d), Annex H
- recovery time for the environmental parameters	4.2.5 e), Annex K
- safety equipment	4.2.5 f)
special air filtration requirements	4.2.6, Annex J
special consideration of	
- chemical contamination	4.2.7 a)
- microbiological contamination	4.2.7 b)
- ionising radiation	4.2.7 c)
- optical radiation	4.2.7 d)
- other electromagnetic radiation	4.2.7 e)
- static electricity	4.2.7 f)

5 Design

The design shall accomodate all of the product and/or process requirements to satisfy/achieve the selected contamination control concept (see Annex A).

The design shall be accepted formally.

NOTE 1: Attention is drawn to all relevant legislation, e. g. building and safety regulations, and good manufacturing practice guidelines.

NOTE 2: Prior to formal agreement, the completed design should be validated to ensure compliance with the specified requirements and the approved concept (see Annex C).

6 Construction of installation

(See Annex F)

Construction work shall comply with the drawings and specifications. Any changes required during the course of construction shall be checked for acceptance and approved.

Construction work, whether carried out at a manufacturing site or in-situ, shall be accurate and shall take into consideration the contamination control requirements.

NOTE 1: Controlled cleaning should be carried out frequently. This is essential in cases where later cleaning is difficult or impossible. In the case of in-situ works, assembly filters or other physical barriers such as screens or temporary walls should be considered to protect the contamination control system from excessive pollution. The final air filters should be installed at the completion of all work that may influence the final filter integrity.

NOTE 2: Particular attention should be given to the programming of the work, e. g. programming contaminant-generating work early in the programme, prior to cleaning work.

7 Qualification and testing

7.1 General

A defined and agreed series of documented tests shall be undertaken during and upon completion of construction work prior to operational use of the installation (see Annex K). In the absence of explicit specification, this series of tests shall by default correspond to installation qualification in the as-built occupancy state. However, the user and the supplier may agree to specify tests in one or more occupancy states, and one or more stages of qualification. Typical phases of qualification are presented hereafter.

7.2 Installation qualification (as-built or at rest condition)

A systematic series of inspections, adjustments, measurements and tests shall be carried out to ensure that each part of the installation complies with the design requirements (see Annex C).

7.3 Functional qualification (at rest condition)

A series of tests and measurements shall be made to determine that all parts of the installation operate together to achieve the required conditions.

7.4 Operational qualification (operational condition)

A series of tests shall be carried out to determine that the complete installation achieves the required performance with the process activity functioning.

7.5 Requalification

After repair, maintenance, significant shut down periods, changes in processing methods, and on a routine basis, specifically selected tests and measurements shall be carried out to prove continued performance compliance.

NOTE: In the case of operational qualification, it is advisable to conduct beforehand a qualification in one of the other two occupancy states, i.e. 'as-built' or 'at rest'.

8 Operation and maintenance

8.1 General

All operation and maintenance procedures shall be documented and the documents made readily available to all personnel concerned.

NOTE: All personnel using or working within the installation should fully understand the need for these operational procedures.

There shall be a system for assessing the training needs of the operators, for ensuring that training is

given, for monitoring the effectiveness of such training and for maintaining records of the training.

Procedures relating to safety regulations in controlled spaces shall ensure that any periodic safety checks or drills (such as fire drills) are suitably arranged to minimize the effect on the environmental state and/or work in progress.

8.2 Materiel management

8.2.1 Selection of materiel

NOTE: Purchasing arrangements should be aimed at obtaining materiel that has a level of contamination consistent with that required for the particular class designation.

8.2.2 Entry of materiel

Procedures relating to the entry of materiel into a controlled space shall ensure that all materiel undergoes an appropriate cleaning operation immediately prior to its entry into the controlled space. This shall apply to process materials, piece parts, sub-assemblies, test equipment, tools, documentation, garments and consumables.

NOTE 1: All materiel should be limited to the minimum necessary for the work in hand.

NOTE 2: Where microbiological contamination is of critical importance, consideration should be given to means of controlling the microbiological contamination of materiel entering the controlled space.

NOTE 3: Cleaned materiel should be transported and stored in sealed plastic bags or other sealable containers.

8.2.3 Storage of materiel

Where materiel is retained within a controlled space, consideration shall be given to possible contamination hazards arising from its storage and subsequent use. Materiel so retained shall be subject to specified procedures and shall be held in storage compartments or containers which are closed or covered when not in use.

8.2.4 Handling of waste materials

Any waste materials produced as a result of operations shall be collected in clearly identified enclosed containers for disposal. Care shall be taken to ensure that the accumulation of waste material does not compromise the cleanliness of the controlled space.

NOTE: Waste materials should be removed frequently and in a manner which does not compromise the cleanliness of the controlled space or the safety of personnel.

8.3 Initial operation

In the case of start-up of new systems, or restarting after repairs or modifications, as cleaning of the controlled space is necessary, provision shall be made for the removal of adherent, drag-in or released impurities.

NOTE 1: This is because the installation is able to maintain the airborne cleanliness but will not clean surfaces.