

**Implementation of
ENV 1631:1996**

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

ICS 13.040.30; 13.100

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Committees responsible for this Draft for Development

The preparation of this Draft for Development was entrusted to Technical Committee LBI/30, Cleanroom technology, upon which the following bodies were represented:

- Association of British Health-Care Industries
- British Textile Technology Group
- Chartered Institution of Building Services Engineers
- Chilled Food Association
- Department of Health
- Guild of Hospital Pharmacists
- Heating, Ventilating and Air Conditioning Association
- Institute of Sterile Services Management
- Medical Sterile Products Association
- Parenteral Society
- Pharmaceutical Microbiology Interest Group (Pharmig)
- Scottish Society for Contamination Control
- Society of Environmental Engineers
- Sterilised Suture Manufacturers Association
- Surgical Dressings Manufacturers Association
- User Standards Forum for Information Technology (Institute of Data Processing Management)

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National foreword

This Draft for Development is published under the direction of the Sector Board for Materials and Chemicals whose Technical Committee LBI/30 has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

NOTE International and European Standards, as well as overseas standards, are available from Customer Services, BSI, 389 Chiswick High Road, London, W4 4AL.

This Draft for Development is not to be regarded as a British Standard.

It is issued in the Draft for Development series of publications and is of a provisional nature because further standardization of the subject matter is still under progress¹⁾. It should be applied on this provisional basis so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that the UK experience can be reported to the European organization responsible for the preparation of ENV 1631. A review of ENV 1631 will be initiated not later than 2 years after its publication by CEN so that a decision can be taken on its status at or before the end of its three-year life. The commencement of the review period will be notified by an announcement in *BSI News*.

NOTE This may coincide with the issue of draft EN ISO 14644-4 for public enquiry in ISO and CEN. The latter document if approved and ratified for publication by CEN, would on publication supersede ENV 1631.

According to the replies received by the end of the review period, the responsible BSI Committee will decide what action to recommend to the responsible CEN Technical Committee. Comments should be sent in writing to the Secretary of BSI Technical Committee LBI/30 at BSI, 389 Chiswick High Road, London W4 4AL giving the document reference and proposing, where possible, an appropriate revision of the text.

Cross-references

Publication referred to	Corresponding British Standard
EN 779:1993	BS EN 779:1993 <i>Particulate air filters for general ventilation — Requirements, testing marking</i>
EN 60651:1994	BS EN 60651:1994 <i>Specification for sound level meters</i>
ISO 1940-1:1986	BS 6861 <i>Balance quality requirements or rigid rotors Part 1:1987 Method for determination of permissible residual unbalance</i>
ISO 10816-1:1995	BS 7854 <i>Mechanical vibration — Evaluation of machine vibration by measurements on non-rotating parts Part 1:1996 General guidelines</i>

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the ENV title page, pages 2 to 24, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ See foreword to ENV 1631.

English version

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

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

Reinraumtechnik — Planung, Ausführung und
Betrieb von Reinräumen und Reinraumgeräten

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 a European Standard (EN).

CEN members are required to announce the existence 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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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.

Annex A to Annex K to this European Prestandard are informative.

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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 Annex A to Annex 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

material

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, material 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 Annex A to Annex 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 material 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 utility 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.

5 Design

The design shall accommodate 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.