BRITISH STANDARD

BS 5295-0: 1989

Incorporating Amendment No. 1

Environmental cleanliness in enclosed spaces —

Part 0: General introduction, terms and definitions for clean rooms and clean air devices

ICS 13.040.30

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Laboratory Apparatus Standards Policy Committee (LBC/-) to Technical Committee LBC/30, upon which the following bodies were represented:

Association of the British Pharmaceutical Industry
British Occupational Hygiene Society
British Surgical Trades Association Incorporated
British Telecommunications plc
Chartered Institution of Building Services Engineers
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HM Treasury (Central Computer and Telecommunications Agency)
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This British Standard, having been prepared under the direction of the Laboratory Apparatus Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 29 September 1989

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Foreword

This part of BS 5295 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee.

BS 5295-1 to -3:1976 were replaced by BS 5295-0 to -4:1989. BS 5295-1:1989 and BS 5295-4:1989 were withdrawn upon publication of BS EN ISO 14644-1:1999.

In addition, BS 5295-0, -2 and -3 have been amended pending publication of further parts of BS EN ISO 14644, when they will be withdrawn.

PD 6609:1996, which provides supplementary guidance to BS 5295-1:1989, has also been revised and will be withdrawn upon publication of further parts of BS EN ISO 14644.

In the preparation of the 1989 revision of BS 5295 account was taken of:

a) the United States of America Federal Standard 209D "Clean rooms and work station requirements, controlled environment", and proposals for its revision;

b) the Institute of Environmental Sciences Tentative Recommended Practice IES-RP-CC006-84-T November 1984 "Testing clean rooms".

Particulate contamination, for example dust and dirt, is detrimental to most processes and mechanisms and is instrumental in causing wear, deterioration of performance and, ultimately, failure. Increasingly, modern technology requires that such contamination be excluded particularly from atmospheres in which the manufacture of miniaturized components, and pharmaceutical and medical products, is conducted, and in surgery and nursing.

Moreover, achievement of the highest possible standards of atmospheric cleanliness is necessary if requirements for absolute reliability are to be attained, for example in the manufacture of components and equipment used in the computer and aerospace fields. It is essential therefore that such products are manufactured, assembled and sealed in special areas from which sources of particulate contamination are minimized and where the temperature and humidity may be controlled. These special areas are known as clean rooms or clean air devices.

The clean rooms and clean air devices described in this British Standard are only defined in terms of particulate contamination levels. Levels of other forms of contamination such as gases, vapours or film forming aerosols which may be undesirable to certain products and processes are not defined or controlled in clean installations covered by this standard. Control of such materials may require additional filters of different design.

Airborne particles present in working areas where conditions are not controlled can arise from a number of sources such as:

— atmospheric air, which typically may have 3×10^8 or more particles per cubic metre;

— personnel activity;

— equipment operation (all types of moving equipment including those in which arcing or sparking occur and in soldering, welding and brazing operations);

— material.

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To control such contamination, certain measures are adopted including the following:

— controlling and monitoring the particulate content of the air within the space;

— displacing contaminated air to the exterior as directly as possible and replacing it with clean filtered air;

— adjusting working procedures to produce as little contamination as possible;

— cleaning all materiel before entry to the room;

— controlling the movement of personnel into the area and issuing special clothing to cover garments, hands, hair, etc.;

— protecting materials sensitive to contamination by covering wherever possible;

— through periodic cleaning of the room surfaces.

BS 5295 and BS EN ISO 14644 set out, in detail, the requirements to which clean rooms and clean air devices are to conform in order to provide assurance of achieving the requisite level of cleanliness expressed as a particulate concentration in air. Methods of test and of monitoring to demonstrate these levels are given, together with details of procedures and methods of working which will enable the levels to be maintained.

Application. Products and processes requiring controlled environmental conditions are many and varied. It is neither possible nor desirable in a British Standard to inhibit development by attempting to lay down rules relating product or process requirements to particular classes of environment. This British Standard has been formulated to be as broadly-based and as flexible as possible with the view to embracing varied environmental conditions.

Attention is drawn to the need to refer to or consult standards and/or regulations appropriate to the particular industry or application.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 and 2, an inside back cover and a back cover.

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1 Scope

This part of BS 5295 gives a general introduction to BS 5295 and BS EN ISO 14644 defines terms used in the design, construction, installation, testing, use and monitoring of controlled environment clean rooms and clean air devices.

NOTE The title of the publication referred to in this standard is given on Inside back cover.

2 Parts of BS 5295

The parts of BS 5295 are as follows:

— Part 0: *General introduction, terms and definitions for clean rooms and clean air devices*;

— Part 2: *Method for specifying the design, construction and commissioning of clean rooms and clean air devices*;

— Part 3: *Guide to operational procedures and disciplines applicable to clean rooms and clean air devices*.

NOTE The minimum requirements for installations for which compliance with BS 5295 is claimed are specified in Part 1.
Requirements for monitoring continued performance compliance are specified in Part 4.
Additional requirements may be set by interested parties for contractual purposes using the method for specifying given in Part 2, which also includes guidance on design and construction.
Further information in the form of guidance for designers, constructors and operators is given in Part 3.

3 Safety

BS 5295 does not specify requirements for safety. In addition to statutory requirements and general considerations of safety particular provisions may be needed, e.g. for solvents, explosives and radioactive materials. It is necessary for any written guidance to be supplemented by thorough training.

4 Definitions

For the purposes of BS 5295, the following definitions apply, except where they are superseded by those given in BS EN ISO 14644-1:1999.

4.1
clean room

a room with control of particulate contamination, constructed and used in such a way as to minimize the introduction, generation and retention of particles inside the room and in which the temperature, humidity and pressure shall be controlled as necessary

4.2
clean air device

a small enclosure that has its own filtered air (or gas) supply and which may or may not be located in another controlled space, e.g. a clean room

4.3
controlled space

a clean zone of a clean room or clean air device

4.4
installation

a controlled space and associated structures and services

4.5
changing room

a room or area where personnel using the clean room can change into or out of clean room apparel

4.6
materiel

a generic term embracing all items which could be taken into a controlled space

4.7
material

in relation to a process carried out in a controlled space, refers to any item of materiel which is consumable or transformable during the process or is a product of it

4.8
particle size

NOTE This term is defined in two ways depending on the method of measurement.

a) for measurement using light scattering instruments, the diameter of a sphere having the same optical response as that of the particle being measured.

b) for microscopic measurement, the maximum linear dimensions.

4.9
high efficiency filter

an air filter with an efficiency not less than 95 % when tested in accordance with BS 3928

4.10
prefilter

an air filter fitted upstream to protect another filter

4.11
final filter

the last filter between the air supply and the controlled space

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4.12
terminal filter

a final filter where the discharge is within 150 mm of the entry plane to the controlled space

4.13
purchaser

the authority responsible for ordering and paying, or authorizing payment, for the installation

4.14
supplier

the authority responsible for the provision of installation to the purchaser's specification

4.15
user

the authority responsible for the operation of the installation

4.16 Occupancy states

4.16.1
as-built condition

when the installation is complete with all services working, but has no production equipment, materiel or personnel present

4.16.2
unmanned condition

when the production equipment and materiel are installed but not functioning and no personnel are present

4.16.3
manned condition

when the installation is functioning in the production mode and with a specified level of personnel present

4.17
balanced condition

the condition when all final adjustments to air flow parameters have been completed

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Publication referred to

BS 3928, *Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors).*

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