

Environmental cleanliness in enclosed spaces —

Part 1: Specification for clean rooms and clean air devices

UDC 725.4.055:658.2:628.511.052:697.94

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
- Department of Health
- HM Treasury (Central Computer and Telecommunications Agency)
- Heating and Ventilating Contractors' Association
- Institute of Environmental Science and Technology
- Institute of Sterile Services Management
- Medical Sterile Products Association
- Ministry of Defence
- Parenteral Society
- Society of British Aerospace Companies Limited
- Society of Environmental Engineers
- Surgical Dressings Manufacturers Association
- United Kingdom Atomic Energy Authority
- User Standards Forum for Information Technology
(Institute of Data Processing Management)

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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First published April 1976
First revision September 1989

The following BSI references relate to the work on this standard:
Committee reference LBC/30
Draft for comment 88/50885 DC

ISBN 0 580 17531 6

Amendments issued since publication

Amd. No.	Date of issue	Comments
6602	December 1990	
8818	October 1995	Indicated by a sideline in the margin

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Foreword

IMPORTANT NOTE It is essential that this Part is read in conjunction with BS 5295-0, issued separately.

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

This revision supersedes BS 5295-1:1976, which is withdrawn.

In preparing this revision, the Technical Committee considered specifying limits for the number of 0.1 μm particles for class C (to 1 200 particles/ m^3) and class D (to 12 000 particles/ m^3). The Technical Committee recognized that many of the instruments available for the measurement of 0.1 μm particles were of an experimental nature, and very few users currently required limits on 0.1 μm particles. If a user demand for a limitation is identified, and a number of instruments for measuring 0.1 μm particles have become established, further consideration will be given to specifying limits for 0.1 μm particles.

The principal differences between this edition and BS 5295-1:1976 are.

- a) Definitions are now contained in BS 5295-0.
- b) Details concerned with design, construction and commissioning requirements which are not directly concerned with air quality (e.g. noise, lighting, temperature and humidity) are now contained in BS 5295-2.
- c) The four classes of environment designated 1 to 4 in the 1976 edition have been replaced by twelve classes. Two classes (C and D) with lower particulate contamination levels are introduced, one class (M) with a higher particulate contamination level has been introduced to replace the “controlled area”. Five of the remaining six new classes approximately correspond to the four classes originally defined as set out in Table 1. There was a large gap between the concentration levels defined in class 1 and class 2, and hence extra classes (G and H) have been introduced between them (see Table 1).

Classes E and F correspond approximately in terms of content of 0.5 μm particles with class 1 of the 1976 edition but are distinguished by an additional requirement for 0.3 μm particles in class E.

Classes A and B have not been allocated. It is anticipated that future requirements may need to specify classes of environmental cleanliness superior to those contained in this revision and classes A and B have been reserved for such possible future requirements when known.

Table 1 — Comparison with classes of 1976 edition

New class	1976 class	Comment
A	Non-existent	{ Not to be used. Reserved for future use
B		
C	Non-existent	{ New classes with lower particulate contamination
D	Non-existent	
E and F	Approximately class 1	Too large a gap between 1 and 2
G and H	Non-existent	
J	Approximately class 2	
K	Approximately class 3	
L	Approximately class 4	
M	Non-existent	Replaces controlled area

d) Three occupancy states are now defined because it is recognized that the state of occupancy influences the level of particulate contamination.

e) The microscopic method for the determination of airborne particulate matter has been largely replaced by a method using light scattering instrumentation because microscopic methods are laborious, time-consuming, subject to large errors, lack repeatability and they are now rarely used to commission a clean environment facility.

f) Guidance on selection of classes of clean rooms, work stations and clean air devices (appendix C of the 1976 edition) has been deleted.

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 to 14, 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 Scope

This Part of BS 5295 specifies the classification of and related performance requirements for ten classes of environmental cleanliness for clean rooms and clean air devices, each in three occupancy states (i.e. “as-built”, “unmanned” and “manned”), according to the amount of airborne particulate matter present. In assessing airborne particulate matter no specific reference is made to microbial contamination.

NOTE 1 Where the level of microbial contamination is important, the method of test and the maximum level of contamination for the as-built and/or unmanned state should be specified by the purchaser.

This Part of BS 5295 also includes environmental, construction and design requirements, and methods of test to demonstrate compliance with the requirements, as well as describing the procedures to be undertaken prior to the issue of a certificate of compliance in respect of an installation.

NOTE 2 The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 5295, the definitions given in BS 5295-0 apply.

3 Designation of environmental cleanliness

The environmental cleanliness of the installation shall be defined in one of three conditions of occupation, as-built (see 4.16.1 of BS 5295-0:1989), unmanned (see 4.16.2 of BS 5295-0:1989), or manned (see 4.16.3 of BS 5295-0:1989).

The environmental cleanliness of the installation shall be designated as class C, D, E, F, G, H, J, K, L or M in accordance with the size and maximum permitted number of airborne particles as given in Table 2.

NOTE Appendix A illustrates the particle size distribution which may be expected for the various designated classes.

The designation of the installation shall include the class followed by the occupancy state, e.g.

class E (as-built); or

class E (unmanned); or

class E (manned).

Table 2 — Requirements for controlled environment installations

Class of environmental cleanliness	Maximum permitted number of particles/m ³ (equal to, or greater than, stated size)					Maximum floor area per sampling position for clean rooms m ²	Minimum pressure difference ^a	
	0.3 µm	0.5 µm	5 µm	10 µm	25 µm		Between classified area and unclassified area Pa	Between classified area and adjacent area of lower classification Pa
C	100	35	< 1	NS ^b	NS	10	15	10
D	1 000	350	< 1	NS	NS	10	15	10
E	10 000	3 500	< 1	NS	NS	10	15	10
F	NS	3 500	< 1	NS	NS	25	15	10
G	100 000	35 000	200	< 1	NS			
H	NS	35 000	200	< 1	NS			
J	NS	350 000	2 000	450	< 1	25	15	10
K	NS	3 500 000	20 000	4 500	500	50	15	10
L	NS	NS	200 000	45 000	5 000	50	10	10
M	NS	NS	NS	450 000	50 000	50	10	NA ^c

^a This applies only to clean rooms and totally enclosed devices.
^b NS: no specified limit.
^c NA: not applicable as no limit specified.