

Environmental cleanliness in enclosed spaces —

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

ICS 13.040.30

Committees responsible for this British Standard

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- 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)

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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This revision supersedes BS 5295-2:1976, which is withdrawn.

The principal differences between BS 5295-2:1976 and this edition are:

- a) it is prepared as a method for specifying instead of a guide to construction and installation; and
- b) it includes many of the subjects previously covered by BS 5295-1:1976, but not directly related to the classification of environmental cleanliness.

Upon publication of BS EN ISO 14644-1:1999, BS 5295-1 and BS 5295-4 were withdrawn.

BS 5295-0, -2 and -3 have been amended pending publication of further parts of BS EN ISO 14644, when they will be withdrawn.

PD 6609:1996, which provides supplementary guidance to BS 5295-1:1989, has also been revised and will be withdrawn upon publication of further parts of BS EN ISO 14644.

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.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 10, an inside back cover and a back cover.

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Sidelining in this document indicates the most recent changes by amendment.

1 Scope

This part of BS 5295 describes a method for specifying requirements for clean rooms and clean air devices. It is intended for use by purchasers of clean air installations and provides a check list of design, construction, furniture and fittings, and commissioning requirements which might or might not be relevant. Further guidance in respect of these requirements is given in appendices A to H.

This part of BS 5295 does not give detailed recommendations concerning the control or level of microbiological contamination, but allows for them to be agreed by interested parties.

NOTE 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, except where they are superseded by those given in BS EN ISO 14644-1:1999.

3 Information to be supplied by the purchaser to the supplier

NOTE A summary of the information to be supplied is given in Table 1.

3.1 Essential information

The information listed in items a) to g) shall be supplied by the purchaser to the supplier, if necessary in consultation with the user and/or supplier.

a) The number and date of this British Standard, i.e. BS 5295-2:1989.

b) The required class or classes of environmental cleanliness in accordance with BS EN ISO 14644-1:1999 and details of their associated states of occupancy as specified in clause 4 of this part of BS 5295.

NOTE It may be necessary to specify the cleanliness of a controlled space for more than one state of occupancy, e.g. class E (unmanned) [class G (manned)].

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

d) The required schematic layout.

NOTE Guidance on the layout of controlled spaces is given in appendix A.

e) All critical dimensions, including those relating to the available space.

f) The services required.

NOTE Guidance on the provision of services is given in appendix G.

g) Responsibility for performing and witnessing commissioning tests and procedures.

NOTE Guidance on commissioning is given in appendix H.

3.2 Additional information

The additional information listed in items a) to g), as applicable, shall be supplied by the purchaser, if necessary in consultation with the user and/or supplier.

a) Any special requirements concerning design.

NOTE Guidance on design is given in appendix B.

b) Any special requirements concerning construction.

NOTE Guidance on construction is given in appendix C.

c) Any requirements for determining environmental cleanliness at sampling positions additional to those given in BS EN ISO 14644-1:1999.

d) Any requirements for periodic or continuous in-use monitoring and associated alarms, if required.

NOTE Requirements for monitoring are given in prEN ISO 14644-2:1998.

e) Any requirement for control of the following environmental parameters:

- 1) temperature and humidity (see clause 6);
- 2) lighting and glare (see clause 7);
- 3) noise and vibration (see clause 8);
- 4) ventilation and air change rate.

NOTE Guidance on air movement and ventilation is given in appendix E.

f) Any requirements concerning microbiological contamination (see clause 9).

g) Any special filtration requirements.

NOTE Guidance on air filtration systems is given in appendix D.