BRITISH STANDARD

BS 5295-3: 1989

Incorporating Amendment No. 1

Environmental cleanliness in enclosed spaces —

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

ICS 13.040.30

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)

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Contents

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This revision supersedes BS 5295-3:1976, which is withdrawn.

The principal differences between this edition and BS 5295-3:1976 are:

a) material concerning monitoring has been deleted and is now covered in prEN ISO 14644-2;

b) items relating to work stations have been deleted as these are not separately covered in the revised standard.

Upon publication of BS EN ISO 14644-1:1999, BS 5295-1 and BS 5295-4 were withdrawn.

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BS 5295-0, -2 and -3 have been amended pending publication of further parts of BS EN ISO 14644, when they will be withdrawn.

PD 6609:1996, which provides supplementary guidance to BS 5295-1, has also been revised and will be withdrawn upon publication of further parts of BS EN ISO 14644.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 4, 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 gives guidance on the operational procedures and disciplines applicable to clean rooms and clean air devices to ensure that the required levels of environmental cleanliness are achieved and maintained.

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 shall apply, except where they are superseded by those given in BS EN ISO 14644-1:1999.

3 General

3.1 Operational procedures have a profound effect on the levels of environmental cleanliness achieved during operational use of clean rooms or clean air devices, i.e. controlled environment facilities. It is therefore important that procedures which will minimize or prevent environmental contamination are documented and followed by all personnel who enter the facility and/or who are concerned with the operation or maintenance of the facility.

3.2 The procedures adopted should recognize and provide for any factors relevant to the specific product or process used in the facility.

3.3 All operational procedures should be documented and the documents made readily available to all personnel concerned.

3.4 All personnel working within controlled environment facilities should fully understand the need for these operational procedures. There should be a system for assessing the training needs of the operators, ensuring that training is given and for monitoring the effectiveness of such training and maintenance of records of the training.

3.5 Any testing or monitoring routinely carried out in addition to that required by prEN ISO 14644-2:1998, e.g. microbiological monitoring, should be included in the documented operational procedures.

3.6 Procedures relating to safety regulations in controlled environment facilities should 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.

4 Clean room operations

Procedures relating to the activities within the controlled environment facilities should ensure the following.

a) The facility should be operated within the parameters given in its original purchasing specification, as described in BS 5295-2, or as subsequently agreed and documented.

b) Full account should be taken of the products and processes associated with the operational use of the facility.

c) Movement of personnel should be not more than that necessary to carry out the work in a controlled and disciplined way.

d) Any operation likely to generate contamination such as swarf, dust or fibres should be prohibited unless adequate precautions have been taken to minimize any deleterious effect on products or processes. Such precautions may require segregation of the operation either by physical barriers or airflow arrangements or the provision of special tools or equipment.

e) Precautions should be taken to minimize contamination arising from documentation. Where appropriate, the use of pencils, erasers, fountain pens, fibre-tipped pens and correcting fluid should be prohibited.

All documentation should be on plastics or sealed in plastics envelopes. Similarly, where records have to be made in the clean room, non-shedding paper and clean ball-point pens should be provided and kept in the facility.

f) The airflow via filtration devices should be maintained at all times in order to prevent shedding of intercepted particulates from the filter, caused by pressure pulses arising from abrupt variations in the airflow. When shutdowns are essential, they should be planned if possible and sufficient time should be allowed before production activities restart.

5 Personnel

Procedures relating to personnel should ensure the following.

a) Entry into a controlled environment facility by non-essential personnel should be prohibited, and all authorized persons entering a facility should follow the appropriate documented procedure.

All necessary entry and exit procedures, including cleaning of the person, should be specified, including those to be applied to normal clothing and footwear to be contained within the protective clothing. For certain applications, this will include handwashing procedures.

b) Protective garments (see clause **6**) should be specified together with the method of wearing them and the procedure for donning them before entry into the controlled environment.

The correct wearing of protective garments should be strictly enforced at all times.

Arrangements for the disposal of protective garments on leaving the controlled environment facility should be specified. These should be such that clean and contaminated garments cannot be confused. The frequency at which protective garments are to be changed and replaced by clean garments should also be specified and enforced.

c) Personnel should report any physical ailments, such as respiratory or skin conditions which are likely to cause droplet, particulate or microbial contamination or which would cause personnel to leave the controlled area frequently. Arrangements should be made for the redeployment of personnel thereby rendered unsuitable for controlled environment operations whilst such ailments persist.

d) Eating, drinking, smoking or chewing in controlled environment facilities should be prohibited.

The wearing of exposed jewellery and wristwatches which could harbour or generate particulate, chemical or biological contamination should be avoided.

The use of cosmetics should be discouraged and those which can shed particles should be prohibited.

Personnel belongings should not be taken into controlled environment facilities.

6 Protective garments

6.1 General

Protective garments should minimize the amount of contamination, generated by the body or by normal clothing, transmitted into a controlled environment facility. The choice of garment will depend on the class of the environment and the nature of the work being carried out.

6.2 Materials

Protective garments should be double hemmed and manufactured from material with the following properties:

a) lint free;

b) fine weave in the case of textiles;

c) low level of particulate shedding;

d) easily washed and durable or disposable;

e) comfortable in use.

For certain operations anti-static and non-flammability properties may be required.

6.3 Description of protective garments

Garments should comprise the following.

a) Headware to cover and enclose the hair and, with certain processes or if moustaches or beards are worn, special masks or hoods;

If a separate head covering is used it should be tucked inside the jacket or smock where possible.

b) A garment which fits closely at the neck and wrists and which fastens throughout its length. It may be:

1) a smock of sufficient length to extend below the knees of the wearer;

2) a short smock worn in conjunction with trousers which are close fitting to the smock and ankles;

3) a one-piece suit close fitting at the neck, wrists and ankles.

Pockets in protective garments should be avoided wherever possible.

c) Dedicated footwear or protective overshoes which should be close fitting.

Particular applications could require the following.

d) Special protective garments, such as aprons, required by the process.

e) Visors, protective goggles or masks with an integral air supply.

If gloves are considered necessary, they should be lint free, powder free, non particle shedding and disposable.

NOTE Many disposable gloves are powdered to assist donning. These should be donned and decontaminated before entry into the controlled environment.

6.4 Laundering and cleaning of protective garments

Procedures relating to the laundering or cleaning of protective garments used in controlled environment facilities should ensure the following.

a) Consideration should be given, particularly for use in clean rooms of class 3 to 7 (see BS EN ISO 14644-1:1999), to the provision of protective garments cleaned to an appropriate level of cleanliness using laundry facilities adjacent to or within the controlled environment facility.

Alternatively, consideration should be given to the use of specialist laundering firms equipped to launder and certify garments to the required level of cleanliness.

b) Washing and drying methods should be chosen to minimize the generation of contaminating particles.

c) Consideration should be given to an anti-static treatment during laundering.

d) Consideration should be given to the means and frequency of cleaning dedicated footwear, if provided.

e) Consideration should be given to the sterilization of garments for applications in which microbiological contamination is of critical importance.

f) Garments should be afforded adequate protection, e.g. in sealed plastics bags, to maintain their state of cleanliness and sterility until used.

7 Materials and materiel

7.1 Purchasing

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

7.2 Entry of materiel

Procedures relating to the entry of materiel into a controlled environment facility should ensure that all materiel undergoes any cleaning operation immediately prior to its entry into the facility. This will apply to process materials, piece parts, sub-assemblies, test equipment, tools and documentation. All such items should be limited to the minimum necessary for the work in hand.

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

Cleaned materiel should be transported and stored in sealed plastics bags or other sealable containers.

7.3 Storage of materiel

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

7.4 Handling of waste materials

Any waste material produced as a result of manufacturing operations should be collected in clearly identified enclosed containers for disposal. Care should be taken to ensure that the accumulation of waste material does not compromise the cleanliness of the facility. Waste material should be removed frequently, but in a manner which does not compromise the cleanliness of the facility.

8 Cleaning and decontamination of the facility

8.1 Cleaning

Procedures relating to the routine cleaning of controlled environment facilities should be fully documented and should ensure the following:

a) all process materials and work in progress present within a facility should be covered or otherwise protected during cleaning operations;

b) arrangements should be made for the periodic cleaning of the whole of the facility, e.g. walls, fittings and working surfaces, including storage areas;

c) cleaning materials and equipment should be subject to the same controls as other process materials and equipment;

d) if microbiological contamination is of importance, special care should be taken to ensure a high level of cleanliness of all surfaces, particularly the absence of substances which could promote or sustain the growth or survival of micro-organisms.

NOTE In exceptional circumstances the use of anti-microbial agents may be required.

8.2 Cleanliness checks

Routine surface cleanliness checks should be specified and carried out to ensure that the level of cleanliness appropriate to the use is being maintained.

8.3 Decontamination

If a controlled environment facility becomes contaminated, procedures relating to the actions required should ensure the following:

a) arrangements should be specified to control and remedy the situation when monitoring has revealed that unacceptable contamination of the facility has occurred;

b) work should be suspended until the facility has returned to acceptable levels of cleanliness;

c) consideration should be given to methods of decontamination or disposal of potentially contaminated product or work in progress.

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Publications referred to

BS 5295, *Environmental cleanliness in enclosed spaces.*

BS 5295-0, *General introduction, terms and definitions for clean rooms and clean air devices.*

BS 5295-2, *Method for specifying the design, construction and commissioning of clean rooms and clean air devices.*

BS EN ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness.*

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