BRITISH STANDARD

BS 2646-2: 1990

Autoclaves for sterilization in laboratories —

Part 2: Guide to planning and installation

Confirmed December 2011

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/35, upon which the following bodies were represented:

Associated Offices Technical Committee
Association of British Health Care Industries
Association of British Sterilizer Manufacturers
Association of Clinical Pathologists
Association of National Health Service Supplies Officers
British Dental Trade Association
British Surgical Trades Association
Central Sterilising Club
Department of Health
Health and Safety Executive
Infection Control Nurses Association
Institute of Hospital Engineering
Institute of Purchasing and Supply
Institute of Sterile Services Management
Joint Committee of Professional Nursing, Midwifery and Health Visiting Associations (England)
Medical Sterile Products Association
National Blood Transfusion Service
Public Health Laboratory Service
Regional Hospital Boards Engineers' Association
Royal College of Pathologists
Royal Pharmaceutical Society of Great Britain
Scottish Health Services
Society for General Microbiology
Stainless Steel Fabricators Association of Great Britain

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

British Glass Manufacturers' Confederation
British Laboratory Ware Association
Copper Development Association
Institute of Medical Laboratory Sciences
Manufacturing Science Finance
Milk Marketing Board
Ministry of Agriculture, Fisheries and Food
Royal Association of British Dairy Farmers
Society for Applied Bacteriology

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 31 October 1990

The following BSI references relate to the work on this standard:
Committee reference LBC/35
Draft for comment 90 52264 DC

ISBN 0 580 18995 3

Amendments issued since publication

Amd. No.	Date	Comments

Contents

Foreword

This Part of BS 2646 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee. It provides guidance on the planning and installation of laboratory autoclaves specified in Part 1 of this standard.

It covers the installation of autoclaves for sterilization of materials and goods including those which may be contaminated with organisms categorized in Hazard Groups 1, 2 and 3 (see footnote to clause **1**). It does not cover materials infected with any organisms in Hazard Group 4.

Autoclaves covered by BS 2646 are not intended for the sterilization of goods or fluids directly concerned with patient care nor for fabrics subjected to sterilization which are required to be dry at the end of the cycle. Sterilizers suitable for those applications are covered by BS 3970.

This revision of BS 2646 will comprise several separate Parts as follows:

— *Part 1: Specification for design and construction;*

— *Part 2: Guide to planning and installation;*

— *Part 3: Guide to safe use and operation;*

— *Part 4: Guide to maintenance;*

— *Part 5: Specification for functional design and performance.*

Part 1 was published in 1988 and Parts 3 to 5 are in preparation.

It is anticipated that autoclaves to which this standard applies will be used for the following processes:

a) liquids sterilization (see **2.2**).

b) equipment and glassware sterilization (see **2.3**).

c) make-safe (see **2.4**).

An analysis of all the factors covered in this Part of BS 2646 should be carried out at the earliest possible planning stage.

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 and ii, pages 1 to 6, 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 2646 gives guidance on the planning for, and installation in laboratories of, autoclaves for the sterilization of material and equipment, including those which may be contaminated with organisms categorized as Hazard Groups 1, 2, or 3[1)]. It does not cover the installation of autoclaves used for material contaminated with organisms categorized as Hazard Group 4, for which complete containment of condensate is considered to be essential.

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 2646 the definitions given in Part 1 apply, together with the following.

2.1
autoclave

a machine, which incorporates a steam pressure vessel, designed to sterilize laboratory materials and equipment

NOTE It may also be used for other processes, such as heat disinfection and heat treatment, which may be selected according to the laboratory requirements and the nature of the load.

2.2
liquids sterilization

a process to sterilize a variety of liquids, including culture media, in containers of various types

NOTE Due to the heat sensitive nature of some constituents of nutrient media, time and temperature controls should allow the user to select cycle characteristics separately for each load.

2.3
equipment and glassware sterilization

a process strictly limited to the sterilization of clean items which do not contain fluids

2.4
make-safe

a process which reduces the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard or environmental contamination

NOTE Material may include single-use items to be discarded, e.g. plastics specimen tubes and culture plates, and/or items for cleaning and reuse, e.g. glass containers and filter assemblies.

3 Planning

3.1 General

Autoclaves are often heavy and bulky pieces of equipment. The accessibility of the chosen site and maximum floor loadings should therefore be considered, together with autoclave capacity, plant room and loading area design and whether the autoclave is to be front loading or top loading.

3.2 Site access

Particular attention should be given to the following:

a) sizes of door openings;

b) staircases and steps;

c) size and load capacity of lifts.

NOTE It may be possible to remove external panels and pipework thereby reducing the overall autoclave size.

3.3 Floor loading

Building construction methods require that the permanent position of equipment weighing above a specified value be restricted to designated floors or areas of floors.

NOTE 1 The total mass of an autoclave of chamber capacity 290 L could be as much as 700 kg. The inclusion of a steam generator (i.e. types II or III of BS 2646-1) could increase the total mass to approximately 1 000 kg.

NOTE 2 Information to be supplied by the manufacturer should include the expected total weight of the autoclave and point loading when fully loaded.

3.4 Floor surface

It should be anticipated that leakages from pipework connections and spillage in the vicinity of the autoclave may occur. For these reasons flooring finishes in the loading and plant room areas should be non-slip and impervious to water. To facilitate cleaning, the floor should fall naturally to an open gully (see also **7.2** note 2).

3.5 Autoclaving capacity

The capacity required will depend on the workload of the laboratory, the autoclave cycle time, and the purchasing policy for single-use sterile apparatus and media.

The size and number of autoclaves should allow the expected daily workload to be processed within normal laboratory working hours.

Where possible, autoclaves designated specifically to making safe contaminated waste should be installed; a separate loading room should be provided for these. It is recommended that a minimum of two autoclaves be installed in a laboratory suite.

[1)] The groups of organisms referred to are those listed in *"Categorization of pathogens according to hazard and categories of containment"* produced by the Advisory Committee on Dangerous Pathogens and published by HMSO.

NOTE Where a single autoclave is provided, contingency plans should be made for the safe disposal of contaminated waste in the event of breakdown.

It is recommended that autoclaves with chambers which exceed 450 L should be of type I of BS 2646-1 (see also **6.1**).

3.6 Siting

Autoclaves should be installed so as to facilitate the provision of services to them. Siting near an outside wall will assist in the provision of ventilation and drainage.

Autoclaves for the sterilization of waste materials should be readily accessible and should be sited in, or as close as possible to, the area in which the potentially contaminated material is examined, e.g. the microbiology laboratory suite.

NOTE 1 It is not advisable to transport waste material through rooms where it would not normally be stored or handled.

A microbiology media preparation area will also require the provision of autoclaves and therefore should be located in the same vicinity. Access for loading and unloading sterilized fluids and apparatus, but not for contaminated discards, should be directly from the media preparation area.

NOTE 2 If the volume of contaminated material does not justify the provision of an autoclave in the laboratory suite, suitable arrangements should be made for its secure transport to an autoclave elsewhere. (Guidance on this subject will be given in BS 2646-3.)

3.7 Space requirements

3.7.1 *Maintenance access*

Adequate clearance is necessary for maintenance. This should be 1 000 mm around parts to which access for routine maintenance is required. For top loading autoclaves sited in a laboratory room, a minimum distance of 300 mm behind the machines is recommended although additional clearance may be required for the withdrawal of any electrical or ancillary equipment rearwards from the autoclave. Minimum clearance between autoclaves should be 1 000 mm; additional clearance may be needed if sideways sliding doors are fitted.

Steam generators, which are not part of the autoclave, should have similar clearance to that of an autoclave.

Space should be available for the installation and maintenance of air compressor/receiver assemblies, water treatment plants, water break tanks and water pressure pumping systems where these are planned.

3.7.2 *Operator access*

Where carriage and trolley loading is required the minimum clearance for access to the autoclave should be 2 000 mm or twice the length of the carriage loading system, whichever is the greater. Shelves for the storage of empty discard-containers should not impede door or trolley movement or restrict access to autoclaves.

4 Heating and ventilation

4.1 General

Autoclaves can be expected to produce heat, some steam and foul odours particularly on unloading after a make-safe cycle. Mechanical ventilation is therefore necessary to maintain the desired air flow pattern in the vicinity of the autoclaves; this should be by a total loss system.

4.2 Ventilation design

Ventilation design should take particular note of the energy output of the autoclave(s) and its effect on the working environment.

4.3 Separate plant room

Where the laboratory and plant room are separated by the autoclave(s) (in the case of front loading autoclaves) the loading area should be at a lower pressure than a main laboratory corridor and at a higher pressure than the plant room. There will be air movement past the autoclave door mechanisms into the plant room. The discharge to the outside should not be sited where the extracted air will be drawn into the building via windows or ventilation inlets. Frost protection should be provided to the plant room, e.g. by the use of thermostatically controlled background heating.

5 Noise transmission

The room in which the autoclave is installed should be planned and designed so that the noise transmitted does not give rise to excessive noise levels in the autoclave room or adjoining rooms. Assessment of noise levels should take into consideration the room conditions which will exist after installation of the autoclave.

NOTE For autoclaves installed in the laboratory room, large air compressors or vacuum pumps installed within the autoclave frame or alongside the autoclave are likely to create a level of noise which is unacceptable.

6 Services to autoclaves and associated areas

6.1 Steam service

6.1.1 *General*

A supply of saturated steam from an external source is required for autoclaves of type I of BS 2646-1. The steam can be generated within the laboratory building or generated elsewhere and piped to the laboratory.

Where it is not possible to maintain a continuous steam supply with the properties recommended in **6.1.2** to **6.1.4**, one of the following should be used:

a) an autoclave which generates its own steam (types II or III of BS 2646-1);

b) an autoclave in which steam is generated within the autoclave chamber (type IV of BS 2646-1).

See also **3.5**.

6.1.2 *Steam supply*

Where steam is supplied from elsewhere, the pipeline which supplies the steam should be fitted with a pressure gauge inside the plant room (or laboratory room) and terminated within 2 m of the autoclave installation by means of an isolation valve. The pressure gauge should be an industrial gauge of the bourdon type and complying with BS 1780.

Adequate trapping, straining and venting of the steam supply system, good installation practice to remove condensate and non-condensable gases, together with efficient thermal insulation are important to the operation of laboratory autoclaves.

6.1.3 *Steam supply pressure*

Steam pressure at the isolation valve at the end of the steam supply should be not less than 3 bar[2)].

A reducing valve or other automatic device should be fitted to reduce the pressure of the steam delivered to the autoclave to not more than the maximum working pressure of the autoclave (see **2.2** of BS 2646-1:1988).

6.1.4 *Dryness value*

Autoclaves in laboratories are not intended for the sterilization of fabrics which are required to be dry at the end of the cycle. For this reason and because of the nature of the loads, dryness values of steam supplied to laboratory autoclaves need comply only with the following.

a) The need to minimize condensate in the supply line to the autoclave which would affect the efficient and reliable operation of reducing valves.

b) The need for rapid heating of the autoclave load. The heating action is slower when water, which carries no specific enthalpy, is present in the steam.

NOTE Steam supply lines should be fitted with sufficient steam drainage facilities, with steam traps, to prevent accumulation of condensate.

6.1.5 *Superheat*

Attention to the details in **6.1.2** should prevent the steam becoming superheated. However, superheat, if present in steam injected into an autoclave chamber, is quickly converted to latent heat, because of the nature of laboratory-generated loads.

NOTE Problems associated with superheated steam have not been reported in laboratory autoclaving practice.

6.1.6 *Boiler and feed-water treatment*

Consideration should be given to the use of methods of "external treatment" of boiler feed water. Guidance on these methods and the recommended levels of purity are given in BS 2486 (see also **6.3**).

NOTE Chemicals used for treatment of boiler feed water may be carried over into the autoclave and adversely affect autoclave loads which may consist of defined microbiological culture media or glassware cleaned to high standards for critical laboratory procedures.

6.1.7 *Condensate return*

The condensate return should lead from the separator and steam-trap, but not from the autoclave chamber drain (see **7.1**).

6.2 Electrical services

6.2.1 *Electrical supply*

The electrical power requirements will depend on a number of factors including autoclave type (see clause **3** of BS 2646-1:1988) and method of automatic control. The most suitable type and its power rating should be considered at an early planning stage. Autoclaves of types II, III and IV of BS 2646-1 will probably require a three-phase supply.

6.2.2 *Electrical isolators*

All installations should incorporate a switch, isolating at least each supply main line conductor. The switch should be positioned within 2 m of the autoclave.

NOTE 1 This switch is in addition to the device specified in **35.5** of BS 2646-1:1988.

Isolators in a single-phase supply for autoclaves with a maximum current demand of 13 A may be of the simple plug and socket outlet type, with the plug correctly fused and the socket outlet switched.

[2)] 1 bar = 10^5 N/m^2 = 10^5 Pa.

Where a three-phase supply is provided, or where the maximum current demand is more than 13 A, the autoclave should be wired directly to the isolator.

NOTE 2 The cable from isolator to autoclave should be suitably fixed and suitably protected from the effects of heat, water and steam.

6.2.3 *Electrical safety*

Attention is drawn to clause **35** of BS 2646-1:1988 concerning electrical safety requirements. Attention is also drawn to clauses **44** and **45** of BS 2646-1:1988 which cover details to be marked on the plate attached to the framework and which include certain electrical data.

6.2.4 *Emergency electrical supply*

Autoclaves should be connected to the essential supplies circuit, if available, i.e. connected to a standby supply of electricity in the event of failure of the normal supply.

6.2.5 *Lighting*

Fluorescent lighting should be used. The recommended level of illumination of floor level in both plant rooms and loading rooms is 250 lx at equipment glare index 19 (see BS 8206-1).

The stroboscopic effect of the lighting should be minimized in the plant room by the use of two tube fittings suitably adapted for this purpose or by the use of two phases for the lighting circuits. The fittings should be sited longitudinally between the autoclaves.

6.3 Water supply

6.3.1 *General*

A supply of water may be required for cooling, for the operation of water-sealed pumps and, for autoclaves of types II, III and IV of BS 2646-1, for boiler feed water. Details of the required pressure, flow rate and quality should be obtained from the autoclave manufacturer

6.3.2 *Supply water temperature*

For their optimal performance, water supplied to water-sealed pumps, condensers and heat exchangers and used for cooling autoclave discharge, should be at a temperature below 12 °C.

6.3.3 *Supply water treatment*

For autoclaves of types II, III and IV of BS 2646-1, treatment may be required of hard water or water which contains impurities. This may be achieved by the installation of a simple water treatment plant at the autoclave installation (see **6.1.6**).

6.4 Compressed air

6.4.1 *Air supply*

Compressed air may be required for chamber ballasting and/or operating of autoclave controls. The air may be supplied from a compressor which is part of the autoclave or from a central laboratory supply.

If air is supplied by pipeline from a central air compressor system this should be fitted with a pressure gauge inside the plant room (or laboratory room) and terminated with an isolation valve within 2 m of the autoclave installation. The pressure gauge should be an industrial gauge of the bourdon type and comply with BS 1780. A reducing valve or other automatic device should be fitted to reduce the pressure of the air delivered to the autoclave to not more than the maximum working pressure of the autoclave (see **2.2** of BS 2646-1:1988).

6.4.2 *Air quality*

6.4.2.1 *Air for chamber ballasting*

This will come into direct contact with the materials being processed and should therefore be filtered to remove contaminating oil-mist and micro-organisms. The required levels of cleanliness may be achieved as follows.

a) *Oil.* By using a filter capable of removing droplets 1.0 μm in diameter. This filter may also serve as a prefilter.

b) *Micro-organisms.* A High Efficiency Particulate (HEPA) filter with a sodium penetration of not more than 0.001 % when tested in accordance with BS 3928 at the designed maximum volumetric rate for the filter.

6.4.2.2 *Air for operating controls*

This should be suitable for the continual operation of controls as required by their manufacturers. Equipment for achieving this should be located where it can be readily serviced or exchanged and should form part of the autoclave.

7 Autoclave discharge

7.1 General

The total discharge from the autoclave may comprise:

a) air, condensate and steam from the chamber drain which may contain chemicals and other materials and micro-organisms, especially those from a make-safe process;

b) discharge from a vacuum pump, ejector or chamber vent, which may also contain micro-organisms;

c) water from a chamber cooling system;

d) water introduced to cool the discharge condensate which will further dilute it.

Therefore, discharge from the autoclave is unsuitable for recovery.

7.2 Drainage system

The drainage system from the autoclave should prevent the dispersion of splashes and steam into the working area. For autoclaves designed for a make-safe process, discharge should be directed to a sealed discharge system; the system should lead by direct connection to a building drain or catchment tank.

An open tun dish is not suitable for the discharge line of a laboratory autoclave which is to be used for a make-safe process.

The sealed discharge system should be vented to a high level by a pipe not less than 30 mm in diameter. The vent pipe should be directed outside the building. Steam should not emit from the vent pipe.

The autoclave discharge temperature is unlikely to exceed 80 °C but, in the event of failure of the diluting and cooling system it might be expected to reach a temperature of not more than 100 °C. The materials used for the building drain should therefore be chosen to withstand this temperature.

NOTE 1 Attention is drawn to the legal requirement (Public Health Act 1936, Paragraph 27) that the maximum temperature of any liquid to be emptied into a public sewer or communicating drain is 43 °C. This may be interpreted as relating to the main building connection to the sewer and not the internal building drain.

The connection between discharge system and building drain should be of sufficient size and the vent pipe should preserve an air-break at all times, so that the autoclave chamber and its associated pipework cannot be contaminated by reverse flow.

NOTE 2 Drainage problems will be encountered when autoclaves are sited below the level of the main building drain, e.g. in basement rooms.

In certain circumstances, e.g. special research activities involving high concentration and/or large volumes of agents in Hazard Group 3, additional safeguards may be required. The advice of the Health and Safety Executive should be sought in each such case. Further containment than that detailed above, filtration or heat treatment of discharge is only necessary for autoclaves used to process material contaminated with organisms in Hazard Group 4 (see footnote to clause **1**).

blank

Publication(s) referred to

BS 1780, *Specification for bourdon tube pressure and vacuum gauges.*

BS 2486, *Recommendations for treatment of water for land boilers.*

BS 2646, *Autoclaves for sterilization in laboratories.*

BS 2646-1, *Specification for design and construction.*

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

BS 3970, *Sterilizing and disinfecting equipment for medical products.*

BS 8206, *Lighting for buildings.*

BS 8206-1, *Code of practice for artificial lighting.*

"Categorization of dangerous pathogens according to hazard and categories of containment" HMSO 1984.

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: 020 8996 9000. Fax: 020 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: 020 8996 9001. Fax: 020 8996 7001.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: 020 8996 7111. Fax: 020 8996 7048.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: 020 8996 7002. Fax: 020 8996 7001.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL