BRITISH STANDARD

BS 2646-1: 1993

Autoclaves for sterilization in laboratories —

Part 1: Specification for design, construction, safety and performance

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:

Association of British Health Care Industries
Association of National Health Service Supplies Officers
Association of Sterilizer and Disinfector Equipment Manufacturers
British Dental Trade 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
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:

Association of Clinical Pathologists
British Glass Manufacturers' Confederation
British Laboratory Ware Association
Copper Development Association
Institute of Medical Laboratory Sciences
Manufacturing Science Finance
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 Standards Board and comes into effect on
15 March 1993

First published December 1955
First revision as BS 2646-1 August 1988
Second edition March 1993

The following BSI references relate to the work on this standard:
Committee reference LBC/35
Draft for comment 91/53015 DC

ISBN 0 580 21336 6

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 specifies requirements for the design, construction, safety and performance of laboratory autoclaves for the purposes of sterilization. It does not cover autoclaves for use with material infected with organisms in Hazard Group 4 (see **1.1**, footnote 3). This Part of BS 2646 supersedes BS 2646-1:1988 which is withdrawn. This new edition introduces requirements for function and performance, related to the methods of test contained in BS 2646-5.

BS 2646 comprises several separate Parts. The other Parts of the standard are as follows.

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

— *Part 3: Guide to safe use and operation*[1)];

— *Part 4: Guide to maintenance*;

— *Part 5: Methods of test for function and performance*.

This Part of BS 2646 specifies requirements for the design and construction of the pressure vessel and also includes details of necessary pressure vessel and electrical safety features. It is intended that in conforming to this standard the design and manufacture of autoclave pressure vessels will also conform to the relevant requirements of BS 5500:1991.

It is acknowledged that copper and copper alloys are not covered by BS 5500, and neither are rectangular pressure vessels. The design criteria for autoclave pressure vessels constructed of copper or copper alloys and for rectangular chambers are included in this Part of BS 2646.

A section has also been included on steam generators heated by electricity where these form part of the autoclave unit.

This new edition of the standard introduces requirements for the performance and testing of autoclaves. Autoclaves may be suitable for a single process where the displacement of air is by steam, or they may be multi-purpose and incorporate a number of operating cycles for more than one process, some having a mechanical air removal system such as vacuum and/or a succession of pressure reductions and steam pulses. The testing programme is described in Annex A and covers tests on the pressure vessel and on the completed and installed autoclave, including commissioning. The tests themselves are described in BS 2646-5. Guidance on validation and in-use tests will be given in BS 2646-3.

Autoclaves covered by this standard are not intended for the sterilization of goods or fluids which are 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 these applications are covered by Parts of BS 3970.

It is intended that consideration will be given to replacement of the references to BS 3456-101:1987 in **9.6**, relating to electrical safety requirements, by references to BS EN 61010-1, when that standard is published. BS EN 61010-1 will include safety requirements for various types of laboratory equipment.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity to this British Standard based on testing and continuing product surveillance which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes are forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

[1)] In preparation.

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 36, 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.

Section 1. General

1.1 Scope

This Part of BS 2646 specifies requirements for the design, construction, safety and performance of autoclaves for operation with saturated steam at temperatures up to 138 °C and pressure not exceeding 2.4 bar[2)] nominal and for operation under vacuum (subject to external pressure).

This standard covers laboratory autoclaves for the sterilization of goods and material which could be infected with organisms categorized as Hazard Group 1, 2 or 3[3)]. It does not cover autoclaves for use with material infected with organisms in Hazard Group 4, for which complete containment and sterilization of infected condensate is considered to be essential.

This standard does not apply to sterilizers or disinfectors used for medical, dental, pharmaceutical or veterinary purposes which are directly concerned with patient care, or to those used for fabrics subjected to sterilization which are required to be dry at the end of the cycle. These are covered by BS 3970.

1.2 References

1.2.1 Normative references

This Part of BS 2646 incorporates, by reference, provisions from specific editions of other publications. These normative references are cited at the appropriate points in the text and the publications are listed on page 35. Subsequent amendments to, or revisions of, any of these publications apply to this Part of BS 2646 only when incorporated in it by updating or revision.

1.2.2 Informative references

This Part of BS 2646 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

1.3 Definitions

For the purposes of this Part of BS 2646, the following definitions apply.

1.3.1
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.

1.3.2
maximum permissible working pressure

the maximum internal pressure, not higher than the design pressure, at which the autoclave chamber and/or generator can be operated

NOTE To prevent unnecessary lifting of the safety valve, there should be an adequate margin between the actual pressure at which the autoclave is operating and the lowest pressure at which the safety valve is set to lift.

1.3.3
design pressure

the maximum internal pressure, not lower than the safety valve set pressure, that the autoclave chamber and/or generator is designed to withstand and that is therefore used in the design equations

1.3.4
safety valve set pressure

the pressure at which a safety valve is set to lift

1.3.5
operating pressure

the pressure at which the autoclave operates

1.3.6
design temperature

the saturated steam temperature corresponding to the design pressure of the autoclave chamber and/or generator. Its value is used to determine the appropriate nominal design strengths for the selected materials and is not lower than the actual metal temperature prevailing in service (see **5.3.1**)

1.3.7
door

the closure of the autoclave chamber. In the case of a top loading autoclave, it is the lid of the chamber

1.3.8
purchaser

the individual or organization that buys the completed autoclave for its own use or as an agent for the user

1.3.9
manufacturer

the organization that designs, constructs and tests the autoclave in accordance with this Part of BS 2646 and with the purchaser's specification

---

[2)] 1 bar = 1×10^5 N/m^2 = 0.1 N/mm^2 = 1×10^2 kPa = 14.5038 lbf/in^2. Pressures referred to are measured from atmospheric and not on the absolute scale.

[3)] The Hazard Groups of organisms referred to are those listed in *Categorization of pathogens according to hazard and categories of containment*, Second Edition, 1990 [1], produced by the Advisory Committee on Dangerous Pathogens, and published by HMSO.

NOTE By agreement, the design, construction and testing may be carried out by different organizations (see **1.5**).

1.3.10
inspecting authority

the independent body or association appointed to check that the manufacturer's quality system, and the design, materials and construction of the autoclave pressure vessel(s) conform to this Part of BS 2646

1.3.11
regulating authority

the authority, in the country in which the autoclave is to be installed, that is legally charged with the enforcement of the requirements relating to autoclave pressure vessels of the law and regulations of that country

1.3.12
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.

1.3.13
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.

1.3.14
equipment and glassware sterilization

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

1.3.15
operating cycle

the complete set of stages of the autoclaving process carried out in the sequence regulated by the controller

1.3.16
sterilizing stage

the part of the operating cycle which comprises the equilibration time and the holding time

1.3.17
controller

a device which, in response to predetermined cycle variables, operates the autoclave through the required stages of the process in the correct sequence

1.3.18
operator

the person trained to use the autoclave

1.3.19
double-ended autoclave

an autoclave with a horizontally mounted chamber which has a door at each end

1.3.20
usable chamber space

the maximum volume of load which the chamber, with load support, is designed to accommodate

1.3.21
discard-container

a receptacle for material (including containers) to be subjected to a make-safe process

NOTE Guidance on the design of discard-containers is contained in *Safety in Health Service Laboratories — Safe working and the prevention of infection in clinical laboratories* [2], produced by the Health Services Advisory Committee and published by HMSO. Guidance will also be given in BS 2646-3.

1.3.22
container

a laboratory vessel in which liquids, including culture media, are processed in the autoclave

1.3.23
holding time

the period for which the chamber and load are at sterilizing temperature

NOTE The holding time may be set by the operator before the operating cycle commences but is not adjustable by the operator during the cycle.

1.3.24
sterilizing temperature

the temperature to be attained in all parts of the load throughout the holding time

NOTE The sterilizing temperature need not be the same for each process.

1.3.25
equilibration time

the period between attainment of the sterilizing temperature in the chamber drain (or vent) and in all points of the load

NOTE This has also been known as "load-lag".

1.3.26
steady state

a state in which the controlled temperature and corresponding pressure within the chamber are in equilibrium

1.3.27
commissioning

the inspection and testing of the autoclave to confirm that it conforms to this Part of BS 2646 (see **A.4**)

1.3.28
performance tests

the tests to be carried out at the time of manufacture, at the time of commissioning and subsequently during the life of the autoclave

1.3.29
validation

the specified procedures which provide evidence that the particular operating cycle is capable of producing a repeatable assurance of effectiveness (see **A.5**)

1.3.30
fault

the recognition by the controller or the operator that the predetermined or pre-set variables for the operating cycle have not been attained and that the process has been jeopardized

1.4 Classification

1.4.1 General

Autoclaves are classified into types, according to the source of steam, (see **1.4.2**) and into processes, according to the process(es) for which they are suitable (see **1.4.3**).

1.4.2 Autoclave types

For the purposes of this Part of BS 2646, autoclaves are classified according to the source of steam as follows.

Type 1. Steam from an external source (see also **9.2.1**).

Type 2. Steam from a generator forming part of the autoclave but capable of being isolated from the autoclave chamber, the generator being heated by means of an electric immersion heater see also **9.2.2**).

Type 3. Steam from a generator, as in type 2, but without means of isolation from the autoclave chamber (see also **9.2.3**).

Type 4. Steam produced from water contained within the autoclave chamber and heated by means of an electric immersion heater (see also **9.2.4**).

1.4.3 Autoclave processes

Autoclave processes are as follows.

a) Liquids sterilization (see **1.3.12**).

b) Make-safe (see **1.3.13**).

c) Equipment and glassware sterilization (see **1.3.14**).

1.5 Responsibilities

1.5.1 Responsibilities of the purchaser

The purchaser shall be responsible for supplying the manufacturer with the information specified in **1.6.1**.

If there is a Regulating Authority, it shall be the responsibility of the purchaser to ensure before the order is placed, that the Inspecting Authority is acceptable to the Regulating Authority.

1.5.2 Responsibilities of the manufacturer

1.5.2.1 The manufacturer shall be responsible for the completeness and accuracy of all design calculations and for conformity of the whole autoclave to the relevant requirements of this Part of BS 2646. If, during fabrication or design of the autoclave or pressure vessel, unexpected factors arise which justify deviations from the specified requirements but which do not affect the safety as intended by this Part of BS 2646, such deviations shall be submitted to the purchaser for approval and shall be recorded in accordance with item c) of **1.6.2.3**.

1.5.2.2 If the design and fabrication functions are carried out by separate organizations, the manufacturer's responsibilities as laid down in this standard shall be discharged in a manner agreed and documented by the parties concerned in accordance with item a) of **1.6.3**.

1.5.2.3 Examinations of a pressure vessel carried out by the Inspecting Authority shall not absolve the manufacturer from his responsibility for compliance with the relevant requirements of this Part of BS 2646.

1.5.2.4 The manufacturer shall be responsible for supplying the Inspecting Authority with two copies of the information specified in **1.6.2.2** for each autoclave pressure vessel or batch of nominally identical vessels serially produced.

1.5.2.5 The manufacturer shall be responsible for supplying the purchaser with the information specified in **1.6.2.3**, and for making it also available to the Inspecting Authority and the Regulating Authority.

1.5.3 Responsibilities of the Inspecting Authority

The Inspecting Authority shall be responsible for checking the design of the autoclave pressure vessel for conformity to this Part of BS 2646. The Inspecting Authority shall be responsible for inspection and testing as specified in section **7**.

Certificate of compliance (to be completed for each pressure vessel)

Autoclave type .....

Vessel description
Boiler/receiver .....
Approximate internal dimensions .....
Approved drawing number(s) .....
.....
.....

Manufacture
Year of manufacture .....
Name of manufacturer .....
Manufacturer's serial no. or cipher (see note) .....
Name of Design Organization
(if other than manufacturer) .....
Name of Inspecting Authority,
design approval .....
Name of Inspecting Authority, testing
and inspection (where appointed) .....

Design
Design pressure (in bar) .....
Design temperature (in °C) .....
Construction category .....

Post welded heat treatment (where applicable)

Component	**Temperature** (in °C)	**Holding time** (in h)
.....	.....	.....

Hydraulic pressure test

Location	**Test pressure** (in bar)	**Test medium and temperature** (in °C)	**Date**
.....	.....	.....	.....

Deviations and concessions

NOTE. The suffix 'XX' is to be added to the serial number of each vessel for which any deviations or concessions have been authorized (see item c) of **1.6.2.3**).

Figure 1 — Certificate of compliance *(continued)*

Certificate of compliance (design)

We hereby certify that the design of this vessel conforms to BS 2646 : Part 1 : 1993, and has been approved by .....
(Name of Inspecting Authority)

Reference of Inspecting Authority, approval .....

For manufacturer ..... Date .....

Position ..... Name of company .....

Certificate of compliance (construction and testing)

We hereby certify that this vessel has been constructed and tested and conforms to BS 2646 : Part 1 : 1993.

For manufacturer ..... Date .....

Position ..... Name of company .....

This section to be completed if an Inspecting Authority has been appointed to examine and test this pressure vessel

We hereby confirm that the above vessel has been examined and tested and that to the best of our knowledge and belief it conforms to BS 2646 : Part 1 : 1993.

For Inspecting Authority ..... Date .....

Position .....

Name of company (where relevant) .....

Figure 1 — Certificate of compliance *(concluded)*

1.5.4 Certificate of compliance

On completion of construction of the pressure vessel, the manufacturer shall issue a certificate of compliance (see Figure 1) to certify that the vessel has been designed, constructed and tested in every respect in accordance with this Part of BS 2646. The certificate of compliance shall be countersigned by the Inspecting Authority if such an authority has been appointed.

1.6 Information and requirements to be agreed and to be documented

1.6.1 Information to be supplied by the purchaser

The following information shall be supplied by the purchaser, if required by the manufacturer, and shall be fully documented. Documented items shall be satisfied before a claim of compliance with this Part of BS 2646 can be made and verified.

a) A specification of the normal working conditions of the autoclave together with details of any transient and/or adverse conditions under which the autoclave is required to operate and of any special regulations for in-service inspection.

b) Any additional requirements not given in this standard.

c) Any special statutory or other regulations with which a finished autoclave pressure vessel is required to comply.

d) The name of the Regulating Authority (if any).

e) Whether or not an Inspecting Authority is to be nominated by the purchaser (see **7.1**).

f) If an Inspecting Authority is to be nominated by the purchaser, the name of the Inspecting Authority.

1.6.2 Information to be supplied by the manufacturer

1.6.2.1 The information listed in **1.6.2.2** to **1.6.2.4** shall be supplied by the manufacturer and shall be fully documented. Both the definitive requirements of this Part of BS 2646 and the agreed and documented items (see **1.6.3**) shall be satisfied before a claim of compliance with this Part of BS 2646 can be made and verified.

1.6.2.2 For each autoclave pressure vessel or batch of nominally identical vessels serially produced, the manufacturer shall supply the Inspecting Authority with two copies of the information detailed in items a) to e), as follows.

a) A fully dimensioned drawing of the vessel, as designed, together with any relevant supporting information in accordance with **4.1.1** of BS 5500:1991 which is not covered by items b) to e) or by **1.6.2.3**.

b) A list of materials (including welding consumables) used in the construction of the vessel(s), together with details of any special heat treatments carried out by the material supplier. For materials for which compliance with a British Standard is claimed, the date of the standard shall be given.

c) Any requirements for non-destructive testing of the pressure vessel in accordance with clause **7.5** (for aluminium alloy vessels only).

d) The welding procedures used during vessel manufacture (see **7.2.3**).

e) Any procedures used for inspection and/or crack detection of welds (see **7.6.1**).

1.6.2.3 The manufacturer shall supply the purchaser with the following information, which shall also be available to the Inspecting Authority and the Regulating Authority.

a) A certificate of compliance for each pressure vessel (see **1.5.4**).

b) A facsimile of the marking as required by section **13**.

c) Records of authorized deviations or concessions (see **1.5.2.1**). The manufacturer shall add the suffix "XX" to the serial number of each vessel and autoclave for which any deviation or concessions have been authorized.

d) Details of any alternative specifications in this standard which require the approval of the purchaser (see **1.6.3**).

e) Details of the services required on site for the satisfactory operation of the autoclave.

f) If an Inspecting Authority is to be nominated by the manufacturer, the name of the Inspecting Authority.

1.6.2.4 The manufacturer shall indicate to the purchaser, for each relevant autoclave process (see **1.4.3**), the duration of the operating cycle as measured in accordance with BS 2646-5:1993, provided that the autoclave performance conforms to section **12** of this Part of BS 2646. Where the alternative test(s) B or C have been performed, details of the challenge load, including the load container(s) and/or discard-container(s) shall also be provided.

1.6.3 Items to be agreed and documented

The following items to be agreed, as appropriate, between the parties concerned, which are specified in the clauses referred to, shall be fully documented. Both the definitive requirements specified throughout this standard and the following documented items shall be satisfied before a claim of compliance with this standard can be made and verified.

a) The manner in which the manufacturer's responsibilities are to be discharged in cases where the design and fabrication functions are carried out by separate organizations (see **1.5.2.2**).

b) The use of materials of construction that are not listed in Table 1 or Table 2 (see item b) of **1.6.2.2**).

c) Whether welder approval tests that have been completed to the satisfaction of another recognized Inspecting Authority are acceptable (see note 2 of **7.3.4**).

d) Acceptance criteria for defects revealed by visual examination, including aided visual examination (see **7.6.1**).

e) The autoclave type (see **1.4.2**).

f) The process(es) for which the autoclave is suitable (see **1.4.3**).

g) The nature of loads for which the autoclave is to be used (see **A.5**).

h) Any specific requirements which may be evident to the purchaser or manufacturer after consideration of the guidance given in BS 2646-2:1990, BS 2646-3 and BS 2646-4:1991.

NOTE A list of optional requirements is contained in Annex B.

Section 2. Materials

2.1 Selection of materials

2.1.1 General

2.1.1.1 The selection of the materials of construction for pressure-containing parts and their integral attachments shall take into account the suitability of the material with regard to fabrication and to the conditions under which they will eventually operate. Due attention shall be paid to the effects of galvanic attack and differential expansion when dissimilar metals are used in contact and also to the susceptibility of some stainless steels to stress and crevice corrosion.

2.1.1.2 The materials used in the manufacture of pressure-containing parts shall be one of the following:

a) materials conforming to the appropriate British Standard listed in Table 1 and Table 2;

b) other materials, subject to agreement with the Inspecting Authority and the purchaser (see item b) of **1.6.3**).

2.1.2 Welding and brazing materials

2.1.2.1 Welding materials for autoclaves constructed from materials listed in Table 1 shall be selected in accordance with **4.3.2** of BS 5500:1991 or **4.3.2** of Annex AA of BS 5500:1991.

2.1.2.2 Brazing materials for the copper and copper alloys listed in Table 2 shall be in accordance with **6.4**.

2.2 Nominal design strength

The nominal design strength of every material used in the manufacture of the shell and ends of the autoclave chamber and generator, including the door and frame, shall, as appropriate, be as listed or referred to in Table 1 and Table 2.

Table 1 — Materials

Material	British Standard	Designation	Nominal design strength
Carbon steel plates	BS 1501-1:1980	151–360 151–400 151–430	
Stainless steel plates	BS 1501-3:1990	316S11 316S31 321S31 247S31 347S51	As specified in **3.4.2.2** of BS 5500:1991
	BS 1449-2:1983 (see note 1)	316S11 316S31 321S31 347S31	
Stainless steel tubes	BS 3605:1973	316S14 316S18 321S18 and 321S59 347S18 and 347S59	As specified in Table 2.3 (j) of BS 5500:1991
Stainless steel castings	BS 1504:1976	316C12A 316C16A 318C17A 347C17A	As specified in **3.4.2.3** of BS 5500:1991
Carbon steel to BS 1501-1:1980 clad on the inner surface (not less than 10 %) with nickel[a] Carbon steel to BS 1501-1:1980 clad (not less than 10 %) with corrosion resisting steel[a]	(see note 2)		As specified in **3.4.2.2** of BS 5500:1991
Aluminium alloys	BS 1470:1987, BS 1471:1972, BS 1472:1972, BS 1473:1972, BS 1474:1987, BS 1475:1972, BS 4300	5154A or 5083	As specified in Table 2.3 of Annex AA of BS 5500:1991

NOTE 1 For materials to BS 1449-2:1983, the steel supplier shall provide a certificate which shall also state:
a) the ladle analysis of the material supplied;
b) the results of mechanical tests on test pieces taken from samples representing the material supplied.

NOTE 2 These materials were formerly covered by BS 1822 and BS 3740 (both withdrawn).

[a] The nominal design strength is that of the carbon steel base plate.

Table 2 — Copper and copper alloys: nominal design strength values

Material	British Standard	Designation	Tensile strength (min.)	0.2 % proof stress (min.)	Nominal design strength values[a] at				
					50 °C N/mm²	100 °C N/mm²	150 °C N/mm²	175 °C N/mm²	200 °C N/mm²
Copper plate Copper sheet	BS 2875:1969 BS 2870:1980	C106	220	62	41	40	34	26	18
Gunmetal castings	BS 1400:1985	G1	270	130	55	55	55	52	49
		LG2	200	100	48	48	48	47	45
		LG4	250	130	59	59	59	55	51

[a] Values at temperatures between those given may be obtained by interpolation.

Section 3. Autoclave chamber

3.1 General

The autoclave chamber shall be either front loading or top loading.

The interior of the chamber shall be provided with a load support which shall allow condensate to drain away and steam to circulate to all parts of the load.

3.2 Chamber doors

3.2.1 Vertically mounted chambers shall be fitted with a single door.

3.2.2 Doors shall be fitted to one or both ends of a horizontally mounted chamber.

NOTE It is recommended that a single door only is fitted. Only in exceptional circumstances is the use of a door at each end of the chamber necessary, i.e. for the sterilization of equipment or materials entering or leaving a containment suite.

Section 4. Steam generators

4.1 General

Steam generators shall be fitted to autoclaves of types 2 and 3 (see **1.4.2**).

The steam generator shall be designed and installed to permit access for inspection and cleaning.

4.2 Generator-to-chamber pipework assemblies

If copper pipework and fittings are used to connect the steam generator to the autoclave chamber they shall conform to BS 1306:1975 (see also note to **7.7.2.2**).

Section 5. Design

5.1 General

NOTE This section is intended solely for the purpose of determining the minimum thicknesses and dimensions required in order to ensure safety of the pressure vessel(s) within the autoclave.

Except where otherwise stated, the application of design criteria and formulae shall conform to section **3** of BS 5500:1991. Precautions to be taken to safeguard against corrosion and its effects shall be in accordance with **3.3** of BS 5500:1991.

5.2 Construction categories

The autoclave pressure vessels shall be constructed to one of the categories given in Table 3 depending on the material employed.

NOTE The construction categories are identified in Table 3.4 of BS 5500:1991.

Table 3 — Construction categories

Construction category	Test requirements	Permitted materials	Thickness (max.) mm
2	Non-destructive (see **7.5**)	Aluminium alloys	40
3	Visual only (see **7.6**)	Carbon steel	16
3	Visual only (see **7.6**)	Stainless steel	25
3	Visual only (see **7.6**)	Copper	10

5.3 Design stress

5.3.1 The design stresses shall not exceed the nominal design strength values, referred to in Table 1 and listed in Table 2, for the material of construction at the design temperature.

5.3.2 Where the design of any part of the pressure vessel is such that an assessment of stress values by prior calculation is not practicable, before being adopted for production, a prototype of the vessel shall be subjected to a proof hydraulic test which meets the requirements of the Inspecting Authority (see **7.7.1.2**).

5.4 Wall thickness

5.4.1 The wall thickness of any pressure vessel shall be not less than that given in Table 4.

Table 4 — Minimum wall thickness

Material	Minimum thickness mm
Carbon steel	4.75
Stainless steel	1.65
Aluminium alloys	2.00
Copper	2.00 or chamber diameter × 1/150 (whichever is greater)

5.4.2 The wall thickness of any pressure vessel shall be not more than that given in Table 3.

5.5 Vessels under internal pressure

5.5.1 Cylindrical pressure vessels

5.5.1.1 The design of cylindrical shells and shell-ends fabricated from any materials listed in Table 1 or Table 2 shall be in accordance with **3.5** of BS 5500:1991.

NOTE The materials listed in Table 2 are not covered in BS 5500. Nevertheless the design criteria adopted by that standard are suitable for other materials (see also **5.5.1.2**).

5.5.1.2 For pressure parts of copper incorporating welded seams, the design strength values given in Table 2 shall be multiplied by a factor of 0.8 (see BS 853:1990).

5.5.1.3 For steam generators with bolted flanged connections, the connections shall conform to **3.8** of BS 5500:1991.

5.5.2 Rectangular pressure vessels

5.5.2.1 *General*

For rectangular pressure vessels subjected to internal pressure, the design calculations and formulae shall conform to **5.5.2.2**, **5.5.2.3** and to section **3** of BS 5500:1991. The minimum thickness requirements given in Table 4 shall apply.

5.5.2.2 *Design calculation*

The minimum calculated thickness e_r (in mm) of flat, rectangular plates subjected to a uniform load over the entire surface is given by equation (1):

$$e_r = b\,(KP/f)\ ½ \qquad (1)$$

where

P is the design pressure (in N/mm^2);

f is the nominal design stress (in N/mm^2);

b is the width of the shorter side (in mm);

K is determined from Table 5 for the appropriate a/b ratio, where a is the length of the longer side (in mm).

Table 5 — Values of *K* for use in equation (1)

a/*b* ratio	Value of *K*
1.0	0.2874
1.2	0.3762
1.4	0.4530
1.6	0.5172
1.8	0.5688
2	0.6102
3	0.7134
4	0.7410
5	0.7476
6	0.75

5.5.2.3 *Stiffeners for flat plates*

Where required, stiffeners of a suitable section shall be welded to the flat plate (see Figure 2). Stiffeners or other means of support for flat plates shall be designed for transmission of the loads they carry to the adjacent side of the chamber, to the stiffeners on the latter or to some other suitable part of the structure.

The design stress f (in N/mm^2) shall be determined from equation (2):

$$f = \frac{P\,(s_1 + s_2)\,L_s^2}{K_s Z} \qquad (2)$$

where

P is the design pressure (in N/mm^2);

s_1 and s_2 is the pitch of adjacent stiffeners (in mm);

L_s is the length of the stiffener (in mm);

K_s is a constant equal to:

16 for stiffeners with ends not built in;

24 for stiffeners with ends built in.

Z is the modulus of the stiffener (in mm^3).

In calculating the modulus of the stiffener, it is permissible to take into consideration a portion of the flat plate having a length of $(10e_r + T_s)$ (see Figure 2):

where:

e_r is the minimum calculated thickness (see **5.5.2.2**);

T_s is the thickness of the stiffener (in mm);

the ratio H_s/T_s is not more than 6 where H_s is the height of the stiffener (in mm).

5.6 Vessels under vacuum (subject to external pressure)

5.6.1 Cylindrical pressure vessels

5.6.1.1 For cylindrical pressure vessels constructed from materials listed in Table 1, design calculations and formulae shall conform to **3.6** of BS 5500:1991 (see also **5.4** of this Part of BS 2646).

5.6.1.2 For cylindrical pressure vessels constructed from materials listed in Table 2, the design calculations and formulae shall be as those for vessels under internal pressure (see **5.4** and **5.5**).

5.6.2 Rectangular pressure vessels

For rectangular pressure vessels, the determination of the design calculations and formulae shall be as those for vessels under internal pressure (see **5.4** and **5.5**).

5.7 Doors and frames

5.7.1 General

Doors shall be flat or domed.

The door gasket shall be replaceable. Connecting compounds shall not be used to attach the door gasket to the door or chamber.

The face of the door gasket shall be completely exposed for inspection, cleaning and replacement purposes when the door is open.

Hinges and other supporting structures shall be designed to compensate for working variations in the thickness of the door gasket.

If a door is not supported against pressure continuously along the whole of its periphery but only at a number of separate points (e.g. when radial arms of interlocking lugs are used), the edge of the door shall be designed to be sufficiently rigid between the points of support to prevent deformation which might cause leakage past the joint between the point of support.

The sizes of wheels or levers used to close the doors shall be such as to ensure that no part of the pressure vessel or securing mechanism is damaged when a force of 500 N is used to close and secure the door during normal operation.

5.7.2 Door types

5.7.2.1 Doors shall be either multi-bolted or quick-opening doors.

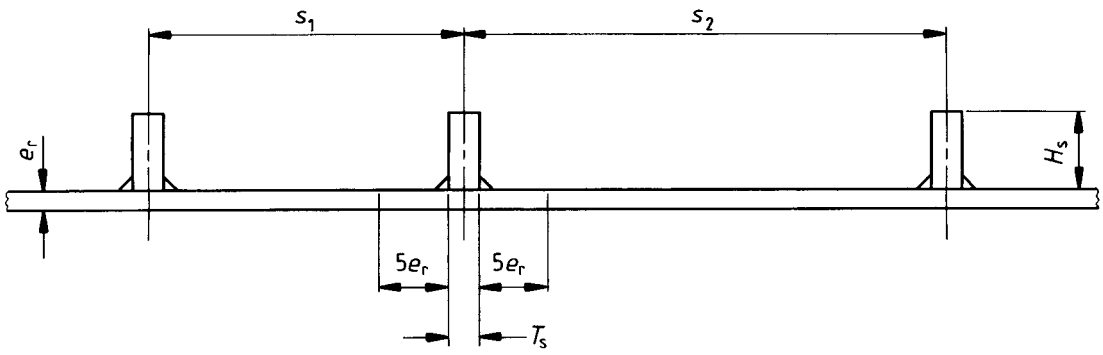

Figure 2 — Stiffeners for flat plates

5.7.2.2 Multi-bolted doors shall be locked by bolts at the periphery, and shall be designed in accordance with the requirements for pressure vessel ends given in **3.5.5** and **3.5.6** of BS 5500:1991. The door frame for multi-bolted doors shall be designed in accordance with the requirements for bolted flanged connections given in **3.8** of BS 5500:1991.

5.7.2.3 Quick-opening doors shall be of the following types depending upon the type of securing mechanism.

Type A. Doors secured by radial pivoted locking levers engaging at their outer ends with the door frame and operated by a mechanism attached to the centre of the door. In consequence, an outward force (acting in the same direction as the internal pressure load on the door) is applied between door and frame when the mechanism is tightened. The door shall have a central boss with a diameter not less than 0.1 times the door diameter, or 0.1 times the diagonal in the case of a rectangular door. The total thickness of boss and door shall be not less than 2.5 times the thickness of the door adjacent to the boss, and a radius factor of 0.1 shall be provided at the change of thickness.

Type B. Doors secured entirely by a force opposing the pressure load and applied at the centre of the door by a screw or lever mechanism from a transverse bridge or beam. The closing force shall be applied to a central boss having a diameter not less than 0.1 times the diameter of the door and a thickness not less than 1.5 times the thickness of the door immediately adjacent to the boss, a suitable radius being provided at the change of thickness.

Type C. Doors secured at the periphery and to which no load is applied at the centre.

5.7.3 Mode of operation

Doors shall be manually operated or power operated.

If a manually-operated door is fitted, the force required to open or close and secure it in normal operation shall not exceed 150 N.

If a power-operated door is fitted, provision shall be made for this to be opened manually using a key or tool(s) not required for the normal operation of the autoclave. The use of this key or tool(s) shall not override the safety devices specified in **9.2**.

Section 6. Manufacture and workmanship

6.1 General aspects of construction

6.1.1 Vessels manufactured from materials listed in Table 1 or Table 2, with the exception of aluminium alloy, shall conform to **4.1.3** and **4.1.4** of BS 5500:1991. Vessels manufactured from aluminium alloy shall conform to **4.1.3** of BS 5500:1991. Additionally, vessels made from any material listed in Table 1 shall conform to **4.1.2** of BS 5500:1991.

6.1.2 Cylindrical shells shall be constructed from tube or plate of the designation listed in Table 1 or Table 2.

NOTE Shells constructed from plate bent cold should preferably be made from a single plate.

6.2 Cutting, forming and tolerances

For all vessels manufactured from materials listed either in Table 1 or in Table 2, the cutting and forming of the material and the allowed tolerances shall be in accordance with **4.2** of BS 5500:1991. In the case of vessels manufactured from aluminium ahoy, **4.2** of Annex AA of BS 5500:1991 shall also apply.

6.3 Welded joints

6.3.1 The main seams of pressure vessels shall be fusion welded.

6.3.2 For vessels constructed of carbon steel or stainless steel, welded joints, heat treatment and surface finishes shall be in accordance with **4.3**, **4.4** and **4.5** of BS 5500:1991.

6.3.3 For vessels constructed of aluminium alloy, welded joints, heat treatment and surface finishes shall be in accordance with **4.3**, **4.4** and **4.5** of BS 5500:1991, except where replaced by corresponding subclauses **4.3** and **4.4** of Annex AA of that standard.

6.3.4 For vessels constructed of copper or copper alloy, welded joints shall be tested in accordance with BS 4206:1967.

6.3.5 For vessels constructed of clad carbon steel, the sealing welds on the clad side shall be of nickel or stainless steel compatible with the cladding material.

6.4 Brazed joints

If stiffeners or other attachments are brazed to copper chambers, the brazing process shall be carried out in accordance with BS 1723-1:1986. Brazing filler alloys shall conform to group AG or group CP of BS 1845:1984.

NOTE Guidance on brazing is given in BS 1723-2.

Section 7. Inspection and testing of pressure vessels

7.1 General

7.1.1 Each pressure vessel shall be either:

a) manufactured under a quality system accepted by the Inspecting Authority in accordance with BS 5750-1:1987; or

b) inspected by the Inspecting Authority to ensure that the design, materials, construction, testing and certification conform in all respects to this Part of BS 2646.

7.1.2 If a quality system in accordance with BS 5750-1:1987 has been agreed by the inspecting Authority, the inspection stages listed in Table 6 shall form part of the manufacturer's quality system. The manufacturer's quality system shall be subject to audit by the Inspecting Authority.

7.1.3 Where each pressure vessel is to be inspected by the Inspecting Authority for conformity with section **6** and section **7** of this Part of BS 2646, inspection and testing stages shall be as given in Table 6. The manufacturer shall give reasonable notice to the Inspecting Authority of when such stages will be reached.

7.2 Approval testing of welding procedures

7.2.1 Approval testing of fusion welding procedures carried out on vessels manufactured from materials listed in Table 1 shall be conducted in accordance with BS 4870-1:1981 or BS 4870-2:1982.

7.2.2 Approval testing of welding procedures carried out on vessels manufactured from materials listed in Table 2 shall be in accordance with procedures agreed between the manufacturer and the Inspecting Authority.

7.2.3 The manufacturer shall supply a list of the welding procedures required in the fabrication of the vessel, together with test pieces which are representative of the various thicknesses and materials to be used to prove each welding procedure. The production and testing of these test pieces shall be witnessed by the Inspecting Authority unless the procedures have already been approved. Methods of testing of fusion welds in copper and copper alloys shall be in accordance with BS 4206:1967.

7.3 Welder and operator approval

7.3.1 For materials listed in Table 1, approval testing of welders and operators shall be conducted, recorded and reported in accordance with BS 4871-1:1982 and BS 4871-2:1982.

7.3.2 For materials listed in Table 2, approval testing of welders and operators shall be conducted, recorded and reported in accordance with procedures agreed between the manufacturer and the Inspecting Authority.

7.3.3 All welding of pressure parts of vessels fabricated in accordance with this Part of BS 2646 shall be undertaken by welders and welding machine operators who have successfully completed such welder approval tests as demonstrate their competence to make sound welds of the types on which each is to be employed.

7.3.4 Welders who have passed successfully the prescribed tests in accordance with **7.3.3** shall be approved for all welding within the limits of the procedure provided they remain in the employ of the same manufacturer. A welder who welds successfully all the test pieces required for a welding procedure test in accordance with **7.2** shall not normally be required to undertake separate welder approval tests.

NOTE 1 If a welder has less than 6 months experience of the fabrication of vessels using the process and equipment appropriate for the procedure, or if there is any reason to doubt his ability to make satisfactory production welds, the Inspecting Authority may require him to retake the whole or part of the approval test.

NOTE 2 Unless otherwise stated in the enquiry and order, the approval tests of a welder, when completed to the satisfaction of a recognized Inspecting Authority, may be accepted by other Inspecting Authorities, subject to agreement prior to the commencement of welding (see item c) of **1.6.3**).

7.3.5 A list of welders and operators, together with records of their approval tests, shall be retained by the manufacturer to submit to the Inspecting Authority, if required, as evidence of approval of any welder or welding machine operator engaged in the fabrication of a vessel.

7.4 Production control test plates

Production control test plates shall be required only for vessels constructed from aluminium alloys which are in construction category 2 (see **5.2**). Control test plates shall conform to **5.4** of Annex AA of BS 5500:1991.

7.5 Non-destructive testing of pressure vessels

7.5.1 Non-destructive testing shall be required only for vessels manufactured from aluminium alloys which are in construction category 2 (see **5.2**).

NOTE Vessels manufactured from any other materials listed in Table 1 or Table 2 are in construction category 3 for which non-destructive testing is not required.

Table 6 — Inspection and testing stages

Inspection stage	Clause reference	Remarks
1. Correlation of material certificates with materials and check for conformity to material specifications	Section **2**, Table 1 and Table 2	The manufacturer shall make the certificates available to the Inspecting Authority for independent checking
2. Approval of welding and brazing procedures	Section **6** and clause **7.2**	Inspecting Authority to witness tests unless the procedures are already approved
3. Approval of welders and operators	Clause **7.3**	Inspecting Authority to witness tests unless the welders and operators are already approved
4. For aluminium alloys only. Examination of non-destructive test reports and check for conformity to agreed procedure and acceptability of any defects	Clause **7.5**	The manufacturer shall make the reports available to the Inspecting Authority for independent checking
5. Witness of the hydraulic pressure test	**7.7.2**	
6. Examination of completed vessel and check of markings	Section **13**	

7.5.2 For vessels in construction category 2, the timing, amount, choice of method, acceptance criteria for non-destructive testing and the qualification of testing personnel shall be in accordance with **5.6** and **5.7** of Annex AA of BS 5500:1991 and with those parts of **5.6** and **5.7** of BS 5500:1991 not replaced in the Annex AA.

7.6 Visual examination of pressure vessels

7.6.1 General

For vessels in construction category 3 (see **5.2**), visual examination only shall be required.

NOTE Insofar as magnetic particle or penetrant methods are aids to visual examination, they may be used.

Acceptance criteria for defects revealed by visual examination, including aided visual examination, shall be by agreement between the manufacturer and the Inspecting Authority (see item d) of **1.6.3**).

7.6.2 Magnetic particle techniques

Magnetic particle inspection techniques shall conform in all respects to BS 6072:1981. Their use shall be limited to applications where surface flaws are being sought.

NOTE Particular care should be taken to avoid damage to surfaces by misuse of the magnetic equipment employed. If such damage occurs it should be remedied to the satisfaction of the Inspecting Authority.

7.6.3 Penetrant technique

Examination of welds by methods using dye or fluorescent penetrant shall be carried out in accordance with BS 6443:1984.

7.7 Pressure tests

7.7.1 General

7.7.1.1 A pressure test shall be carried out on all vessels constructed in accordance with this Part of BS 2646, to demonstrate the integrity of the finished product. The first pressurization shall be carried out under controlled conditions with appropriate safety precautions.

NOTE Guidance on basic requirements, including safety, is given in **5.8.2** of BS 5500:1991 and Guidance Note GS4 *Safety in pressure testing* [3], published by HMSO for the Health and Safety Executive (HSE).

7.7.1.2 The finished vessel, to which post-weld heat treatment has been applied, if required (see **4.4.3** of BS 5500:1991), shall, in the presence of the Inspecting Authority or under the agreed quality system, pass satisfactorily whichever of the following pressure tests is relevant.

a) Standard hydraulic test for acceptance where the required thickness of all pressure parts can be calculated (see **7.7.2**).

b) Proof hydraulic test where the required thickness cannot be determined by calculation see **5.3.2** and **7.7.2.2**).

7.7.2 Hydraulic testing

7.7.2.1 *Standard hydraulic test*

The test shall be carried out in accordance with **5.8.3** of BS 5500:1991, except that the standard test pressure used for the hydraulic test shall be 1.5 times the design pressure (see note to **7.7.2.2**).

7.7.2.2 *Proof hydraulic test*

If a proof hydraulic test is required, it shall be carried out and the result interpreted in accordance with **5.8.6** of BS 5500:1991 or **5.8.6** of Annex AA of BS 5500:1991.

NOTE Hydraulic testing of vessels for autoclaves classified as type 2 or type 3 may be carried out on each vessel separately or on the whole pressure system, i.e. steam-generator, autoclave chamber and interconnecting pipework (see also **4.2**).

7.8 Stamping and marking of pressure vessels

Each pressure vessel shall be legibly stamped with visual marking on the vessel or on a permanently attached name plate with the manufacturer's cipher identifying the vessel (see also section **13**).

Section 8. Inspection and testing of the completed autoclave

8.1 General

NOTE Testing requirements and the stages of testing which comprise the testing programme are described in Annex A, which draws attention to the limitations of the performance tests.

8.1.1 In addition to inspections during manufacture, final inspections and tests on safety devices (see this section and section **2** of BS 2646-5:1993) shall be carried out on the completed autoclave at the manufacturer's premises.

8.1.2 If the autoclave conforms to **8.1.1**, and where required by the purchaser, tests shall be carried out at the manufacturer's premises on instrument accuracy (**11.11.1**) and on the control system (**11.11.2**).

NOTE 1 The system used for carrying out the tests specified in **8.1.1** and **8.1.2** should take into account test procedures and personnel, the accuracy and suitability of test equipment and the environmental conditions for testing.

NOTE 2 By agreement between manufacturer and purchaser, the final works inspection and tests may be carried out in the presence of representatives of the purchaser. However, if a quality system as described in BS 5750-1:1987 is operated, the presence of the purchaser's representatives at the tests may not be necessary.

8.2 Commissioning

8.2.1 If the results of tests on instrument accuracy and on the control system conform to **11.11.1** and **11.11.2**, and where required by the purchaser, commissioning shall be carried out by the manufacturer at his premises and/or on site after installation of the autoclave.

8.2.2 Commissioning tests shall comprise:

a) inspections and tests on safety devices (see this section and section **2** of BS 2646-5:1993).

b) tests on instrument accuracy and the control system (see **11.11.1** and **11.11.2**).

c) autoclave performance tests (see section **12**).

Section 9. Safety and safety devices

9.1 General

NOTE 1 This section specifies the provision and design of safety devices and attachments concerned with the pressure vessel(s) of the autoclave, and also electrical safety and surface temperatures.

Unless otherwise stated, conformity to the requirements of **9.2** to **9.7** shall be checked by visual inspection and/or calculation and, where practicable, by direct measurement.

NOTE 2 The methods of test given in BS 2646-5:1993, by which conformity is measured in the individual clauses or subclauses, are indicated in *italic type*.

9.2 Provision of pressure vessel safety devices

9.2.1 Safety devices for autoclaves of type 1 (see **1.4**)

Chambers of type 1 autoclaves shall be fitted with the following safety devices:

a) a safety valve conforming to **9.4.1**;

b) a steam pressure gauge conforming to **11.4**;

c) means for attaching a test pressure gauge;

d) a reducing valve or other suitable automatic device which prevents the safe working pressure being exceeded;

e) a manually operated isolation valve fitted upstream of the reducing valve or device.

9.2.2 Safety devices for autoclaves of type 2 (see **1.4**)

9.2.2.1 Chambers of type 2 autoclaves shall be fitted with the following safety devices:

a) a reducing valve or other suitable automatic device which prevents the safe working pressure being exceeded;

b) a manually operated isolation valve fitted between the generator and the chamber upstream of the reducing valve or device;

c) a safety valve conforming to **9.4.1**;

d) a steam pressure gauge conforming to **11.4**;

e) means for attaching a test pressure gauge.

9.2.2.2 Steam generators of type 2 autoclaves shall be fitted with the following safety devices:

a) a safety valve conforming to **9.4.1**;

b) a steam pressure gauge conforming to **11.4**;

c) a water level-indicating device;

NOTE Water level gauges conforming to BS 759-1:1984 are suitable for this purpose.

d) a low-water level alarm conforming to BS 759-1:1984;

e) a device which disconnects the electricity supply to the elements when a set water level is reached. The device shall be resettable manually but not automatically to reconnect the electricity supply. The device shall not be a fusible link. If an over-temperature thermostat is used for this purpose, it shall not be part of the process control system;

f) means for attaching a test pressure gauge.

9.2.3 Safety devices for autoclaves of type 3

Chamber and steam generator assemblies of type 3 autoclaves shall be fitted with the following safety devices:

a) a safety valve conforming to **9.4.1**;

b) a steam pressure gauge conforming to **11.4**, connected to the chamber;

c) a water level-indicating device connected to the steam generator;

NOTE Water level gauges complying with BS 759-1:1984 are suitable for this purpose.

d) a low-water level alarm conforming to BS 759-1:1984;

e) a device which disconnects the electricity supply to the elements when a set water level is reached. The device shall be resettable manually but not automatically to reconnect the electricity supply. The device shall not be a fusible link. If an over-temperature thermostat is used for this purpose, it shall not be part of the process control system;

f) means for attaching a test pressure gauge.

9.2.4 Safety devices for autoclaves of type 4 (see **1.4**)

Chambers of type 4 autoclaves shall be fitted with the following safety devices:

a) a safety valve conforming to **9.4.1**;

b) a steam pressure gauge conforming to **11.4**;

c) a water level-indicating device;

NOTE Water level gauges conforming to BS 759-1:1984 are suitable for this purpose.

d) a low-water level alarm conforming to BS 759-1:1984;

e) a device which disconnects the electricity supply to the elements when a set water level is reached. The device shall be resettable manually but not automatically to reconnect the electricity supply. The device shall not be a fusible link. If an over-temperature thermostat is used for this purpose, it shall not be part of the process control system;

f) means for attaching a test pressure gauge.

9.3 Attachments for autoclaves heated by electrical immersion heaters

9.3.1 Autoclaves heated by electrical immersion heaters shall be fitted with a means of draining the chamber and/or generator.

NOTE This may be either a drain valve or cock, as specified in BS 759-1:1984, or a plug.

9.3.2 Fusible plugs, as defined in BS 759-1:1984, shall not be fitted.

9.4 Safety devices for pressure vessels

9.4.1 Safety valves

9.4.1.1 *General*

Safety valves shall be of the enclosed type fitted with discharge piping and connected directly to the pressure vessel by means of the shortest possible length of pipe and used solely for this purpose, without any intervening cock or valve. The internal diameter of this pipe shall not be smaller than the nominal bore of the valve.

9.4.1.2 *Safety valve design and construction*

The safety valve shall conform to the following requirements.

a) It shall be designed and constructed to conform to BS 6759-1:1984, except that the requirements for minimum bore size of the body seat shall not apply. However, the bore size shall be sufficiently large to ensure conformity to item b) of this clause.

b) It shall be so locked as to prevent the pressure in the chamber and/or steam generator exceeding 110 % of its maximum permissible working pressure.

c) The set pressure of the safety valve shall be not more than the maximum permissible working pressure of the chamber and/or steam generator and not less than a value above the operating pressure which prevents unnecessary blowing off of the valve.

*Conformity shall be checked by the test given in **2.1** of BS 2646-5:1993.*

d) It shall shut down at a pressure not less than the operating pressure; blowdown shall be a maximum of 0.3 bar.

e) It shall be mounted in accordance with Annex B of BS 6759-1:1984.

9.4.2 Door interlocking safety devices

9.4.2.1 *Autoclaves with quick-opening doors*

For autoclaves with quick-opening doors, means shall be provided whereby:

a) the chamber cannot be subjected to steam pressure unless the door is completely closed and sealed, with the securing mechanism fully engaged;

*Conformity shall be checked by the test given in **2.2.1** of BS 2646-5:1993.*

b) it is not possible to release the door securing mechanism until the chamber has been vented to atmosphere and until the chamber pressure has fallen below 0.2 bar;

c) the door cannot open violently because of the residual pressure remaining in the autoclave;

NOTE A safety device, which is released independently of, and after, the door securing mechanism has been released and the seal between the door and vessel is broken, is an example of a suitable device.

d) power-operated doors shall remain in position should the autoclave become isolated from any of the services powering the door movement, whether or not the autoclave cycle is in operation;

*Conformity shall be checked by the test given in **2.2.2** and **2.2.3** of BS 2646-5:1993.*

e) power-operated doors of autoclaves shall be equipped with devices which reverse the door's motion when it is obstructed during closing, except where the door cannot impose a force greater than 150 N. Any safety edge shall be operated by a force of not more than 15 N;

f) doors shall be so designed and constructed that no danger to personnel within the plant room arises from their movement; where this cannot be achieved in the design, and traps are created by association with other moving or fixed parts, guarding conforming to BS 5304:1988 shall be provided;

g) if the capacity of the autoclave chamber exceeds 0.6 m^3, a device shall be fitted so that the door can be secured open by a lock, the key of which can be removed and kept by any person who has to enter the chamber;

h) door interlock switches shall be positively operated;

Conformity shall be checked by the test given in **2.2.3** *of BS 2646-5:1993.*

i) there shall be a visual indication when the door is closed and secured;

j) provision shall be made to permit any door to be closed without locking so that it may be opened subsequently without a test or operating cycle having been initiated.

These safety provisions shall apply to both doors of a double door autoclave.

9.4.2.2 ***Autoclaves with multi-bolted doors***

For multi-bolted doors, means shall be provided whereby:

a) the chamber cannot be subjected to steam pressure unless the door is in the closed position and all bolts are secured;

Conformity shall be checked by the test given in ***2.2.1*** *of BS 2646-5:1993.*

b) the seal between the door and chamber is broken and the chamber is vented to atmosphere before all the bolts are released. The means for achieving this shall affect one or more of the bolts, preferably opposite the door hinge, so that the door will remain captive until the seal is broken. During venting, the door opening shall be restricted to not more than 5 mm;

NOTE 1 An example of a suitable device is a safety catch which has to be released independently of the door being unbolted and which cannot be released until the door has been "cracked" open and the seal broken.

NOTE 2 Door interlocks should comply with BS 5304:1988.

c) there shall be a visual indication when the door is closed and secured;

d) door interlock switches shall be positively operated.

9.5 Safety devices to protect the operator when unloading the autoclave

9.5.1 Door securing mechanisms

9.5.1.1 The autoclave shall have a device to prevent the release of the door securing mechanism until the contents of the chamber have cooled to less than the boiling point, at atmospheric pressure, of any liquid present in the chamber.

9.5.1.2 In addition to the requirement given in **9.5.1.1**, for autoclaves classified as suitable for liquids sterilization or make-safe (see **1.4.3**), except in the case of autoclaves designed solely for processing plastics loads for make-safe, a thermal door interlock shall be provided to prevent release of the door securing mechanism until the load reaches a set temperature.

NOTE This interlock may be omitted on autoclaves designed solely for processing plastics loads for make-safe.

9.5.1.3 There shall be a visual warning to the operator in the unloading position that the mechanisms described in **9.5.1.1** and **9.5.1.2** are released.

Conformity shall be checked by the test given in ***2.2.4*** *of BS 2646-5:1993.*

9.5.2 Chamber seal

Means shall be provided to prevent the uncontrolled discharge of the chamber contents, e.g. steam, vapour or fluid, from the chamber into the laboratory or plant room.

Conformity shall be checked by the test given in ***2.3*** *of BS 2646-5:1993.*

9.5.3 Microprocessor control

Where the door safety mechanisms are microprocessor based, the design of the software shall conform to *Programmable electronic systems in safety related applications* [4], published by HMSO.

Conformity shall be checked by manufacturer's certification.

9.5.4 Double-ended autoclaves

For a double-ended autoclave, the safety mechanisms detailed in **9.5.1** to **9.5.3** shall operate on both doors. In addition, the following shall apply.

a) When the loading door is closed and secured it shall not be possible to open the unloading door until the autoclave has completed a successful operating cycle.

b) After a fault it shall only be possible to open the loading door.

c) It shall not be possible to open or close the door at one end of the autoclave using controls fitted at the other end.

d) It shall not be possible for both doors to be in the released position at the same time.

e) Visual displays at both ends of the autoclave shall indicate when each door is closed and secured.

f) It shall not be possible to release the loading door until the unloading door has been opened and subsequently closed and locked.

9.6 Electrical safety requirements

9.6.1 The autoclave shall conform to the relevant requirements of BS 3456-101:1987.

NOTE Information about BS 3456-101 is given in the foreword.

9.6.2 For the purposes of clause **6** of BS 3456-101:1987, the autoclave shall be classified as an ordinary appliance class I.

9.6.3 An autoclave of type 2, 3, or 4 shall conform to **15.3** of BS 3456-101:1987 relating to appliances subject to spillage of liquid in normal use.

9.6.4 The autoclave shall conform to **18.2** of BS 3456-101:1987 relating to endurance and, for the purposes of Table 6 of that standard, shall be deemed to be an "other appliance".

9.6.5 The autoclave shall be fitted with a device which separates the autoclave from the mains supply on all poles simultaneously. The device shall be prominently located and accessible to the operator in the event of an emergency without the need to move from the loading area.

9.7 Temperature of autoclave surfaces

9.7.1 Surface temperature increase

The temperature increase of external surfaces, handles and controls shall not exceed the values given in Table 7.

9.7.2 Temperature measurements

9.7.2.1 Temperature rises shall be determined by means of fine wire thermocouples so chosen and positioned that they have the minimum effect on the temperature of the part under test.

9.7.2.2 In determining the temperature rises of handles, knobs, controls, etc., consideration shall be given to all parts that are gripped in normal use and, if of insulating material, to parts in contact with hot metal.

9.7.2.3 Temperatures shall be monitored continuously throughout a sterilizing "hold-period" of 30 min, the autoclave having been set to operate at the temperature corresponding to the maximum working pressure.

Table 7 — Maximum surface temperature increases

Surfaces accessible to the operator	Material		
	Metal	Vitreous and ceramic	Moulded plastics and rubber
	°C	°C	°C
a) Handles, grips (see note 1)	30	40	50
b) Controls (see note 2)	35	45	60
c) Surfaces (see note 3)	85	100	105

NOTE 1 These include door handles, knobs, etc. intended to be held by hand during use of the autoclave and where the handle is attached to the autoclave.

NOTE 2 These include knobs, controls, switches, keys, etc. which, when operated, are touched for short periods and not gripped.

NOTE 3 These include surfaces, where contact by the operator would be exceptional but could happen accidentally.

Section 10. Load supporting and handling equipment

10.1 Internal shelf framework system

If the autoclave is supplied with a system for transferring the load into and out of the chamber, the following shall apply.

a) The force required, either directly or by the application of a mechanical device supplied as part of the autoclave, to remove the load shall not exceed 250 N.

b) The shelf-framework shall either:

1) be restrained in the chamber by a mechanism which may be released only when the transfer system is in place; or

2) remain stable when withdrawn to a distance equal to two-thirds of the chamber length and be restrained by a mechanism which prevents it being withdrawn further.

c) If the framework is fitted with wheels, these shall not come into contact with the chamber base.

d) The shelf-framework shall be constructed from corrosion-resistant materials.

e) The shelf-framework shall allow condensate to drain away and steam to circulate to all parts of the load.

10.2 Loading trolley

If a loading trolley is supplied as part of the system for use outside the autoclave chamber, it shall remain stable when supporting the system with its maximum design load and when a 250 N lateral force is applied in any direction to the highest point of the load, the trolley wheels being locked or blocked.

Section 11. Instrumentation and control

11.1 General

11.1.1 Pressure and temperature gauges shall conform to BS 1780:1985 or to BS 5235:1975, as appropriate.

11.1.2 Pressure and temperature indicators shall conform to the requirements of BS 5164:1975 where such requirements do not conflict with the requirements of this Part of BS 2646, otherwise the requirements of this Part of BS 2646 shall apply.

NOTE The gauges and indicators should be located so as to be clearly visible to the operator when operating the autoclave controls.

11.1.3 Instrumentation and control systems shall be tested in accordance with **11.11**.

11.1.4 Instruments fitted to the autoclave shall be capable of being checked and recalibrated without removal from their case or panel.

11.2 Gauge dials

Gauge dials shall be 100 mm in nominal diameter. Scales and indexes shall be selected in accordance with recommendations of BS 3693:1992 for a reading distance of 1 000 mm and a resolution factor of 0.5.

11.3 Illuminated digital displays

Illuminated digital displays, other than those on cathode ray tubes or vacuum fluorescent modules, shall have characters not less than 10 mm in height.

11.4 Pressure gauges

11.4.1 General

A pressure gauge shall be fitted to each pressure vessel.

Unless an autoclave is designed to operate under vacuum, a combined pressure and vacuum gauge shall not be fitted.

NOTE For an autoclave designed to operate under vacuum, a combined pressure and vacuum gauge is a permitted alternative.

The pressure gauge shall be an industrial gauge of the Bourdon type and conform to BS 1780:1985.

11.4.2 Pressure gauge scale

11.4.2.1 *Scale range*

The total scale range shall be chosen from BS 1780:1985 such that the maximum permissible working pressure is between 40 % and 75 % of the scale range. Each dial shall be marked in purple with the maximum permissible working pressure of the vessel.

NOTE Attention is drawn to the requirements regarding the marking of pressure gauges in section 32 (2) c) of the Factories Act 1961 [5] and to any subsequent legislation.

11.4.2.2 *Scale markings*

The scale shall be marked only in bar units and indicate 0 bar when the gauge is open to the atmosphere.

11.5 Pressure indicators

11.5.1 Electrical measuring pressure transducers, if fitted in addition to the pressure gauge specified in **11.4.1**, shall conform to BS 6253-1:1982.

11.5.2 The combined error of the transducer indicator system shall not exceed 1.5 % of the autoclave design pressure when the transducer is subjected to temperatures up to the design temperature of the autoclave.

11.6 Temperature indicators

11.6.1 General

A dial-type temperature gauge or an electrical indicating thermometer shall be fitted to indicate the temperature of the chamber or chamber drain/vent. The indicator shall conform either to **11.6.2** or to **11.6.3**, as appropriate. Sensors shall be sited in accordance with **11.6.4**.

11.6.2 Dial-type temperature gauge

11.6.2.1 *General*

The dial-type temperature gauge shall be one of the following:

a) a liquid-filled or gas-filled thermometer conforming to BS 5235:1975;

b) a bi-metallic mechanical thermometer.

11.6.2.2 *Temperature gauge scales*

Temperature gauge scales shall conform to the following.

a) The scale shall be marked only in °C.

b) Maximum permissible errors under reference conditions shall not exceed ± 1 % of the difference between the minimum and maximum values of the scale range.

NOTE The scale range should be + 40 °C to + 160 °C.

11.6.3 Electrical indicating thermometer

11.6.3.1 *Resolution and accuracy*

The resolution and accuracy of the electrical indicating thermometers shall conform to the following.

a) The resolution of the digital readouts shall be 0.1 °C.

b) The maximum permissible error under the reference conditions specified in BS 5235:1975 shall be ± 1 °C over the scale range.

11.6.3.2 ***Sensing element***

The sensing element for the electrical indicating instrument shall be either:

a) a thermocouple conforming to BS 4937-5:1974; or

b) a platinum resistance element conforming to BS 1904:1984. The tolerance class shall be chosen to achieve the accuracy specified in item b) of **11.6.3.1**.

11.6.4 Siting of the temperature sensing element

11.6.4.1 For types 1, 2 and 3 autoclaves (see **1.4**), the sensing element of the temperature indicator shall be sited in the chamber exhaust or vent line.

11.6.4.2 For type 4 autoclaves (see **1.4**), the sensing elements shall be sited either:

a) in the chamber below the bottom shelf and above the hot water level; or

b) in the chamber vent pipe not more than 50 mm from the connection of the vent pipe to the chamber.

11.6.4.3 The autoclave chamber shall be fitted with a readily accessible female entry, with an R_p ¾ thread conforming to BS 21:1985, to accept a sealing gland for thermocouple leads. The entry shall be fitted with a blanking plug of compatible thread sealed with suitable sealing tape when not in use.

11.7 Temperature recorders

If fitted, temperature recorders shall conform to BS 5164:1975.

11.8 Controller settings

It shall not be possible for the operator to alter or adjust controller settings during an operating cycle.

11.9 Microprocessor control systems

If a microprocessor control is used the following shall apply.

a) It shall be mounted in a protective case.

NOTE 1 If necessary to maintain a constant internal environment, the case should be ventilated by means of a fan via a coarse filter.

b) It shall be protected from fault conditions caused by interference or surge voltages generated within the machine or introduced into the machine via the supply cables.

c) It shall be provided with means for a service engineer to monitor the voltage or current present at each output and the condition of each input.

d) It shall be provided with means of electrically isolating digital inputs from the processor, e.g. opto-isolators, and with means for a service engineer to monitor the condition of each input and the adjustment or performance of each sensor.

NOTE 2 A "Manual" mode of the controller, giving visual access to input states would meet the requirements of items c) and d).

e) It shall not be possible to change process parameters without use of codes or keys, and the control shall not require the use of additional external equipment. If the variable process parameters are affected by internal automatic controller action, or by remote control functions, they shall be protected such that their value is not changed beyond such limits set by the manufacturer or service engineer, as will prevent the process integrity or safety being prejudiced. Where such a variable is adjustable by more than one control, any value displayed shall be the value currently active, or shall have a clear indication that this is not the current value. Documentation shall explain the effects and sources of such adjustments.

f) It shall be provided, where applicable, with batteries for maintaining the program data memory. Such batteries shall either have a life of not less than 5 years or shall be replaceable using normal hand tools without loss of data unless such loss of data can be easily rectified.

NOTE Where the rated life exceeds 5 years, loss of data is permissible if the data can be replaced by a simple procedure which is described in the documentation. In this case the recommended replacement intervals should be specified.

Soldered or crimped connections shall not be used.

The loss of battery power shall not cause a fault condition which could affect the process or cause a safety hazard, and shall be evident to the operator.

g) It shall be fail safe.

h) It shall contain all the components necessary for its function (excluding sensors and their controller).

i) It shall be provided with a watchdog system for the safe operation of the process (see paragraph 199 of *Programmable electronic systems in safety related applications, Part 2* [4]). The processor shall monitor all sensors, at not greater than 2 s intervals.

j) It shall be provided with an indication system for displaying faults and errors. The display shall be easily understood and shall identify the fault error.

k) Access shall be restricted by a code and/or mechanically to prevent unauthorized alterations to programs.

l) The complete program and software for machines controlled by a microprocessor shall be lodged with an independent body so that, in the event of the manufacturer ceasing to trade or failing to attend to software-related problems, or of defect or hazard investigations, the purchaser has access to the program and software. The manufacturer shall supply, in writing to the purchaser, the identity of the independent body and the means of access to it.

11.10 Radio-frequency (RF) interference

11.10.1 When the autoclave is undergoing any of the tests given in BS 2646-5:1993, the functioning of the automatic controller and the instrumentation shall, when tested in accordance with any of the methods given in BS 6667-3:1985, be unaffected by electromagnetic interference of severity level 3 as specified in BS 6667-3:1985.

11.10.2 When tested in accordance with BS 800:1988, any RF interference generated by the autoclave shall not exceed the limits specified in that standard.

11.11 Testing

NOTE The tests given in section **3** of BS 2646-5:1993 measure the accuracy of the autoclave pressure and temperature gauges, indicators and recorders against test instruments. They also confirm the ability of the control system to maintain steady state conditions in the chamber and to reproduce the operating cycle.

11.11.1 Tests on instrument accuracy

When tested in accordance with section **3** of BS 2646-5:1993:

a) the accuracy of the autoclave pressure gauges shall be as specified in clause **7** of BS 1780:1985;

b) the accuracy of the autoclave pressure transducers, if fitted, shall be as specified in **11.5.2**;

c) the accuracy of the autoclave temperature gauge, if fitted, shall be as specified in item b) of **11.6.2.2**;

d) the accuracy of the autoclave electrical indicating thermometer, if fitted, shall be as specified in item b) of **11.6.3.1**;

e) the accuracy of the autoclave temperature recorders, if fitted, shall be as specified in BS 5164:1975.

11.11.2 Steady state and operating cycle

When tested in accordance with Section **3** of BS 2646-5:1993, the autoclave shall conform to the following requirements.

a) The stages of the operating cycle shall be completed in the correct sequence.

b) Each stage time shall be within the prescribed limits.

c) The steady state shall be maintained for not less than 10 min.

d) During the steady state, the temperature recorded shall not vary by more than ± 0.5 °C.

Section 12. Performance requirements

NOTE The stages of testing which comprise the testing programme are described in Annex A, which draws attention to the limitations of the performance tests.

12.1 Performance test for autoclaves designed for a liquids sterilization process

When tested with the standard challenge load in accordance with BS 2646-5:1993, the following shall apply.

a) The stages of the operating cycle shall be completed in the correct sequence.

b) A fault shall not have been indicated.

c) The holding time shall be within the prescribed limits.

d) During the holding time, all thermocouples shall be at sterilizing temperature.

e) After the first 5 min of the holding time, the temperature difference between each test bottle shall be not more than 2 °C.

f) The maximum permitted loss from any one of the weighed bottles shall be 5 g and the mean loss shall be less than 2 g. In calculating the mean loss, any broken bottle shall be excluded.

g) Not more than one in 50 bottles shall have broken during the test.

h) None of the bottles containing test liquid, or in which temperature sensors were placed, shall have been broken during the test cycle.

i) The temperature of any water, or other liquid, present in the chamber at the end of the operating cycle shall be below 95 °C.

j) The temperature of all monitored bottles shall be not more than 80 °C and not less than 65 °C at the end of the operating cycle or when the door securing mechanism releases (see **9.5.1**.).

k) The duration of the operating cycle shall be not greater than that stated by the manufacturer for the standard challenge load.

12.2 Performance tests for autoclaves designed for make-safe

12.2.1 General

The make-safe process test shall be in accordance with test A, test B or test C described in **3.3** of BS 2646-5:1993. Test A shall be performed, except when the autoclave chamber size or configuration, or the processing technique is unsuitable for the standard challenge load, in which case, by agreement between the manufacturer and the purchaser, the alternative test B or test C shall be performed.

12.2.2 Make-safe process test

When tested with a challenge load in accordance with **3.3** of BS 2646-5:1993, the following shall apply.

a) The stages of the operating cycle shall be completed in the correct sequence.

b) A fault shall not have been indicated.

c) The equilibration time shall be not more than 10 min.

d) The holding time shall be within the prescribed limits.

e) During the holding time, all sensors shall indicate the prescribed sterilizing temperature.

f) The temperature of any water, or other liquid, present in the chamber at the end of the operating cycle shall be below 95 °C.

g) The temperature of liquid in the test bottle shall be not more than 80 °C at the end of the operating cycle or when the door securing mechanism releases (see **9.5.1**).

h) The duration of the operating cycle shall be not greater than that stated by the manufacturer for the standard challenge load (test A) or the manufacturer's challenge load (test B or test C).

12.3 Performance tests for autoclaves designed for equipment and glassware sterilization

12.3.1 General

The equipment and glassware sterilization test shall be in accordance with test A or test B described in **3.4** of BS 2646-5:1993. Test A shall be performed, except when the autoclave chamber size or configuration, or the processing technique is unsuitable for the standard challenge load, in which case, by agreement between the manufacturer and the purchaser, the alternative test B shall be performed.

12.3.2 Equipment and glassware sterilization test

When tested with a challenge load in accordance with **3.4** of BS 2646-5:1993, the following shall apply.

a) The stages of the operating cycle shall be completed in the correct sequence.

b) A fault shall not have been indicated.

c) The holding time shall be within the prescribed limits.

d) During the holding time, all sensors shall indicate the prescribed sterilizing temperature.

e) The temperature of any water, or other liquid, present in the chamber at the end of the operating cycle shall be below 95 °C.

f) There shall be no visible condensate in the test bottles or containers.

g) The duration of the operating cycle shall be not greater than that stated by the manufacturer for the standard challenge load (test A) or the manufacturer's challenge load (test B).

Section 13. Marking

13.1 General

The autoclave shall be provided with a permanent plate (or plates). The plate(s) shall be affixed on the outside of the autoclave framework and shall be clearly visible without the need to remove any panel work.

The plate(s) shall be permanently and legibly inscribed with the information given in **13.2** and **13.3** relating to the autoclave and each pressure vessel.

13.2 Information relating to the autoclave

The following information relating to the autoclave shall be inscribed on the plate:

a) the number of this British Standard, i.e BS 2646-1:1993[4)];

b) the name and/or trademark of the autoclave manufacturer;

c) the manufacturer's cipher or serial number identifying the autoclave and its pressure vessel(s);

d) the date of manufacture of the autoclave;

e) the rated supply voltage (in V);

f) the symbol for the nature of the electrical supply, number of phases and type of current;

g) the supply frequency (in Hz);

h) the power input (in kW).

13.3 Information relating to each pressure vessel

The following information relating to each pressure vessel shall be inscribed on the plate:

a) the name and/or trademark of the vessel manufacturer;

b) the manufacturer's cipher or serial number identifying the vessel;

c) the date of manufacture of the vessel;

d) the design pressure;

e) the design temperature;

f) the hydraulic test pressure;

g) the identifying mark of the Inspecting Authority;

h) the maximum permissible working pressure.

[4)] Marking BS 2646-1:1993 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is solely the claimant's responsibility. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

Annex A (informative) Description of the testing programme

A.1 Testing to the requirements of a quality system

For autoclaves that conform to this Part of BS 2646, as a minimum, inspection, checking and testing of the pressure vessel (see **7.1**) and of the safety devices (see **9.1**) should be carried out at the manufacturer's premises.

A.2 Testing instruments and controls

By agreement, additional testing may be carried out on the completed autoclave at the manufacturer's premises (see **11.11.1** and **11.11.2**) which will confirm the accuracy of instruments and controls during an operating cycle.

A.3 Performance tests

The performance tests (see section **12**) confirm the autoclave's ability to reproduce operating cycles correctly using challenge loads for each autoclaving process chosen (see **1.6.3**) from those processes listed in **1.4.3**.

However, it is essential to note that laboratory autoclaves are used to process a variety of items and solutions in a variety of containers within each of the processes specified (see **1.3.12**, **1.3.13** and **1.3.14**).

It should not be expected that autoclave controller settings which achieve the results with the standard challenge loads will necessarily provide effective results when the autoclave is put into general use. For example, if larger volumes of liquids are included or loads consist mainly or wholly of disposable polystyrene items, heat penetration times and cooling times will be different.

Allowance for this has been made in BS 2646-3[1)] which includes guidance on validation (see **1.3.29**) and performing validation tests, in addition to advice on the choice of process and controller settings.

Confirmation of satisfactory validation and also the reproducibility of the autoclave controller are achieved by regular in-use tests, which are also described in BS 2646-3.

A.4 Commissioning (see **1.3.27**)

A.4.1 Commissioning tests comprise checks on safety devices (see **8.1.1**), tests on the accuracy of instruments and of controls (see **11.11.1** and **11.11.2**) under operating conditions and also performance tests (see section **12**).

Commissioning on site will also confirm that the services are adequate and have been correctly connected.

A.4.2 Only if the autoclave conforms to the requirements of the tests referred to in **A.1** and **A.2** are performance tests carried out.

A.4.3 Commissioning tests are carried out either at the manufacturer's premises and/or on site after installation.

NOTE For autoclaves of type 1 (see **1.4.1**), an adequate steam supply is necessary (see clause **6** of BS 2646-2:1990). It is particularly important that commissioning of this type is carried out after installation.

A.5 Validation (see **1.3.29**)

A.5.1 Validation is the responsibility of the purchaser. By agreement, validation may be carried out by the manufacturer.

A.5.2 Validation is carried out after installation and commissioning. Validation procedures will be described in BS 2646-3.

A.5.3 Validation tests the ability of the autoclave effectively to perform each autoclaving process when loaded with user-defined loads.

A.6 In-use tests

A.6.1 In-use tests are performed by the user at intervals after installation, commissioning and validation of the autoclave. In-use tests will be described in BS 2646-3.

A.6.2 In-use tests confirm that the autoclave is effectively performing each process on loads for which it has been validated.

Annex B (informative) Optional requirements to be agreed between the purchaser and the manufacturer

B.1 Door(s) and loading arrangements

With regard to door(s) and loading arrangements, the following should be agreed between the purchaser and the manufacturer:

a) whether the autoclave is front loading or top loading (see **3.1**);

b) whether the chamber is single or double ended (see **3.2**);

c) whether doors are multi-bolted or quick-opening (see **5.7.2**);

d) whether the load support incorporates a fixed shelf-framework or a load transfer system (see BS 2646-3);

e) whether a loading trolley is required (see BS 2646-3);

f) the approximate maximum mass which the load support will carry.

B.2 Autoclave instruments and their type

With regard to autoclave instruments and their type, the following should be agreed between the purchaser and the manufacturer:

a) whether the pressure indicator(s) is digital (see **11.5**);

b) whether the temperature indicator(s) is:

1) a dial-type temperature gauge; or

2) an electrical indicating thermometer (see **11.6**).

c) whether a temperature recorder is required (see **11.7**) and, if so, whether with a strip-chart or a circular chart, including details of chart width, chart speed, number of channels and the range of each channel;

d) any other instruments which may be required.

B.3 Autoclave use

With regard to autoclave use, the following should be agreed between the purchaser and the manufacturer:

a) whether fixed operating cycles are required (see BS 2646-3);

b) operating cycle conditions required (see BS 2646-3);

c) whether a flexible probe is required for load temperature monitoring, and details of its function (see BS 2646-3);

d) whether keys or codes are required to restrict access to controls;

e) details of the types of loads intended for each process, including loading containers and discard containers (see BS 2646-3);

f) the usable chamber space (see **1.3.20**).

B.4 Services

Details of services to the autoclave and associated areas (see clause **6** of BS 2646-2:1990) should be agreed between the purchaser and the manufacturer.

B.5 Autoclave testing

With regard to autoclave testing, the following should be agreed between the purchaser and the manufacturer.

a) *Commissioning* (see **1.3.27**): whether commissioning tests are to be carried out on site in addition to the manufacturer's premises (see **A.4**).

b) *Performance tests* (see **1.3.28**): for make-safe and equipment and glassware sterilization processes (see **1.3.13** and **1.3.14**), whether alternative performance test B or test C is required (see **1.6.2.4**).

c) *Validation* (see **1.3.29**): whether validation tests are to be carried out by the manufacturer and details of typical loads for each process (see **A.5**).

B.6 Documentation

The required number of copies of the instruction manual (see **4.1** of BS 2646-4:1991) should be agreed between the purchaser and the manufacturer.

blank

List of references (see 1.2)

Normative references

BSI standards publications
BRITISH STANDARDS INSTITUTION, London

BS 21:1985, *Specification for pipe threads for tubes and fittings where pressure-tight joints are made on the threads (metric dimensions).*

BS 759, *Valves, gauges and other safety fittings for application to boilers and to piping installations for and in connection with boilers.*

BS 759-1:1984, *Specification for valves, mountings and fittings.*

BS 800:1988, *Specification for limits and methods of measurement of radio interference characteristics of household electrical appliances, portable tools and similar electrical apparatus.*

BS 853:1990, *Specification for calorifiers and storage vessels for central heating and hot water supply.*

BS 1306:1975, *Specification for copper and copper alloy pressure piping systems.*

BS 1400:1985, *Specification for copper alloy ingots and copper alloy and high conductivity copper castings.*

BS 1449, *Steel plate, sheet and strip.*

BS 1449-2:1983, *Specification for stainless and heat-resisting steel plate, sheet and strip.*

BS 1470:1987, *Specification for wrought aluminium and aluminium alloys for general engineering purposes: plate, sheet and strip.*

BS 1471:1972, *Specification for wrought aluminium and aluminium alloys for general engineering purposes — drawn tube.*

BS 1472:1972, *Specification for wrought aluminium and aluminium alloys for general engineering purposes — forging stock and forgings.*

BS 1473:1972, *Specification for wrought aluminium and aluminium alloys for general engineering purposes — rivet, bolt and screw stock.*

BS 1474:1987, *Specification for wrought aluminium and aluminium alloys for general engineering purposes: bars, extruded round tubes and sections.*

BS 1475:1972, *Specification for wrought aluminium and aluminium alloys for general engineering purposes — wire.*

BS 1501, *Steel for pressure purposes.*

BS 1501-1:1980, *Specification for carbon and carbon manganese steels: plates.*

BS 1501-3:1990, *Specification for corrosion- and heat-resisting steels: plates, sheet and strip.*

BS 1504:1976, *Specification for steel castings for pressure purposes.*

BS 1723, *Brazing.*

BS 1723-1:1986, *Specification for brazing.*

BS 1780:1985, *Specification for bourdon tube pressure and vacuum gauges.*

BS 1845:1984, *Specification for filler metals for brazing.*

BS 1904:1984, *Specification for industrial platinum resistance thermometer sensors.*

BS 2646, *Autoclaves for sterilization in laboratories.*

BS 2646-5:1993, *Methods of test for function and performance.*

BS 2870:1980, *Specification for rolled copper and copper alloys: sheet, strip and foil.*

BS 2875:1969, *Specification for copper and copper alloys. Plate.*

BS 3456, *Specification for safety of household and similar electrical appliances.*

BS 3456-101:1987, *General requirements.*

BS 3605:1973, *Specification for seamless and welded austenitic stainless steel pipes and tubes for pressure purposes.*

BS 3693:1992, *Recommendations for design of scales and indexes on analogue indicating instruments.*

BS 4206:1967, *Methods of testing fusion welds in copper and copper alloys.*

BS 4300, *Wrought aluminium and aluminium alloys for general engineering purposes (supplementary series).*

BS 4300-1:1967, *Aluminium alloy longitudinally welded tube.*

BS 4300-4:1973, *6463 Solid extruded bars and sections suitable for bright trim/reflector applications.*

BS 4300-5:1973, *2011 Free cutting bar and wire.*

BS 4300-10:1969, *5454 Drawn tube.*

BS 4300-11:1969, *5454 Forging stock and forgings.*

BS 4300-12:1969, *5454 Bars, extruded round tube and sections.*

BS 4300-13:1969, *5554 Welding wire.*

BS 4300-14:1973, *7020 Plate, sheet and strip.*

BS 4300-15:1973, *7020 Bar, extruded round tube and sections.*

BS 4300-16:1984, *Specification for sheet and strip in 8011 material.*

BS 4870, *Specification for approval testing of welding procedures.*

BS 4870-1:1981, *Fusion welding of steel.*

BS 4870-2:1982, *TIG or MIG welding of aluminium and its alloys.*

BS 4871, *Specification for approval testing of welders working to approved welding procedures.*

BS 4871-1:1982, *Fusion welding of steel.*

BS 4871-2:1982, *TIG or MIG welding of aluminium and its alloys.*

BS 4937, *International thermocouple reference tables.*

BS 4937-5:1974, *Copper/copper-nickel thermocouples. Type T.*

BS 5164:1975, *Specification for indirect-acting electrical indicating and recording instruments and their accessories.*

BS 5235:1975, *Specification for dial-type expansion thermometers.*

BS 5304:1988, *Code of practice for safety of machinery.*

BS 5500:1991, *Specification for unfired fusion welded pressure vessels.*

BS 5750, *Quality systems.*

BS 5750-1:1987, *Specification for design/development, production, installation and servicing.*

BS 6072:1981, *Method for magnetic particle flaw detection.*

BS 6253, *Electrical measuring transducers for converting a.c. electrical quantities into d.c. electrical quantities.*

BS 6253-1:1982, *Method for specifying general purpose transducers.*

BS 6443:1984, *Method for penetrant flaw detection.*

BS 6667, *Electromagnetic compatibility for industrial-process measurement and control equipment.*

BS 6667-3:1985, *Method of evaluating susceptibility to radiated electromagnetic energy.*

BS 6759, *Safety valves.*

BS 6759-1:1984, *Specification for safety valves for steam and hot water.*

Other references

[4] *Programmable electronic systems in safety related applications*, Parts 1 and 2. HMSO, 1987.

Informative references

BSI standards publications
BRITISH STANDARDS INSTITUTION, London

BS 1723, *Brazing*.
BS 1723-2:1986, *Guide to brazing*.
BS 2646, *Autoclaves for sterilization in laboratories*.
BS 2646-2:1990, *Guide to planning and installation*.
BS 2646-3, *Guide to safe use and operation*[5)].
BS 2646-4:1991, *Guide to maintenance*.
BS 3970, *Sterilizing and disinfecting equipment for medical products*.
BS 3970-1:1990, *Specification for general requirements*.
BS 3970-2:1991, *Specification for steam sterilizers for aqueous fluids in sealed rigid containers*.
BS 3970-3:1990, *Specification for steam sterilizers for wrapped goods and porous loads*.
BS 3970-4:1990, *Specification for transportable steam sterilizers for unwrapped instruments and utensils*.
BS 3970-5:1990, *Specification for low temperature steam disinfectors*.
BS 3970-6, *Specification for sterilizers using low temperature steam and formaldehyde*[5)].

Other references

[1] *Categorization of pathogens according to hazard and categories of containment*, 2nd edition. HMSO, 1990.
[2] *Safety in Health Service Laboratories — Safe working and the prevention of infection in clinical laboratories*. HMSO, 1991.
[3] HSE Guidance Note GS4 *Safety in pressure testing*. HMSO, 1976.
[5] GREAT BRITAIN. Factories Act 1961. London: HMSO.

[5)] In preparation.

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