BRITISH STANDARD

BS 2646-4: 1991

Autoclaves for sterilization in laboratories —

Part 4: Guide to maintenance

Confirmed December 2011

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Laboratory Apparatus Standards Policy Committee (LBC/-) to Technical Committee LBC/35, upon which the following bodies were represented:

Associated Offices Technical Committee
Association of British Health Care Industries
Association of British Sterilizer Manufacturers
Association of National Health Service Supplies Officers
British Dental Trade Association
British Surgical Trades Association
Central Sterilising Club
Department of Health
Health and Safety Executive
Infection Control Nurses Association
Institute of Hospital Engineering
Institute of Purchasing and Supply
Institute of Sterile Services Management
Joint Committee of Professional Nursing, Midwifery and Health Visiting Associations (England)
Medical Sterile Products Association
National Blood Transfusion Service
Public Health Laboratory Service
Regional Hospital Boards Engineers' Association
Royal College of Pathologists
Royal Pharmaceutical Society of Great Britain
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
Milk Marketing Board
Ministry of Agriculture, Fisheries and Food
Royal Association of British Dairy Farmers
Society of 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
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The following BSI references relate to the work on this standard:
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Contents

Foreword

This Part of BS 2646 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee. It provides guidance on a system for maintenance of laboratory autoclaves of the type specified in Part 1 of this standard.

Regular maintenance is essential for the continued efficiency and safety of laboratory autoclaves and ancillary equipment. A continuing programme of planned preventative maintenance throughout the life of the laboratory autoclave is recommended. The programme should allow for thorough inspection and overhaul at stipulated intervals and should include testing of instruments and control systems. The frequency of inspections will depend on the autoclave workload and the complexity of the controls. In some cases it will be necessary to undertake maintenance checks more frequently than the minimum intervals recommended in this Part of BS 2646. The manufacturer should always be consulted with regard to appropriate maintenance intervals.

Periodic examination of autoclaves. Under the provisions of The Pressure Systems and Transportable Gas Container Regulations 1989, the user of a laboratory autoclave is required to have a suitable written scheme, drawn up or certified by a competent person, for the periodic examination of specified parts of the pressure system. The Regulations also require the user to ensure that examinations are carried out by a competent person at regular intervals specified in the scheme and to keep adequate records of the most recent examination. These requirements will have come fully into force by 1 July 1994.

Many autoclaves are already examined under the provision of Sections 33 and 35 of the Factories Act 1961, and in order to provide an orderly transition from these requirements the intervals laid down in them should be taken as the basis of the new written scheme, i.e. 14 months for a steam boiler and 26 months for a steam receiver, except when there is evidence that longer or shorter intervals are more appropriate.

Attention is drawn to the fact that downtime of the autoclave can be reduced if the periodic examination of autoclaves coincides with work undertaken in accordance with the recommendations of this standard.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 4, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 2646 gives guidance on the factors that should be taken into account when devising a schedule for the maintenance of laboratory autoclaves of the types specified in BS 2646-1, i.e. autoclaves for the sterilization of materials and goods including those which may be contaminated with organisms categorized in Hazard Groups 1, 2 and 3 but not Hazard Group 4 (see note 1.)

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

NOTE 2 The periodic examination of autoclaves as required by legislation (see the foreword) is outside the scope of this standard.

NOTE 3 The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

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

2.1
responsible person

the person responsible for the operating policy of autoclaves within the laboratory

2.2
maintenance/service engineer

the person who performs maintenance/service work on the autoclave. This person may be employed by the laboratory, contracted to the laboratory or employed by the autoclave manufacturer. Maintenance/service engineers are skilled and have a sound knowledge of the general principles of autoclaves and autoclaving (see clauses **3** and **5**)

2.3
operator

the person trained to use the autoclave

3 Staff and training

All staff engaged in the maintenance of autoclaves should have sound knowledge of the general principles of sterilization and operation of autoclaves and be familiar with the type and models for which they are directly responsible. They should receive instructions on the basic microbiology of hygiene in order to appreciate potential hazards to personnel.

Although maintenance may be contracted out, there will always be a number of routine tasks which may be undertaken by local laboratory or maintenance staff who should receive formal training and their staff records should be endorsed accordingly.

It is recommended that training be provided for all concerned with the planned maintenance of the laboratory autoclave. A periodic review of training needs and status should be undertaken, for both contract and local maintenance staff.

4 Schedules and documentation

4.1 Instruction manual

A detailed instruction manual should be provided with the laboratory autoclave. The manual should include a specimen maintenance schedule covering at least the following items:

a) installation instructions;

b) safety features provided;

c) operation instructions;

d) fault-finding procedures;

e) maintenance schedule;

f) spare parts list;

g) autoclave pipework diagram;

h) autoclave electrical circuit diagram.

The manufacturer should be consulted if the information provided is unclear or incomplete.

4.2 Maintenance log

A maintenance log should be kept for every autoclave to record all work carried out on that autoclave, whether as part of a maintenance schedule or as a result of breakdown. The log should include records of any faults or abnormalities found and the remedial action taken. It should also record the signature of the maintenance/service engineer who carried out the work and the countersignature of the responsible person to indicate that the work has been satisfactorily completed and the machine reinstated.

4.3 Autoclave process record

A record should be kept of each operating cycle of the autoclave. The user(s) of the autoclave should be responsible for keeping this record.

4.4 Permit to work certificates

The use of permit to work certificates is strongly recommended. These certificates, signed by or on behalf of the responsible person, are given to the maintenance/service engineer prior to commencement of work to indicate that the laboratory autoclaves and ancillary equipment are safe to handle (i.e. free from infection and other hazards). (See also note 1 to clause **5**.)

5 Safety and performance

A permit to work certificate (see **4.4**) should be handed to the maintenance/service engineer before commencement of work. If this is not possible, it is essential that:

a) the engineer is informed of any hazard involved and fully instructed with regard to any necessary safety precautions; and

b) any relevant protective clothing is supplied and used.

NOTE 1 To satisfy the Health and Safety at Work etc. Act 1974 requirements for safe systems of working, it is necessary to ensure that maintenance/service engineers are made aware of any potential risk of infection from equipment they may be required to work on and of decontamination and/or protection precautions which they need to observe.

A contaminated laboratory autoclave should never be returned to the manufacturer for servicing or repair.

NOTE 2 BS 2646-3 will give guidance on the decontamination of equipment prior to servicing. Safety Information Bulletin No. 41, July 1988, published by the Department of Health and Social Security is also relevant.

After major overhaul or breakdown, recommissioning tests should be conducted to the satisfaction of the responsible person.

To avoid reduction in performance or safety levels only spare parts of the type recommended by the manufacturer should be used.

6 Maintenance schedules

NOTE 1 The recommendations given in this clause are the minimum routines for all types of autoclaves. Increased levels of maintenance may be required (see the foreword).

NOTE 2 Autoclave reliability can be improved by regular attention to the housekeeping aspects of autoclave use and routine attention to cycle control indications and instrument readings (guidance on these points will be given in BS 2646-3).

6.1 General

Any defect noticed during use, maintenance or repair should be reported and recorded in the maintenance log.

6.2 Minimum daily maintenance schedule

The following checks and activities should be carried out daily by the operator.

a) Check that steam pressure from the supply is correct. (This is applicable to types I, II and III as defined in clause **3** of BS 2646-1:1988 only.)

b) Clean chamber internally as recommended by the manufacturer. All internal fittings to the chamber such as brackets, shelves, etc. should be cleaned at this time.

c) Clean drain filter, if fitted.

d) Clean door seal with a damp cloth and examine to ensure that it is in good condition with no cuts or abrasions.

e) Inspect chart recordings for unusual traces and report any abnormalities to the responsible person.

f) Check visually for steam and water leaks.

6.3 Minimum weekly maintenance schedule

The following checks should be made weekly by the responsible person.

a) Check operation of indicator lamps.

b) During an operating cycle check correlation of temperature gauge against pressure gauge and inspect chart recordings of cycle for abnormalities.

The results of these checks should be reported and recorded in the maintenance log.

6.4 Minimum quarterly maintenance schedule

The following checks should be made every 3 months by a maintenance/service engineer.

a) Check all manual valve spindles, open and close all valves, clean, lubricate and repack as required.

b) Inspect all joints in the piping and visually inspect the chamber for any signs of corrosion or wear.

c) Clean water and steam line main strainers, if fitted.

d) Inspect, and tighten if necessary, all electrical heater terminal points.

e) Clean out pipework from chamber drain, clean out steam traps, replace elements and seat of steam trap as required.

f) Check that main drain to waste is clear and operating.

g) Clean and replace parts as required on the steam pressure reducing valve when fitted.

h) Check that safety valves and ancillary pipework are not blocked.

i) Check control instrumentation, including recorders. The instruments may require recalibration or replacement.

j) Check for correct functioning of door interlocks.

k) Report any abnormalities and resulting correcting procedures and record in the maintenance log.

6.5 Minimum annual maintenance schedule and inspection

The following checks and activities should be undertaken annually by a maintenance/service engineer.

a) Check the service history for recurring faults and ensure that correct action has been taken.

b) Remove any scale from the chamber (and the generator on types II and III as defined in clause **3** of BS 2646-1:1988) by a method approved by the manufacturer.

c) Inspect and remove any scale from water level control and indicator systems (types II, III and IV as defined in clause **3** of BS 2646-1:1988).

d) Check the condition and operation of pressure gauge(s).

e) Check the condition and operation of temperature indicator(s).

f) Test the operation of safety devices, including safety valve(s) and door interlocking system, under operating conditions.

g) During a cycle, with the chamber empty, check all control functions, including correlation of pressure and temperature gauges against known references.

h) Test all functions of the autoclave under working conditions to the satisfaction of the responsible person.

i) Carry out thermometric tests of typical laboratory loads as during original commissioning and validation.

j) Prepare a comprehensive report of the annual inspection and make reference to it in the maintenance log.

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Publication(s) referred to

BS 2646, *Autoclaves for sterilization in laboratories.*

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

BS 2646-3, *Guide to safe use*[1)].

"Categorization of dangerous pathogens according to hazard and categories of containment" HMSO 2nd Edition 1990.

Safety Information Bulletin No. 41, 1988[2)].

[1)] In preparation.

[2)] Published by the Department of Health and Social Security.

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W4 4AL