

**BS 2646-3:2023**



**BSI Standards Publication**

# **Autoclaves for sterilization in laboratories**

Part 3: Safe use and operation – Code of practice

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# Contents

|                                                                    | Page       |
|--------------------------------------------------------------------|------------|
| <b>Foreword</b>                                                    | <b>III</b> |
| 0 Introduction                                                     | 1          |
| 1 Scope                                                            | 1          |
| 2 Normative references                                             | 1          |
| 3 Terms and definitions                                            | 2          |
| 4 Operation of autoclaves                                          | 2          |
| 4.1 Training and instruction of operators                          | 2          |
| 4.2 Operating instructions                                         | 2          |
| 4.3 Autoclave process record                                       | 3          |
| 4.4 Plant history file                                             | 3          |
| 5 Maintenance                                                      | 3          |
| 5.1 Maintenance schedule                                           | 3          |
| 5.2 Permit to work certificates                                    | 4          |
| 5.3 Risk of infection during make-safe                             | 4          |
| 5.4 Statutory pressure vessel inspection                           | 5          |
| 6 Protective clothing                                              | 5          |
| 6.1 Laboratory clothing                                            | 5          |
| 6.2 Additional protection                                          | 5          |
| 7 Loading and unloading                                            | 5          |
| 7.1 Loading                                                        | 5          |
| 7.2 Unloading the autoclave                                        | 6          |
| 7.3 Operator protection, loading and unloading                     | 6          |
| 8 Discard containers                                               | 6          |
| 9 Potential hazards in the use of laboratory autoclaves            | 7          |
| 9.1 Spillages                                                      | 7          |
| 9.2 Temperature                                                    | 7          |
| 9.3 Pressure vessel hazard                                         | 7          |
| 9.4 Unloading hazard                                               | 8          |
| 9.5 Failure of a make-safe process                                 | 8          |
| <i>Table 1 — Typical operating cycle conditions</i>                | 9          |
| 10 Operating cycles                                                | 9          |
| 10.1 Functional design                                             | 10         |
| 10.2 Operating cycles for liquids sterilization                    | 10         |
| 10.3 Operating cycles for make-safe                                | 11         |
| 10.4 Operating cycles for equipment and glassware sterilization    | 12         |
| 10.5 Operating cycles for disinfecting fabrics and textiles        | 12         |
| 11 Autoclave performance                                           | 13         |
| 11.1 Installation qualification                                    | 13         |
| 11.2 Operational qualification                                     | 13         |
| 11.3 Performance qualification                                     | 13         |
| 12 Performance tests                                               | 14         |
| 12.1 Instrument accuracy, calibration and operating cycle controls | 14         |
| 12.2 Liquids sterilization                                         | 15         |
| 12.3 Make-safe: mixed waste                                        | 17         |
| 12.4 Equipment and glassware sterilization                         | 20         |
| 12.5 Fabrics and textiles disinfection                             | 21         |
| 12.6 Materials testing and processing                              | 23         |
| 12.7 Hazard group 4 waste                                          | 23         |

|                |                                           |           |
|----------------|-------------------------------------------|-----------|
| 13             | In-use testing                            | 23        |
| 13.1           | Thermometric checks                       | 23        |
| 13.2           | Chemical and biological indicators        | 24        |
| 14             | Removal and disposal                      | 24        |
| <b>Annex A</b> | <b>(informative) Concept of sterility</b> | <b>25</b> |
|                | <b>Bibliography</b>                       | <b>27</b> |

### Summary of pages

This document comprises a front cover, an inside front cover, pages I to IV, pages 1 to 27, an inside back cover and a back cover.

# Foreword

## Publishing information

This part of [BS 2646](#) is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 30 November 2023. It was prepared by Technical Committee CH/198, *Sterilization and associated equipment and processes*. A list of organizations represented on this committee can be obtained on request to the committee manager.

## Supersession

This part of [BS 2646](#) supersedes [BS 2646-3:1993](#) and [BS 2646-4:1991](#), which are withdrawn.

## Relationship with other publications

[BS 2646](#) is published in three parts. The other parts of the standard are as follows:

- Part 1: *Design, construction, safety and performance – Specification*; and
- Part 2: *Planning and installation – Code of practice*.

## Information about this document

This is a full revision of the document, and this part of [BS 2646](#) updates and combines [BS 2646-3:1993](#) and [BS 2646-4:1991](#), bringing together the safe use and operation requirements of [BS 2646-3:1993](#) with the maintenance requirements from [BS 2646-4:1991](#).

This revision aligns BS 2646-3 with the revised BS 2646-1:2021. Pressure system requirements have been aligned with the *Pressure Systems Safety Regulations 2000* [1]. References and clauses have been updated to reflect current Health and Safety Executive (HSE) guidance for laboratories and use of pressure systems, including the Waste from Electrical and Electronic Equipment (WEEE) directive [2]. It updates its references and clauses to reflect current HSE guidance for laboratories and use of pressure systems.

The standard incorporates significant changes to the testing regime for both new and existing autoclaves and includes an additional section on removal and disposal. Most clauses have been significantly revised.

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Where websites and webpages have been cited, they are provided for ease of reference and are correct at the time of publication. The location of a webpage or website, or its contents, cannot be guaranteed.

## Presentational conventions

The provisions of this document are presented in roman (i.e. upright) type. Its recommendations are expressed in sentences in which the principal auxiliary verb is “should”.

*Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.*

Where words have alternative spellings, the preferred spelling of the *Shorter Oxford English Dictionary* is used (e.g. “organization” rather than “organisation”).

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## 0 Introduction

When selecting an autoclave or an autoclaving process there is a clear need to differentiate between the:

- a) sterilization of liquid media and apparatus for use in the laboratory where the presence of viable micro-organisms would spoil the medium or confuse an investigation; and
- b) treatment of discarded, contaminated material so that it can be handled without causing an infection hazard or contaminating the environment.

As defined in [BS 2646-1](#), there are five separate autoclaving processes:

- 1) liquids sterilization (see BS 2646-1:2021, **3.14**);
- 2) make-safe (see BS 2646-1:2021, **3.15**);
- 3) equipment and glassware sterilization (see BS 2646-1:2021, **3.10**);
- 4) fabrics and textiles disinfection (see BS 2646-1:2021, **3.11**); and
- 5) materials testing and processing (see BS 2646-1:2021, **3.17**).

Operating cycles for each process are described in this part of [BS 2646](#), together with recommended time and temperature conditions and recommendations on performance qualification and in-use testing. Variations are adopted within each process for particular load items or for special purposes; the principles which support the conditions recommended in this British Standard also form the basis for other requirements a laboratory might have for an autoclave.

Free-steaming is not defined as an autoclave process. Less energy intensive equipment are used for the steaming, such as a steamer or microwave.

## 1 Scope

This part of [BS 2646](#) gives recommendations for the factors to be taken into account when devising procedures for the safe and effective use of laboratory autoclaves of the types specified in [BS 2646-1](#).

*NOTE 1 For example, autoclaves for the sterilization of goods and material which could be infected with organisms, the sterilization and/or processing of growth media or other materials required for the operation of a laboratory.*

*NOTE 2 The procedures described are designed to:*

- a) minimize risks to operators and other personnel;
- b) confirm the ability of the autoclave to effectively carry out each of the processes defined in [BS 2646-1](#); and
- c) plan and carry out maintenance tasks, including calibration, and to carry out performance qualification of the identified loads.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions, or limits the application, of this document<sup>1)</sup>. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS 2646-1:2021, *Autoclaves for sterilization in laboratories – Part 1: Design, construction, safety and performance – Specification*

<sup>1)</sup> Documents that are referred to solely in an informative manner are listed in the Bibliography.

BS 2646-2:2021, *Autoclaves for sterilization in laboratories – Part 2: Planning and installation – Code of practice*

[BS EN 285](#), *Sterilization – Steam sterilizers – Large sterilizers*

[BS EN ISO 11138](#) (all parts), *Sterilization of health care products – Biological indicators*

[BS EN ISO 11140](#) (all parts), *Sterilization of health care products – Chemical indicators*

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### 3 Terms and definitions

For the purposes of this part of [BS 2646](#), the definitions given in BS 2646-1:2021 apply, together with the following.

#### 3.1 maintenance/service engineer

person who performs maintenance/service work on the autoclave

*NOTE This person can be employed by the laboratory or contracted to the laboratory and completed a suitable course of training in the maintenance of that type of autoclave with further training, as defined by the manufacturer, e.g. a manufacturer of a sterilizer might define maintenance tasks which require specific knowledge and training.*

#### 3.2 responsible person

person(s) responsible for the operating policy of autoclaves within the laboratory and with delegated responsibility for overseeing the management and implementation of safety standards and requirements of local safety rules

*NOTE In HSE publication, Management and operation of microbiological containment laboratories [3], these are defined as competent people. The appointment of a biological safety adviser can assist the responsible person(s) with delivering their responsibilities.*

#### 3.3 test engineer

person employed to carry out performance qualification of the autoclave and load

*NOTE Within NHS laboratories, such individuals have the title “competent person (decontamination)”. This should not be confused with the term “competent person (pressure system)” which is a person responsible for drawing up or certifying schemes of examination and carrying out examinations under the scheme.*

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## 4 Operation of autoclaves

### 4.1 Training and instruction of operators

Autoclaves should only be operated by persons trained and deemed competent in their use. Training should be recorded and include demonstrations of ongoing competence.

Operators should receive the necessary training and instruction from the responsible person (see [3.3](#)) or the manufacturer and should be advised of the importance of conforming to operation instructions.

*NOTE For further information and advice on developing laboratory training programmes, see HSE publication, Management and operation of microbiological containment laboratories [3].*

### 4.2 Operating instructions

The laboratory operating instructions, and the relevant part(s) in the manufacturer’s instruction manual, should be provided for the operator by the responsible person as part of the laboratory’s standard operating procedures (SOP).

If the autoclave is provided with codes or keys, etc. that can be used to override safety features or manually advance the cycle, the operating instructions should specify the necessary authorization and procedures to be followed before their use, including the hazards associated with their use.

Operating instructions should include details of action(s) to be taken by the operator in the event of a fault or abnormality in autoclave performance, including a description of typical faults and how to recognize them.

#### 4.3 Autoclave process record

An autoclave process record for each operating cycle should be kept by the operator. This should contain details of each load processed, data record (hard copy or electronic) and whether the cycle passed or failed.

Process records should be reviewed by the responsible person at an agreed frequency.

#### 4.4 Plant history file

The plant history file should include a record of any fault, and corrective action taken by the operator, including the name of the supervisor to whom the fault is reported.

Additionally, the plant history file should include records of maintenance (see [Clause 5](#)), results of performance qualification tests (see [Clause 7](#)) and results of in-use testing (see [Clause 13](#)).

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## 5 Maintenance

### 5.1 Maintenance schedule

#### *COMMENTARY ON 5.1*

*The continued safe and effective use of the autoclave depends on a programme of planned maintenance throughout its life cycle.*

Maintenance schedules should be provided by the manufacturer; users should follow the recommendations within these schedules.

Required operator maintenance tasks should be commensurate with the operator's skills and training.

Before operating the autoclave, the operator should, as a minimum:

- a) inspect the autoclave chamber for debris and remove it;
- b) inspect the door seal for damage or adhesions, and clean the seal and sealing face (if visible); and
- c) check that all services are available at the required values and that no fault conditions are shown.

The maintenance/service engineer should be an experienced technician who has been specifically trained in the maintenance of the autoclave being serviced.

The maintenance/service engineer should have access to agreed levels of the operating software to allow adjustments to be made. The level of access given should be determined by the manufacturer.

Persons engaged in the maintenance of autoclaves should:

- 1) have sound knowledge of the general principles of sterilization and operation of autoclaves;
- 2) be familiar with the type and models for which they are directly responsible; and
- 3) receive instructions on the basic microbiology of hygiene to appreciate potential hazards to personnel.

Training should be provided for persons involved in planned maintenance of the laboratory autoclave. A periodic review of training needs and status should be undertaken, for both contract and local maintenance staff.

Local laboratory or maintenance staff carrying out routine maintenance tasks should be formally trained, with their staff records endorsed accordingly.

*NOTE* Although maintenance can be contracted out, there are a number of routine tasks which can be undertaken by local laboratory or maintenance staff.

## 5.2 Permit to work certificates

Permit to work certificates should be used when carrying out maintenance and testing activities.

*NOTE 1* Guidance on these and their use is provided by the HSE [\[4\]](#).

A permit to work certificate (see [4.4](#)) should be handed to the maintenance/service engineer before commencement of work. The certificate should confirm the decontamination status of the autoclave. If confirmation of decontamination is not possible:

- a) a risk assessment should be undertaken by the responsible person;
- b) the engineer should be informed of any hazard arising from the risk assessment and be instructed regarding necessary safety precautions; and
- c) relevant protective clothing should be supplied and used where there is a risk of harm.

Maintenance/service engineers should be made aware of potential risk of infection from equipment they might be required to work on and of decontamination and/or protection precautions which need to be observed.

*NOTE 2* Attention is drawn to the Health and Safety at Work etc. Act 1974 [\[5\]](#) regarding safe systems of working.

A contaminated laboratory autoclave should not be returned to the manufacturer's premises for servicing or repair.

After major overhaul or breakdown affecting the performance of the machine, recommissioning tests should be conducted in accordance with the instructions of the responsible person (see [3.1](#)).

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

## 5.3 Risk of infection during make-safe

When a fault occurs during a make-safe cycle, a risk assessment should be undertaken, with appropriate action taken. The assessment of risk should be carried out in accordance with the safety policy of the laboratory.

*NOTE 1* It might be necessary to disinfect those chamber attachments on which engineering work is to be carried out. Knowledge of the contents of the load helps in the choice of method and disinfectant required.

The risk assessment should include a review of those components that require dismantling to achieve decontamination.

The responsible person should consult with the manufacturer/engineer for guidance.

During a make-safe process, chamber condensate should be deemed to be contaminated with viable micro-organisms.

*NOTE 2* On rare occasions, dismantling of the autoclave might be necessary before decontamination.

How decontamination is undertaken and by whom should form part of the risk assessment.

Decontamination of the chamber and/or pipework should not involve prolonged contact with disinfectants corrosive to metal if the sterilizer is being returned to service.

## 5.4 Statutory pressure vessel inspection

### COMMENTARY ON 5.4

Attention is drawn to the Pressure Systems Safety Regulations 2000 [\[1\]](#) regarding the written scheme of examination, which is the responsibility of the management of the entity owning the autoclave.

The pressure vessel inspection should be carried out in conjunction with a routine service of the autoclave.

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## 6 Protective clothing

### 6.1 Laboratory clothing

Protective clothing, in accordance with the laboratory policy, should be worn in autoclave areas.

### 6.2 Additional protection

Additional clothing should be available in the loading/unloading area(s) to protect the operator.

*NOTE 1 Loading hazards include:*

- a) spills of biohazardous material;
- b) broken glass; and
- c) dropped load contents.

*NOTE 2 Unloading hazards include:*

- a) splashes and spillage of hot material from the load;
- b) hot condensate;
- c) hot equipment;
- d) broken glass;
- e) dropped load contents; and
- f) vapour from volatile chemicals (see [7.1.2](#)).

Laboratories should have SOPs and specify additional clothing and personal protective equipment (PPE) to protect operators from hazards.

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## 7 Loading and unloading

### 7.1 Loading

#### 7.1.1 Loading area

Access to the loading area should be limited to persons aware of the hazards from potentially infective material. The loading position should not be obstructed.

All materials awaiting autoclaving should be positioned so that they cannot be overturned, spilled, or damaged.

Discard containers of infected materials should not be stored in the loading area.

*NOTE The HSE might specify additional requirements for the direct movement of laboratory waste from the laboratory to the autoclave.*

Material in discard containers should be handled only, when necessary, prior to autoclaving.