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Autoclaves for sterilization in laboratories

Part 3: Safe use and operation – Code of practice

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Summary of pages
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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This part of BS 2646 supersedes BS 2646-3:1993 and BS 2646-4:1991, which are withdrawn.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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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[1)]. 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*

[1)] Documents that are referred to solely in an informative manner are listed in the Bibliography.

