

NSF International Standard / American National Standard

NSF/ANSI 49 - 2018

Biosafety Cabinetry: Design, Construction, Performance, and Field Certification









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Biosafety Cabinetry: Design, Construction, Performance, and Field Certification

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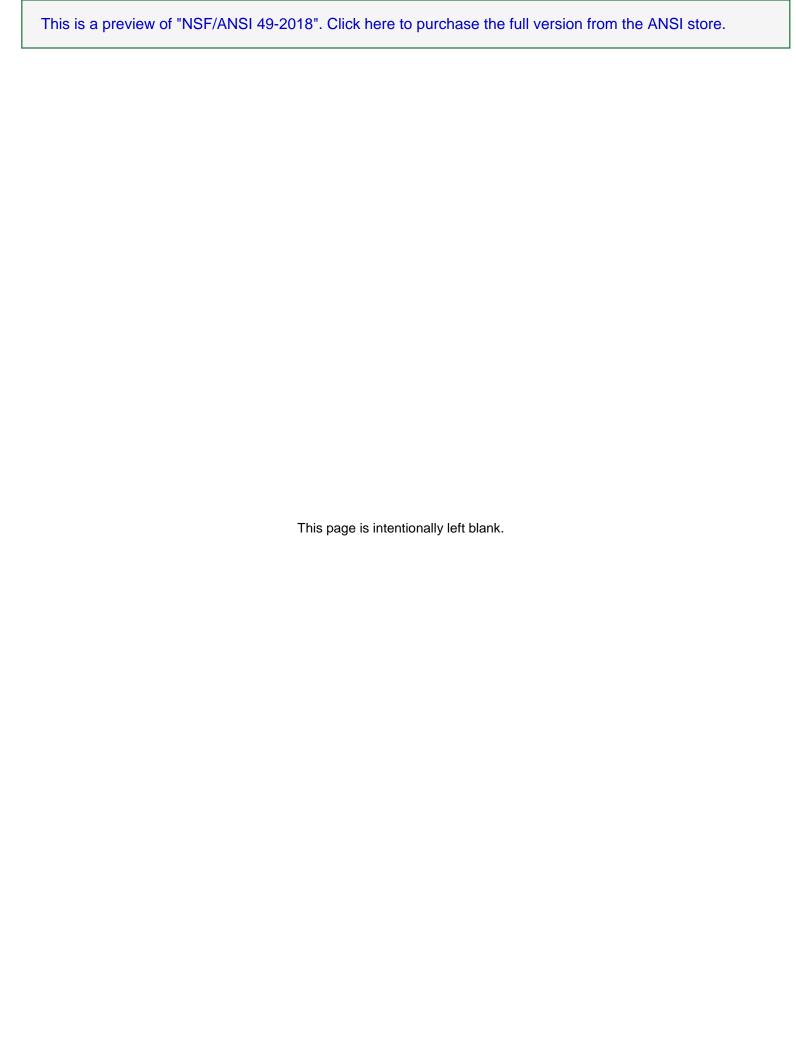
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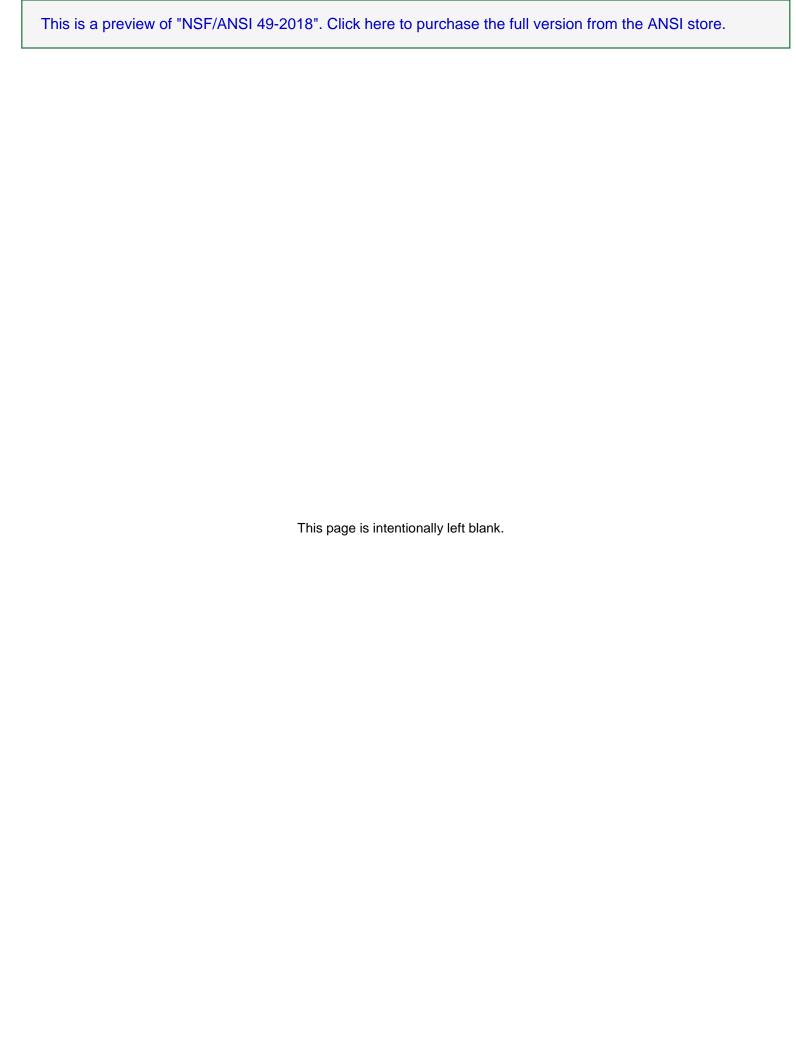


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Foreword²

The purpose of this Standard is to establish minimum requirements for materials, design, construction, and performance of Biosafety Cabinetry that are designed to protect personnel, product, and the environment. This Standard details requirements for performance testing as well as field certification testing.

This edition includes the following revisions:

Issue 47

Revised and added new language in Annex A regarding the cross contamination test procedure.

Issue 59

Revised and added new language for the airflow alarm requirement language for all cabinet types.

Issue 77

Added language to Annex A regarding confirmation tests when there is a test failure.

Issue 105

Added new language in Annex E regarding Risk assessment of biosafety cabinets exhaust system pressurization in the event of an exhaust system failure.

Issue 108

Added new language in Annex F regarding exhaust airflow alarms.

Issue 109

Revised and added new language referring to the term Certification throughout this Standard.

Issue 110

Revised language in Section 1.3 regarding the identification of major software changes to biosafety cabinetss.

Issue 111

Added new and revised language to Section 3 regarding the terms visible and viewable, and added provisions for the optional use of digital data plates to Section 5.

Issue 112

Revised and added new language in Annex G regarding the generation and dispersion of decontamination gas.

² The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

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Issue 115

Added new language in Section 6.10 regarding inflow requirements for Type C1 Cabinets.

Issue 117

Updates the language throughout this Standard regarding the use of the term "and/or".

Issue 118

Revised language in Section 5.25.3 and Annex F regarding the exhaust alarm in Type B biosafety cabinets.

Issue 121

Revised language in Section 5.26.2 regarding electrical wiring.

Issue 125

Revised language in Section 5.26.2 regarding the term 'running power'.

This Standard was developed by the NSF Joint Committee on Biosafety Cabinetry using the consensus process described by the American National Standards Institute.

Suggestions for improvement of this Standard are welcome. This Standard is maintained on a Continuous Maintenance schedule and can be opened for comment at any time. Comments should be sent to Chair, Joint Committee on Biosafety Cabinetry at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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NSF/ANSI Standard for Biosafety Cabinetry —

Biosafety Cabinetry: Design, Construction, Performance, and Field Certification

1 General

1.1 Scope

This Standard applies to Class II (laminar flow) biosafety cabinetry designed to minimize hazards inherent in work with agents assigned to Biosafety Levels 1, 2, 3, or 4. It also defines the tests that shall be passed by such cabinetry to meet this Standard. This Standard includes basic requirements for the design, construction, and performance of biosafety cabinets (BSCs) that are intended to provide personnel, product, and environmental protection; reliable operation; durability and structural stability; cleanability; limitations on noise level; illumination; vibration; and motor / blower performance.

1.2 Minimum requirements

Cabinets qualifying under this Standard shall have passed all of the designated tests. Units with component parts covered under existing NSF Standards or Criteria shall conform to those applicable requirements.

1.3 Variations in design and construction

Cabinetry varying in design, construction, or installation of accessory equipment may qualify under this Standard, if appropriate tests and investigations indicate that the equipment is durable and reliable, can be cleaned and decontaminated, and performs in conformance to this Standard. Such equipment shall meet the requirements for materials and finishes in this Standard.

Major modifications require appropriate tests for conformance. Major modifications include, but are not limited to any of the following changes to the blower / motor(s): location, capacity, quantity, or automatic airflow adjustment; size, or design, or both, of air plenums; position of high efficiency particulate air / ultra low penetrating air (HEPA/ULPA) filters; position or redesign of work surface; work area intake and exhaust air grilles; window placement or design; access opening size; location and size of exhaust port; the visibility or audibility of the safety signaling; and built-in accessory equipment (centrifuges, ultraviolet (UV) lighting, supports for intravenous drug container, arm rests, etc.). Major modifications also include changes affecting the safe use of the cabinet including the ability to see, hear, and understand the required alarms. Relocation of utility service equipment (electrical outlets, petcocks, etc.), the visual appearance of the cabinet, or user interface(s), are not considered a major modification if other provisions of this Standard are not compromised.

2 Normative references

The following documents contain requirements that, by reference in this text, constitute requirements of this Standard. At the time of publication, the indicated editions were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below.