Australian Standard®

Cleanrooms and clean workstations

Part 3: Non-laminar flow cleanrooms—Class 350 and cleaner

This Australian Standard was prepared by Committee ME/60, Controlled Environments. It was approved on behalf of the Council of Standards Australia on 7 April 1989 and published on 19 June 1989.

The following interests are represented on Committee ME/60:

Australian Institute of Refrigeration, Air Conditioning and Heating

Australian Medical Association

Australian Pharmaceutical Manufacturers Association

Commonwealth Serum Laboratories

Confederation of Australian Industry

CSIRO, Australian Animal Health Laboratory

Department of Administrative Services

Department of Community Services and Health

Department of Health, N.S.W

Health Department, Vic.

withdrawn Standards.

National Association of Testing Authorities, Australia

National Council of Chemical and Pharmaceutical Industries

Public Works Department, N.S.W.

Society of Hospital Pharmacists of Australia

State Chamber of Commerce and Industry, N.S.W.

Review of Australian Standards. To keep abreast of progress in industry, Australian Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto. Full details of all Australian Standards and related publications will be found in the Standards Australia Catalogue of Publications; this information is supplemented each month by the magazine 'The Australian Standard', which subscribing members receive, and which gives details of new publications, new editions and amendments, and of

Suggestions for improvements to Australian Standards, addressed to the head office of Standards Australia, are welcomed. Notification of any inaccuracy or ambiguity found in an Australian Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

Australian Standard®

Cleanrooms and clean workstations

Part 3: Non-laminar flow cleanrooms—Class 350 and cleaner

First published as part of AS 1386–1976 and AS 1387—1976.

Parts of AS 1386—1976 and AS 1387–1976 revised, amalgamated and redesignated AS 1386.3—1989.

PREFACE

This Standard was prepared by Standards Australia's Committee on Controlled Environments.

It is Part 3 of a series of seven Standards published simultaneously as a revision and amalgamation of—

AS 1386—1976 Cleanrooms and work-stations; and

AS 1387—1976 Code of practice for cleanrooms and work-stations.

The series consists of the following Standards:

- AS 1386 Cleanrooms and clean workstations
 - Part 1: Principles of clean space control (AS 1386.1)
 - Part 2: Laminar flow cleanrooms (AS 1386.2)
 - Part 3: Non-laminar flow cleanrooms—Class 350 and cleaner (this Standard, AS 1386.3)
 - Part 4: Non-laminar flow cleanrooms—Class 3500 (AS 1386.4)
 - Part 5: Clean workstations (AS 1386.5)
 - Part 6: Operation and inspection of cleanrooms (AS 1386.6)
 - Part 7: Installation and use of clean workstations (AS 1386.7)

The above seven Standards supersede both AS 1386—1976 and AS 1387—1976.

CONTENTS

		Page
1	SCOPE	. 3
2	REFERENCED DOCUMENTS	. 3
	DEFINITIONS	
4	DESIGN AND CONSTRUCTION	. 3
5	PERFORMANCE REQUIREMENTS	. 5

© Copyright - STANDARDS AUSTRALIA

Users of Standards are reminded that copyright subsists in all Standards Australia publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia. Permission may be conditional on an appropriate royalty payment. Requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia.

Standards Australia will permit up to 10 percent of the technical content pages of a Standard to be copied for use exclusively inhouse by purchasers of the Standard without payment of a royalty or advice to Standards Australia.

Standards Australia will also permit the inclusion of its copyright material in computer software programs for no royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia at any time.

STANDARDS AUSTRALIA

Australian Standard

Cleanrooms and clean workstations

Part 3: Non-laminar flow cleanrooms-Class 350 and cleaner

1 SCOPE. This Standard specifies requirements for non-laminar flow cleanrooms with a minimum air cleanness of Class 350 in accordance with AS 1386.1.

NOTES

- Requirements for Class 3500 non-laminar flow cleanrooms are specified in AS 1386.4.
- AS 1386.6 provides requirements for operation and inspection of cleanrooms. Separate specifications and related documents cater for certain vital components, e.g. air filters.
- **2 REFERENCED DOCUMENTS.** The following documents are referred to in this Standard:

AS 1324	Air filters for use in air conditioning and general ventilation
1386	Cleanrooms and clean workstations
1386.1	Part 1: Principles of clean space control
1386.4	Part 4: Non-laminar flow cleanrooms— Class 3500
1386.6	Part 6: Operation and inspection of clean-rooms
1668	SAA Mechanical Ventilation and Airconditioning Code
1668.1	Part 1: Fire precautions in buildings with air-handling systems
1668.2	Part 2: Ventilation requirements
1680	Code of practice for interior lighting and the visual environment
1807	Cleanrooms, workstations, and safety cabinets—Methods of test
1807.6	Method 6: Determination of integrity of terminally mounted HEPA filter installations
1807.8	Method 8: Particle counting in work zone by automatic particle counter
1807.9	Method 9: Particle counting in cleanrooms by microscopic sizing and counting
1807.10	Method 10: Determination of air pressure of cleanrooms
1807.12	Method 12: Determination of temperature in work zones
1807.13	Method 13: Determination of relative humidity in cleanrooms
1807.15	Method 15: Determination of illuminance
1807.16	Method 16: Determination of sound level in cleanrooms
1807.24	Method 24: Determination of recovery times of cleanrooms
2013	Cleanroom garments
2013.1	Part 1: Product requirements
2013.2	Part 2: Processing and use

3 DEFINITIONS. For the purpose of this Standard, the definitions given in AS 1386.1 apply.

4 DESIGN AND CONSTRUCTION.

NOTE: General principles and design criteria for clean spaces are outlined in AS 1386.1.

4.1 Room integrity. The cleanroom shall be constructed so that only HEPA-filtered air enters the room at all times. To achieve this, strict attention shall be paid to sealing of windows, light fittings, power outlets, and all other possible sources of air leaks.

Compressed gases supplied to the cleanroom shall be filtered through a non-shedding filter of adequate efficiency in the particle size ranges specified in AS 1386.1, as applicable for the relevant air cleanness class

4.2 HEPA filters. In all cases, the terminal filters positioned at the point of air entry to the cleanroom shall be HEPA filters and provision for testing the integrity of the filter shall be made.

HEPA filters may be protected with a removable, metal, washable screen. No air diffusers shall be installed on HEPA filter discharges.

NOTES:

- 1. HEPA filters are defined in AS 1386.1.
- 2. HEPA filters may be repaired provided that the performance requirements in Clause 5 are complied with.
- **4.3 Prefilters.** Prefilters complying with AS 1324 should be used to prolong the life of the HEPA filters.

The efficiency and dust-holding capacity of the prefilters should be chosen to handle the expected contamination load with due consideration to the desired life of prefilters and HEPA filters. (See also the general principles and criteria for management of filters outlined in AS 1386.1.)

- **4.4 Filter pressure drop indicator.** Suitable warning device(s) to indicate the condition of prefilters and operation of motor blower(s) are recommended.
- **4.5 Inlet HEPA filter banks.** It is recommended that the area of the inlet HEPA filter bank(s) is designed to provide a maximum average outlet velocity not greater than 0.6 m/s.
- **4.6 Airflow characteristics.** Air supply shall be on a high level, air discharge on a low level in the room at points remote from the air inlets. Particular care shall be taken to ensure that discharge also occurs at or near the entrance to the cleanroom.

NOTE: A typical installation is illustrated in Figure 1.