

STANDARDS AUSTRALIA

Amendment No. 1
to
AS 4273 — 1999
Design, installation and use of pharmaceutical isolators

REVISED TEXT

The 1999 edition of AS 4273 is amended as follows; the amendments should be inserted in the appropriate places.

SUMMARY: This Amendment applies to Clauses 4.3, 4.14, 5.3, and Tables 2 and 3.

Published on 25 May 2000.

AMDT
No. 1
MAY
2000

Page 6 Clause 4.3

Delete 'or microbes'.

AMDT
No. 1
MAY
2000

Page 7 Clause 4.14(b)

Delete 'a remote HEPA filtration system' and *replace* with 'an additional remote HEPA filtration system'.

AMDT
No. 1
MAY
2000

Page 7 Clause 5.3, paragraph 2

- 1 *Delete* 'Average air velocity shall not exceed 0.5 m/s' and *replace* with 'Average air velocity shall be in the range 0.4–0.5 m/s'.
- 2 *Delete* '±15%' and *replace* with '±20%'.

AMDT
No. 1
MAY
2000

Page 15 Table 2, Column 3, Row 3

- 1 *Delete* 'average air velocity ≤0.5 m/s' and *replace* with 'average air velocity in the range 0.4–0.5 m/s'.
- 2 *Delete* 'deviation of individual values from mean ≤15%' and *replace* with 'deviation of individual values from mean ≤20%'.

AMDT
No. 1
MAY
2000

Page 16 Table 3

- 1 *Replace* 'clean environment' by 'clean environment (see Note 3)' wherever it occurs.
- 2 In Note 3, *delete* 'For definition of clean environment see Clause 4.3' and *replace* with the following:

As defined in Clause 4.3, a clean environment is a space surrounding the isolator which is essentially free from unrelated activities and equipment that may shed particles at a significant level and which provides comfortable working conditions for operators having in mind the heat output of the isolator.

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