Australian Standard™

Cleanrooms, workstations, safety cabinets and pharmaceutical isolators—Methods of test

Method 5: Determination of work zone integrity

1 SCOPE This Standard sets out the method for determining the work zone integrity and induced air leakage for laminar flow cleanrooms, workstations, laminar flow safety cabinets and pharmaceutical isolators.

2 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS
1386 Cleanrooms and clean workstations
1386.1 Part 1: Principles of clean space control
1807 Cleanrooms, workstations, safety cabinets and pharmaceutical isolators—Methods of test
1807.0 Part 0: List of methods and apparatus
1807.6 Method 6: Determination of integrity of terminally mounted HEPA filter installations

AS/NZS
1716 Respiratory protective devices

3 DEFINITIONS For the purpose of this Standard the definitions given in AS 1386.1 and AS 1807.0 apply.

4 PRINCIPLE The vicinities of all joints, seals and work apertures relative to the clean work zone are surveyed from within while the exterior is maintained under a high concentration of aerosol. An aerosol photometer is used to detect potential aerosol leakage which may be induced or leak into the clean work zone. Aerosol photometer readings in excess of 0.01 percent are an indication of joint or seal leakage, or induction of contaminants into the clean work zone.

5 AEROSOL TEST LIQUID A liquid which produces a polydispersed aerosol with properties for the testing of filter integrity equivalent to those of cold polydisperse di-octyl phthalate (cold DOP).

6 APPARATUS The following apparatus as specified in AS 1807.0 is required:

(a) Aerosol generator and aerosol delivery hose.

NOTE: The test operator should minimize inhalation of and exposure to the test aerosol, especially at higher concentrations. A P3 respirator, as specified in AS/NZS 1716, should be worn for the duration of the test.

(b) Aerosol photometer.

