

Evaluating Clean-Air Devices

Updated document provides equipment information and test methods to confirm that unidirectional-flow, clean-air devices will maintain specified cleanliness levels per ISO 14644-1.

Keywords

Clean air device, unidirectional flow, cleanliness class, IEST, RP, CC002, ISO 14644

A newly revised Recommended Practice (RP), published by the Institute of Environmental Sciences and Technology (IEST), provides a basis for verifying that a clean-air device will maintain the desired cleanliness level of a cleanroom. IEST-RP-CC002.3, *Unidirectional-Flow, Clean-Air Devices*, incorporates the latest equipment requirements and test procedures to evaluate performance of these devices.

“This revision brings the RP in line with current usage and equipment as well as with other RPs,” noted R. Vijayakumar, Chair of Working Group CC002, which prepared the document. “We have also expanded the discussions on challenge uniformity.”

Unidirectional-flow, clean-air devices provide a stand-alone clean environment in product manufacturing, sterility testing, compounding sterile preparations, and similar applications. IEST-RP-CC002.3 includes an expanded section on types of devices with descriptions and illustrations of 11 configurations. Units added to the section include horizontal flow with exhaust, horizontal flow with recirculation, vertical flow/dual access, and vertical flow/dual access with exhaust. A revised table of recommended tests incorporates data on these devices.

The section on testing has been updated and reorganized into three main categories: primary, secondary, and manufacturer-level tests. According to the RP, unidirectional-flow, clean-air devices should be certified after installation and at routine intervals to verify that the design requirements of a facility are being maintained in accordance with ISO 14644-1 *Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness*. The recommended test procedures are provided for this purpose. Additional tests, such as those related to airflow characteristics, sources of particles, device pressurization and integrity, and environmental issues, provide a more complete characterization of performance of the device.

IEST-RP-CC002.3 may be used to define a basis of agreement between customer and supplier in the specification, procurement, and certification testing of unidirectional-flow, clean-air devices with self-contained motor-blowers and powered terminal units with replaceable filters. Appropriate sections of the RP may be referenced in the purchase order. The document also includes recommendations for recertification of these devices.

IEST-RP-CC002.3, *Unidirectional-Flow, Clean-Air Devices*, is available at www.iest.org.