An update on 14644 cleanroom standards: Parts 3 and 4

Stephen Ward

ISO 14644-3:2019 Cleanrooms and associated controlled environments – Part 3 Test methods

This standard has been reviewed and updated by ISO TC 209 Working Group 3 and was published by ISO in August 2019.

The most significant update from the 2005 edition of this standard is the removal of procedures relating to the classification of cleanrooms by airborne particles. When ISO 14644-1 was updated and issued in 2015 it incorporated these procedures.

This current edition still provides supporting tests for cleanrooms and associated controlled environments and the standard is used to enable selection of appropriate tests methods, for verifying the performance of a cleanroom.

Other notable changes include updates to the procedures relating to installed filter system leakage testing, including changes and additions to the designated leak acceptance criteria. There are changes in the specification requirements for test apparatus and a new procedure for a segregation test has been added.

The procedures within the normative section of the standard remain largely unaltered. It is within the informative annexes where the updates are more noticeable, and these are summarised below.

The annex on installed filter system leakage test has been re-written in most sections. The test now has the same maximum allowable designated leak for both the aerosol photometer method and the Light Scattering Air Particle Counter (LSAPC) method. This means that the results achieved by either method are now directly comparable.

Selecting the appropriate testing method now has fewer restrictions, with the aerosol photometer method being suitable for all installations unless situations exist where outgassing of the oil-based test aerosol could be detrimental to the product or processes in the cleanroom or when high concentrations of test aerosol in the system are not desirable.

In addition to aligning the designated leak for both methods, there are now two limits depending on the filter class being tested. The standard maximum allowable penetration is 0.01%. However, for filters with integral efficiency at MPPS of 99.95% to 99.994%, the maximum allowable penetration is 0.1% (10 times more). This means HEPA filters rated H13 (EN1822-1) or ISO35H (ISO29463) could be tested against the 0.1% criteria. This change is in response to perceived issues when testing these lower rated filters, which the previous LSAPC method's "k" factor had compensated for, by effectively making the maximum allowable designated leak value higher.

Filters with efficiency below 99.95% are not commonly tested but they can be, using this method, with appropriate different acceptance criterion.

Both photometer and LSAPC procedures recommend probe sizes of either 1cm x 8cm rectangular or 3.6cm diameter circular.

For the aerosol photometer procedure, the required upstream concentration has been updated to reflect improvement in instrument technology and current best practice. So, where instruments have the capability, concentrations between 1-100mg/m^3 are acceptable. The former 10-100mg/m^3 requirement and the previous 20-80mg/m^3 recommendation, have both been removed.

For the LSAPC procedure, there is a formula to determine the upstream concentration required, which is based on probe size, scan rate, instrument flow rate, maximum penetration and acceptance count for the scanning stage. A lower upstream concentration will result in alterations to the scan rate or possibly one of the probe dimensions, to enable the test to be performed.

For the overall leak test of filters mounted in ducts or air handling units, the acceptance criterion is now based on the main unified criteria discussed earlier.

Another notable change is in the recovery test, where there has been the introduction of a 10:1 recovery time in addition to the existing 100:1 recovery time. Using 10:1 is useful when testing in ISO 7, 8 and 9 classified cleanrooms, where very high particle concentrations can be difficult to achieve and measure. This can be demonstrated by comparing the recovery rate at a location in the room with the overall air change rate for the cleanroom.

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The new addition to the standard is the segregation test. It provides a method for assessing the effectiveness of segregating two areas by means of airflow. This test is performed across an opening between two areas, for example between an open fronted unidirectional flow workstation (critical area) and the background room (less critical area). The method involves generation of contamination (particles) in one area (the higher classified or less critical area) and determining the level of contamination that reaches the lower classified or more critical area. A particle counter is used to measure the particles in both areas (with a diluter for the contaminated area). A formula is provided to determine a protection index.

The Annex on test apparatus now has three suitability criteria for test instruments to meet. These are the measuring limits, resolution and maximum permissible error. It also highlights the need to ensure calibration points are within the range of use to ensure reliability of the measurement. However, stated calibration frequencies have been removed, therefore moving the responsibility onto the apparatus owner to determine the appropriate frequency.

Other changes within the standard are less significant and relate mostly to improving clarity.

In summary, the standard has seen some significant updates that need to be digested and understood. It is also not without controversy as some elements could have been clearer and better explained. It is important to note that there are currently some editorial errors, which a 2020 version is expected to address.

ISO (CD) 14644-4 Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up

The current 2001 version of this standard is currently under review and revision by ISO TC 209 Working Group 4. Work commenced in 2015 and a draft revision of the document was circulated to ISO TC 209 members for its first round of formal review, as a Committee Draft (CD) in early 2019.

The document is currently being prepared for its second Committee Draft following constructive comments on the first CD. The second CD is expected to be issued shortly.

Now is the best opportunity for the working group to challenge all the technical elements in the document, to develop a clear, concise, and useful document to be published as standard. As document development and review moves on, opportunities to improve become more restricted. The important work in updating this standard happens now, at these CD stages.

The main structure of the proposed revised standard flows through four key normative stages from initial 'requirements', through 'design' and then through 'construction' before finishing with 'start up'. The period once the cleanroom is operating is dealt with by ISO14644-5 – Operations.

These four key normative stages are clearly separated and identified in the CD. The informative annexes have been aligned to match with these four normative sections.

There is the intent to remove some of the outdated information that exists in the current standard, especially around recommended air change rates, which are misleading and should no longer be applied. The proposed revision addresses this with the inclusion of guidance on calculating contamination source strengths within the cleanroom. In a non-unidirectional cleanroom, contamination generated by people, equipment, and processes is diluted by the airflow before removal. This information on source strengths will allow designers a better approach to determining required airflow rates for different classes of non-unidirectional cleanrooms, while also considering ventilation effectiveness in their design and calculations. This aligns well with the recently published new standard ISO 14644-16: 2019, Energy efficiency in cleanrooms and separative devices.

The intention is also to remove information that does not benefit the reader, to make the standard more concise, relevant to the topic and easier to follow.

The section on requirements takes us through the key considerations that become the input into the design section, which is supported by a useful checklist in the related annex. The design section details the potential need for various design stages and the considerations to be made at each stage, from the early concept design through to the end of the detailed design stage.

For the construction section, the revision deals solely with the installing of the cleanroom. All the elements relating to material selection and non-direct construction-based information have been moved to the normative and informative design sections.

Key verification stages are now addressed in each relevant normative section and their associated informative annexes and are linked clearly to the point in the project where these checks and tests will be performed.

Now is the best opportunity for the working group to challenge all the technical elements in the document, to develop a clear, concise, and useful document to be published as standard. As document development and review moves on, opportunities to improve become more restricted.

The original checklists are being updated and moved to annexes that align with the relevant section.

Comments from the second CD will be reviewed by the working group later in 2020 and the output from those reviews will determine the next stage in the process. The current programme target is to see a new updated standard published in 2022.

Stephen is the Managing Director of Validair (Euro) Limited, which is part of the Validair group of companies providing a range of testing services for the cleanroom and contamination control industries. Stephen has been working in the cleanroom industry for over 30 years. He is the UK's technical expert for ISO TC209/WG3 on the revision of the ISO 14644-3 standard and ISO TC209/WG4 for the revision to the ISO14644-4 standard. Stephen's other roles include Deputy Chairman of LBI/30, the Cleanroom Technology Committee at BSI, an examiner for the Cleanroom Testing and Certification Board (CTCBi) and Secretary of the UK Contamination Control Network (CCN).