TECH TALK | Standards Update

Tech Talk provides a medium for industry professionals to share ideas about trends, new methods, and cost-saving techniques. Tech Talk articles are not peer-reviewed, but are selected for general interest and timeliness.

Cornerstone Cleanroom Standards Under Revision

Working Groups aim to clarify provisions and facilitate compliance in revising IEST-STD-CC1246, ISO 14644-1, and 14644-2.

Keywords
IEST-STD-CC1246, ISO 14644, cleanroom classification, cleanroom standard, cleanliness levels, contamination control, particle counting

IEST-STD-1246E to Simplify Particle Counting Process

The purpose of IEST-STD-CC1246D, *Product Cleanliness Levels and Contamination Control Program*, was to provide a uniform method for specifying product cleanliness levels and contamination control program requirements, with an emphasis on contaminants that may impact product performance. However, confusion had arisen among users of the standard due to inconsistencies in nomenclature and methodologies within and across industries, according to Joyce Steakley, Chair of the Working Group (WG-CC901) that is revising the standard. Steakley said IEST-STD-CC1246E, which she expects to be completed this fall, will establish greater uniformity and clarity in several key areas.

Particle Counting Bins

The WG has converted the particulate cleanliness level requirements in Table 1 from maximum cumulative particle counts above a stated size to particle counts within stated size ranges, or bins.

"This significantly simplifies the counting process and will eliminate numerous recurring questions," Steakley explained. "Creating counting bins also allows us to define an uppermost size limit vs. the historic specification allowing one particle above the specified size but without any ultimate size restriction."

She remarked that Table 1 has been frequently misinterpreted and many questions have arisen regarding the table's methodology. "Companies have typically converted the data to a set of counting bins on their own, but this has been inconsistent," she added. "Changing to this [counting bin method] will provide a uniform approach."

Renaming Clean Criteria

The revised standard will introduce a new naming convention for visibly clean criteria that specifies the viewing distance and light intensity in the name. This change was also driven by variability within the industry, Steakley said. "Multiple companies and agencies have definitions for visibly clean levels, but they … have never used a nomenclature that inherently includes the viewing criteria. We believe our new naming convention will be easy to interpret, use, and remember," she explained.

Verification of Surface Cleanliness

The revised standard will also introduce guideline recommendations for the minimum cleanroom cleanliness limits for the cleaning facility being used to attain a defined surface cleanliness level based in *IEST-STD-CC1246D*.

Steakley pointed out that there are no defined guidelines regarding the environmental controls needed to achieve various surface cleanliness levels. "We have always needed cleanrooms to perform cleaning and verification of cleanliness to this standard, but have never been so bold as to specify the cleanroom level needed for cleaning to a hardware cleanliness level," she said. "This revision will do so as a guideline or minimum recommendation."

Cleanroom Fallout Limits

Finally, the revisions include a new set of cleanliness levels for cleanroom particle fallout.

"This standard has always been based on particulate contamination on a *cleaned* surface or dispersed in a fluid as following a log-normal distribution," said Steakley. "However, cleanroom fallout does not follow this distribution, so when people have tried to use it they have been frustrated, confused, and dissatisfied. So, after many years of debate, we have decided to introduce a separate methodology and specification limits for cleanroom fallout."

ISO 14644-1 and 14644-2 Reviewed in Tandem

Airborne particulate classification and sampling methods are modified in a proposed revision of ISO 14644-1:1999 *Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness.* The Committee Draft (CD) is under review by voting members of International Organization for Standardization Technical Committee (ISO/TC) 209, along with a companion revision to 14644-2:2000 *Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.* If approved, these revisions are expected to be available as Draft International Standard (DIS) documents later this year.

Although the two Standards initially were published a year apart, ISO/TC 209 Working Group (WG) 1, Airborne particulate classes, is revising the documents in parallel to put them on the same review schedule. "This is important because they are complimentary documents that need to be well coordinated," Gordon Farquharson, Convenor of WG1, told the *Journal* in an earlier interview (October 2006, V. 49, No. 2).

Classification by Table

The proposed revision of 14644-1 moves from a formula-based to a table-based method for determining the maximum permitted concentration of particles. The 1999 edition supplements the formula with an illustrative table describing ISO Classes 1 through 9 for airborne particulate cleanliness. Reasoning that most users already apply that table instead of the formula, WG1 made clarifications to the table and set it as the primary classification method. The WG also noted that the formula is tricky to use in the opposite direction (i.e., to determine class from input of a value of concentration).

Where allowable concentrations are not specified, the revised table includes footnotes explaining why concentration limits are inappropriate for classification purposes. The table also eliminates concentration limits <10 particles/m^3, citing sampling and statistical limitations. For concentration values <100 particles/m^3, a warning was added that the listed maximum allowable concentrations will lead to large air sample volumes for classification.

Revised Sampling Plan

Another significant change, according to Farquharson, is the modification of the statistical approach for establishing sample locations when using discrete-particle-counting, light-scattering instruments. The 1999 edition directs users to compute the 95% upper confidence limit (UCL) from the average particle concentrations for all sample locations when more than one and fewer than 10 locations are sampled. A flaw in the method provided, according to the WG, is that it assumes an even distribution of contamination in a cleanroom, which is not always the case, particularly in non-unidirectional airflow cleanrooms. Further, computing the UCL is not applicable for a single location or more than nine locations.

The revision proposes a statistically based sampling plan that provides a known confidence level. This plan would deal evenly with all numbers of locations, would assume no statistical distribution, and would not be sensitive to unusually low particle count values. A new table correlates the statistical sampling plan to the size of the cleanroom. The table shows the number of sample locations related to the area of each cleanroom or clean zone to be classified and provides at least 95% confidence that at least 90% of all locations do not exceed the class limits.

According to the WG, this change will require more locations to be tested from about 10 m^2 to 500 m^2 of cleanroom area, with the worst case at about 36 m^2, requiring 14 test locations compared with the current six test locations. Cleanrooms larger than 500 m^2 will require fewer test locations than before. In the past, some commenters expressed concern about the increase in sampling locations. The WG noted that today's high-volume particle counters help to reduce this problem.

Classification vs. Monitoring

The main thrust of modifications to ISO 14644-2 was to improve the clarity of the document. The revision eliminates references to "requalification" and to "continuous" and "frequent" monitoring intervals, terms said to be confusing to users.

The revision mandates a documented testing and monitoring plan to demonstrate a facility's continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness. With separate sections on testing and monitoring, the revision outlines elements to consider in the plan, including definitions of methods, monitoring and testing locations and frequency, data evaluation techniques, instrument calibration, acceptance criteria, and other factors.

A new, informative annex covers considerations for developing the monitoring aspects of the plan, including airborne particle monitoring, pressure differential monitoring, and airflow velocity and volume monitoring. The document encourages users to consider automated systems for performing these functions.