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IEST Leads Development of First ISO 14644 Nanotechnology Standard

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IEST convenes ISO Technical Committee 209 Working Group 10 in the first cleanroom standard for the nanoscale.

Keywords

Nanotechnology, ISO, TC 209, 14644, cleanroom, nanoparticle, ultrafine particle

When the cornerstone cleanroom classification standard *ISO 14644-1: Classification of air cleanliness by particle concentration* was revised in 2015, it was jokingly commented that the ultrafine particle content was still there but too small to be seen. In reality, the information was "on hold" waiting for transfer to the first nanotechnology cleanroom standard: ISO 14644, Cleanrooms and associated controlled environments, Part 12—*Specifications for monitoring air cleanliness by nanoscale particle concentration*. The expert group responsible for creation of the standard—ISO Technical Committee (ISO/TC) 209 Working Group 10 Nanotechnology—is convened under IEST leadership through United States Convenor Anne Marie Dixon. ISO 14644-12 is now available from IEST as a Draft International Standard (DIS).

Airborne *ultrafine particles* have been measured in cleanrooms since the 1980s. At the time, particles smaller than 100 nm were called *ultrafine particles* rather than the more recent term *nanoparticles*. In the 1999 version of ISO 14644-1, the normative requirements were limited to classification of particles greater than 100 nm. However, informative material was included for airborne particles smaller than 100 nm. During the revision process of ISO 14644-1, ISO/TC 209 agreed that placing the guidance in a separate nanotechnology standard would simplify maintenance of the standards due to the rapid pace of development in that field. Supporting information in ISO 14644-12 was also drawn from documents developed by ISO/TC 229 Nanotechnologies.

ISO 14644-12 covers the monitoring of air cleanliness by particles in terms of concentration of airborne nanoscale particles. Monitoring is for use mainly in "operational" states. Within ISO 14644-12, reference made to *nanoparticle* signifies a nano-object with all external dimensions in the nanoscale, where the lengths of the longest and the shortest axes of the nano-object do not differ significantly. If the dimensions differ significantly (typically by more than 3 times), terms such as *nanofibre* or *nanoplate* are more likely to be used.

For organizations that currently monitor nanoparticles for process evaluation, ISO 14644-12 will have immediate process applications. It is anticipated ISO 14644-12 will also have a long-term impact as 1) instrumentation for cleanroom measurement improves, and 2) the number of nano-technology-based products requiring manufacture in cleanrooms increases.

While aerospace and electronics have had interest in this area for decades, new applications are developing in the fields of biotechnology and pharmaceuticals. ISO 14644-12 will allow standardization of measurement of levels of process nanoparticles released in the cleanroom. Health and safety considerations are excluded from ISO 14644-12; industry will need to look to other sources for possible guidance.

Interrelation with ISO 14644-1

While the purpose of ISO 14644-1 is to provide requirements for the classification of cleanrooms and to provide testing to verify the class for particles larger than 100 nm, ISO 14644-12 does not classify the cleanroom for the nanoscale. Instead, ISO 14644-12 provides specifications for monitoring air cleanliness for particles in the nanoscale.

The testing protocol in ISO 14644-1 is effective in detecting cleanroom problems such as leakage of outside air containing a wide range of particle sizes, and this can include nanoparticles. While most sub-micron and macro particles in cleanrooms can be related to human activity, nanoparticles are generated by electrostatic discharge, chemical reactions such as oxidation, and gas phase nucleation. Material properties and the transport of nanoparticles can also be expected to differ from particle sizes classified in ISO 14644-1. Diffusion and mobility in electrical fields increases rapidly with decreasing size. As a consequence, nanoparticles have both higher coagulation rates in the air and deposition rates on surfaces. Therefore, it was not expected that the classification curves as described in ISO 14644-1 could be simply extrapolated to smaller particles than the stated lower limit.

Because filtration in cleanrooms will remove nanoparticles with high efficiency, the majority of the nanoparticles remaining are process related. While the composition of sub-micron and macro particles are generally comparable, each cleanroom will have nanoparticles corresponding to the specific process. Measurement of the nanoparticle concentration is suitable only when the cleanroom is in an *operational* state (as defined in ISO 14644-1:2015). In the *as built* or *at rest* state the lack of process-related particles will lead to data that do not correlate to realistic conditions.

Therefore, the purpose of ISO/DIS 14644-12 is to monitor the cleanroom air near the process equipment under operating conditions. ISO 14644-12 should prove quite useful to process engineers seeking a standardized monitoring protocol in this fast-developing field.

Aligning scopes and efforts of ISO/TC 209 and ISO/TC 229

As technology advances, the need for standardization in the burgeoning field of nanotechnology has expanded. In 2005, ISO/TC 229 Nanotechnologies was created and took center stage in international standards activities related to the nanoscale. However, the committee soon recognized that the crosscutting nature of nanotechnology required the supporting knowledge found in other ISO technical committees. Liaison efforts were established to ensure the development of harmonized standards in nanotechnology throughout the ISO/TC work program.

ISO/TC 229 has a broad scope including terminology, metrology, and environmental health and safety (EHS). The ISO/TC 209 scope does not include the development of EHS requirements. The main components of the ISO/TC 209 scope are facilities and controlled environments, which the ISO/TC 229 scope does not include. Together, these complementary scopes provide broad coverage in the overall nanotechnology standards development program.

The majority of the documents published in the past 10 years by ISO/TC 229 have dealt with basic and generic topics in the area of materials, but recently the committee began moving in the direction of the developmental chain and manufactured goods. It is expected that the interaction of ISO/TC 229 and ISO/TC 209 will increase as the nanotechnology field and standardization work matures.

IEST Nanotechnology Recommended Practices and ISO 14644-12

While nanotechnology is a new endeavor for ISO/TC 209, IEST offers several nanotechnology recommended practices with a focus on facility design. In July, IEST released *IEST-RP-NANO205.1: Nanotechnology Safety: Application of Prevention through Design Principles to Nanotechnology Facilities*. The Recommended Practice (RP) provides facility design information intended to minimize risks for personnel associated with nanotechnology research and production. IEST-RP-NANO205 complements IEST's first published nanotechnology document *IEST-RP-NANO200: Planning of Nanoscale Science and Technologies Facilities: Guidelines for Design, Construction, and Start-up*. The documents are the first core resources for guidance in nanotechnology facility design.

As ISO/DIS 14644-12 moves through the ISO international voting process from DIS to Final Draft International Standard (FDIS) to International Standard, IEST's roles on both ISO/TC 209 WG 10 and the IEST NANO Working Groups will ensure relevant information and the latest citations continue to be incorporated in IEST Recommended Practices for facilities planning.

IEST has served as the Secretariat for ISO/TC 209 for nearly 25 years with an established global leadership role of more than 50 years of expertise in cleanrooms and controlled environments.

IEST thanks ISO/TC 209 WG 10: Nanotechnology for undertaking this exciting new area and recognizes the excellent Secretary support provided by the United Kingdom through the British Standards Institute (BSI).

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To express interest in joining WG 10: Nanotechnology or in sponsoring events related to the group's meetings, please contact the ISO/TC 209 Secretariat IEST at information@iest.org.