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New ISO Draft Standard Classifies Surface Particle Cleanliness

An interview with officers of ISO/TC 209 Working Group 9, "Clean surfaces"

With today's rapid technological progress and miniaturization, clean surfaces are of growing interest and vital importance for many high-tech industries and applications. The International Organization for Standardization Technical Committee (ISO/TC) 209 is taking steps to fill the need for global standards addressing surface contamination.

Keywords
ISO, 14644, 14698, surface contamination

Since its inception in 1993, ISO/TC 209 has produced 10 Standards covering airborne particle contamination: Parts 1 through 8 of *ISO 14644: Cleanrooms and associated controlled environments*, and Parts 1 and 2 of *ISO 14698: Biocontamination control*. In 2003, TC 209 resolved to expand its charter to include Standards covering surface contamination and established Working Group (WG) 9, "Clean surfaces." The WG identified three categories of surface contamination to be considered for Standards: physical (particle), chemical (molecular), and biological.

The first of these potential documents, *ISO/CD 14644-9: Cleanrooms and associated controlled environments — Part 9: Classification of surface particle cleanliness*, has reached the Committee Draft (CD) stage. This document presents a classification system for the determination and designation of cleanliness levels based on surface particle concentrations, and also lists test methods and procedures for determining particle concentration on surfaces.

ISO/CD 14644-9 was sent out for international balloting in June with a voting deadline of September 21, 2007. Depending on the time it takes to process the technical and editorial comments and produce the three required language versions, a Draft International Standard (DIS) might be available to the industry as early as Spring 2008.

The following question-and-answer is based on information provided by Werner Straub, Convener of WG 9; Christine Montigny, Secretariat of WG 9; and Egon Hollaender, Convener of WGs 1 and 6 and a WG 9 member and special adviser, who was instrumental in persuading TC 209 to address surface contamination.

How will this new Standard fill a need in the contamination control industry?

Surface cleanliness is of crucial importance to many industries. There are many national and industry-specific standards on this issue but no international standard was found in a literature search initiated by an ad hoc group headed by Hollaender and continued by WG 9 delegates. The technical community therefore urgently requires a global standard. *ISO 14644-9* will allow glob-

ally active companies to have mutual understanding on quality demands concerning the particle cleanliness of a defined and classified surface.

What industries will benefit from this document?

The main industries that could benefit from the proposed Standard are:

- microelectronics (semiconductor industries, optoelectronics, microelectromechanical systems [MEMS], microelectronic systems);
- life sciences/life technologies (pharmaceutical, medical devices, hospitals, biotechnology, genetic engineering, food industries);
- chemical;
- automotive;
- nuclear;
- aerospace;
- micromechanics.

This list is not exhaustive, and in the spirit of the generic requirements of an ISO Standard, *ISO/CD 14644-9* will not include application-specific requirements. Therefore, the document does not cover requirements on the cleanliness and suitability of surfaces for specific processes.

Scope of *ISO/CD 14644-9: Cleanrooms and associated controlled environments — Part 9: Classification of surface particle cleanliness*

This ISO standard describes the classification of the particle contamination levels on solid surfaces in cleanrooms and associated controlled environments applications. Recommendations on testing and measuring methods as well as information about surface characteristics are given in informative annexes.

This standard applies to all surfaces in cleanrooms and associated controlled environments such as walls, ceilings, floors, working environment, tools, equipment and devices. The surface particle cleanliness (SPC) classification is limited to particles between 0,05 µm and 500 µm.

The aspects of chemical (molecular) as well as biological surface contamination will be specified in further standards of this series.

The following issues are not considered in this standard:

- requirements on the cleanliness and suitability of surfaces for specific processes;
- procedures for the cleaning of surfaces;
- material characteristics;
- other characteristics of particles such as electrostatic charge, ionic charges, biological state and others.

The standard covers the classification system of surface particle contamination with no reference to the interactive bonding forces or generation processes which are usually time-dependent (such as deposition, sedimentation, aging) and process-dependent (such as transportation or handling). Measurement methods of the classification should be adapted for surface characteristics (such as porosity, roughness, electrostatic charge, surface energy etc.).

The surface cleanliness depends amongst others on material and design characteristics, on stress loads (complex of loads acting on a surface) and on the prevailing environmental conditions.

What industries and expertise are represented in the Working Group?

WG 9 delegates from nine countries represent the pharmaceutical, semiconductor, chemical, nuclear, space technology, microelectronics, and other industries, as well as research facilities. These delegates come from the commercial and academic communities and include experts in qualification, validation, measuring techniques, decontamination, contamination control and cleanroom consulting for pharmaceutical, food, semiconductor, and medical devices.

What are the significant provisions of the document?

The document provides a generic definition and classification of surface particle cleanliness (SPC) in cleanrooms and associated controlled environments to allow a global mutual understanding for quality requirements. Demonstration of compliance also is covered in the normative section. Informative annexes include a descriptor for specific particle size ranges, parameters influencing the SPC classification, surface characteristics and measurement methods for testing surface particle cleanliness, and other important factors as defined by WG 9.

What is the rationale behind the SPC classification system and how was it developed?

The SPC classification of particle contamination levels on solid surfaces specifies the maximum total particle concentration on surfaces permitted for a considered particle size. The unit is particles per square meter. The SPC class number is formatted as follows: SPC class N (D µm), where N is the SPC classification number and D is the considered particle size. The designation of SPC class also includes the surface type considered, the surface area measured, and the measurement method applied. The method for classifying SPC classes is a virtual double log graph in metric with a classification sequence from 1 to 8 in regular distances represented with an equation. This system is similar to the airborne particle classification method used in *ISO 14644-1 Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*. The SPC classes are also available in table format.

What is the status of work on a Standard for surface chemical (molecular) contamination?

Working Group 8, which published 14644-8 on airborne molecular contamination in August 2006, has been reactivated to develop a document on surface chemical contamination. There are many overlapping areas between the work of WGs 8 and 9. This has made it difficult for the groups to clarify their missions. To aid in defining the mission of WG 8 and expanding the focus to surface contamination, ISO/TC 209 changed the name of the WG from "Airborne molecular contamination" to "Chemical contamination."

WG 8 has active delegates from seven countries and also benefits from WG 9 observers. The delegates expect to have a draft document prepared for CD release in late 2007. The current working document proposes a unified classification system based on unit nanograms/square meter and covering the full range of clean surfaces. For extremely clean surfaces (such as semiconductors), for which concentration is normally expressed in atoms/square meters, conversion tables and equations are provided. This approach allows a classification based on positive log integer. A second classification for extremely clean surfaces based on atoms/square meter is considered.

Has work begun on a biological surface contamination document?

After some discussion at the September 2006 meeting in Beijing, China, ISO/TC 209 voted to establish an ad hoc subcommittee of WG 2, Biocontamination, consisting primarily of micro-

biologists to review ISO 14698 Parts 1 and 2 to determine issues that need to be addressed. For example, the Standards do not contain classifications for airborne or surface microbial contamination. The ad hoc group will report its findings at the next TC 209 meeting, November 9-10, 2007 in Chicago, in conjunction with the IEST Fall Conference.

What other efforts are under way related to surface cleanliness Standards?

In April 2007, WG 9 submitted a new work item proposal (NWIP) on "Decontamination of surfaces from particle, chemical and biological contamination." Expert delegates recommended the development of this document to standardize methods for the decontamination of surfaces in a wide variety of industries. The document would be the responsibility of WG 9, in cooperation with WG 8.

The proposed standard would correlate decontamination methods with the SPC Classes defined in ISO/CD 14644-9 and Surface Chemical Cleanliness (SCC) Classes defined in the document currently being developed by WG 8. ISO/TC 209 will review the proposal at the November meeting.