E56 on Nanotechnology

Three New ASTM International Standards in the Works for Committee on Nanotechnology

Although ASTM International Committee E56 on Nanotechnology was just established this year, it has already begun an ambitious program of developing new standards. Committee E56 is currently developing the following proposed standards, which deal with environmental safety issues, hemolytic properties and particle size measurement. Interested parties are invited to participate in the development of any of these proposed standards.

WK8985, Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings

Academic, government and industrial laboratories are currently performing nanotechnology research and development and the scope and breadth of this work is expected to grow dramatically. Manufacturing processes involving nanomaterials have begun and commercially available nano-based products have been introduced.

All of this activity in the nanotechnology realm has created the need for the establishment of environmental, health and safety (EHS) methodologies to prevent harmful employee exposures in occupational settings during both research and development activities and manufacturing processes. A proposed new standard being developed by Subcommittee E56.06 on Risk Management and Product Stewardship will address these concerns.

According to Steven Brown, Technology Development, EHS Industrial Hygiene, Intel Corporation, WK8985, Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings, will be utilized by organizations involved

in the handling and processing of nanomaterials in occupational settings to develop internal EHS nanotechnology control programs. "The proposed standard will provide specific guidance on EHS nanotechnology control program elements and workplace administrative and engineering controls to prevent harmful exposure to employees," says Brown.

Brown points out the necessity of such a standard by noting that, as industrial uses of nanomaterials increase, there will be more employees working with them, creating a corresponding increase in the risk of harmful exposures in the absence of EHS controls.

Subcommittee E56.06 is actively soliciting volunteers with knowledge of health and safety plan development or nanotechnology processes in research and development or manufacturing settings who wish to participate in the further development of WK8985.

For further technical information, contact Steven Brown, Intel Corporation, Cloverdale, Ore. (phone: 971/563-6198; steven.w.brown@intel.com).

WK8997, Practice for Analysis of Hemolytic Properties of Nanoparticles

Subcommittee E56.02 on Characterization has begun working on proposed new standard WK8997, Practice for Analysis of Hemolytic Properties of Nanoparticles. This proposed standard would provide a suitable procedure for establishing the safety of nanoparticulate materials that will be used *in vivo*, such as nanoparticles for therapeutics and diagnostics.

"Nanotechnology products will be used in medical areas, primarily for *in vitro* diagnostics, *in vivo* imaging and for drug delivery to targeted tissues," says Scott McNeil, director, Nanotechnology Characterization Laboratory. McNeil points out however, that products used for medical applications will need to meet special criteria for biological responses. In addition to performing the functions for which they were built, nanotechnology products used in the medical realm will need to be biocompatible. WK8997 is an adaptation of biocompatibility standards

developed by ASTM Subcommittee F04.16 on Biocompatibility Test Methods, which is under the jurisdiction of Committee F04 on Medical and Surgical Materials and Devices.

Nanoparticles that are to be used in contact with the blood stream must be composed of materials that meet hemocompatibilty standards. One of these tests is for damage to red blood cells, which can result in hemolysis, that is, rupturing of the cells. WK8997 is particularly based on Subcommittee F04.16' s F 756, Practice for Assessment of Hemolytic Properties of Materials. "F 756 for blood contacting devices has been around for years but was originally designed for materials that are in abundant supply, such as joint replacement devices," says McNeil. "Nanoparticulate materials, on the other hand, are generally not available in large quantities and the specimen size needed for F 756 is prohibitive." McNeil notes that the general concepts in F 756 are maintained in WK8997, but the methodology uses available micro methods, such as 96-well plates, and is appropriate for the use and availability of nanoparticulate material.

Subcommittee E56.02 is actively seeking participation in the development of WK8997. Current stakeholders include representatives of the U.S. Food and Drug Administration, the nano-biotechnology community and drug developers.

For further technical information, contact Scott McNeil, director, Nanotechnology Characterization Laboratory, Frederick, Md. (phone: 301/846-6939; mcneils@ncifcrf.gov).

WK8705, Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photo Correlation Spectroscopy (PCS)

Subcommittee E56.02 was formed to answer questions regarding characterization, such as size and shape of materials. Another proposed new standard under the jurisdiction of Subcommittee E56.02 is WK8705, Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photo Correlation Spectroscopy (PCS), which deals with the vital issue of size

characterization. The purpose of the proposed standard is to set and define the standards for measurement of size distribution in the nano-region.

"Photo correlation spectroscopy is the most important particle size distribution technique for material under 100 nm," says Alan Rawle, divisional manager applications support, Malvern Instruments, Inc. Rawle notes that, while other methods, such as electron microscopy, can provide individual particle and morphology information, there are problems associated with these methods, most importantly being the small amount of sample that is effectively measured. PCS is one of the few techniques that allow the measurement of particle size and distribution on a statistically significant mass of sample.

Rawle says that an early draft of WK8705 is in progress and invites anyone interested to contribute to its further development.

For further technical information, contact Alan Rawle, Malvern Instruments, Southborough, Mass. (phone: 508/480-0200; alan.rawle@malvernusa.com).

Committee E56 will meet Nov. 6-8, 2006, at the November Committee Week in Dallas, Texas. For membership or meeting details, contact Pat Picariello, ASTM International (phone: 610/832-9720; ppicarie@astm.org).

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