Modern Alchemy

Since 2005, an ASTM technical committee has been **developing nanotechnology standards** to meet the needs of regulatory agencies, industry and consumers.

By Alan R. Earls

As long ago as the 1950s, a few visionaries were contemplating a completely new way of looking at the world and a new technology to take us there. The fundamental idea was to reshape the familiar elements of chemistry by building from the atomic level up — a kind of new alchemy. The first use of the term nanotechnology to describe this quest cropped up in the 1970s and 1980s. From there on, science actually began to deliver the breakthroughs that earlier generations had imagined.

In quick succession, researchers discovered buckminsterfullerene C60, a kind of carbon structure not previously known or imagined, which was followed by the creation of carbon nanotubes and the manipulation of individual atoms. In short order, scientific curiosity began to flower, moving beyond a few labs and into industry. In response, Committee E56 on Nanotechnology was formed in 2005. Celebrating its 10th anniversary this year, the committee now has some 170 members representing 19 countries, and has published 12 standards with another five in the drafting stage.

BEGINNINGS

According to Debra Kaiser, Sc.D., a technical program director at the National Institute of Standards and Technology, Gaithersburg, Maryland, and current chair of Committee E56, one of the vitally important standards developed by the committee is E2535, Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings. First promulgated in 2007, it represents a "commitment to safety and controls for all operations and activities involved with handling nanomaterials," says Kaiser.

After that first standard, the committee as a whole was restructured. The goal, according to Vincent Hackley, Ph.D., a project leader at NIST, has been to better address the evolving needs of regulatory agencies as well as of industry.

As an example, Hackley notes, Subcommittee E56.02 on Physical and Chemical Characterization, co-chaired by Alan Rawle, Ph.D., Malvern Instruments, and Hackley, initially covered all types of nanomaterial characterization (traditional and novel techniques for describing and defining a substance), including its relation to biological processes. But the executive subcommittee recognized that physical and chemical standards should be separated from biological standards, so Subcommittee E56.03 on Environment, Health and Safety was revitalized and two chairs from the National Institute for Occupational Safety and Health were recruited to provide expertise on the bio side. Given the importance of biological characterization and safety issues, Subcommittee E56.03 on Environment, Health and Safety has


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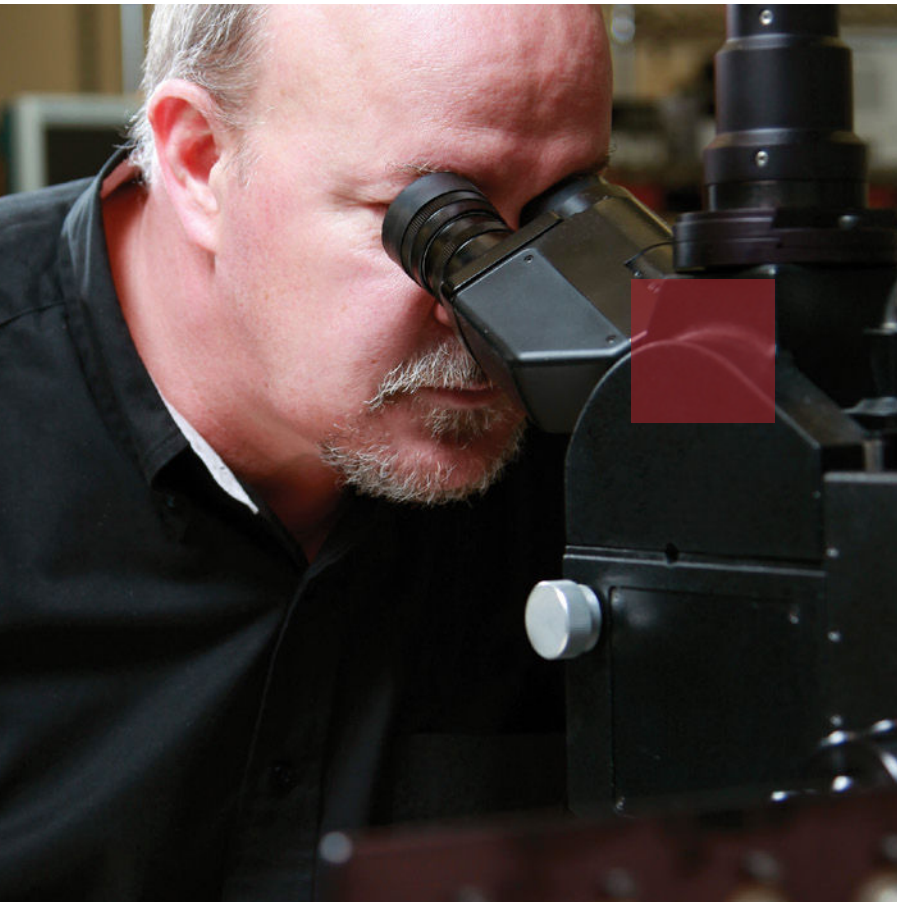
since garnered considerable participation and interest from NIOSH and the U.S. Food and Drug Administration.

Kaiser explains that the agencies each have a big stake in nanotechnology. NIOSH, the federal agency that protects the safety and health of the nation's 155 million workers, requires standards to evaluate potential health effects on workers exposed to nanomaterials in manufacturing settings. For its part, the FDA requires standards to evaluate the safety of new nanomaterial-containing food and drug products and develops regulations for such products.

Subcommittee E56.01, which was first focused on terminology and nomenclature, has evolved into Subcommittee E56.01 on Informatics and Terminology. This group focused on addressing a big concern for the industry, namely that researchers were generating lots of data without a clear means for sharing or exchanging it. The work of the subcommittee led to the development of E2909, Guide for Investigation/Study/Assay Tab-Delimited Format for Nanotechnologies (ISA-TAB-Nano): Standard File Format for the Submission and Exchange of Data on Nanomaterials and Characterizations.



This document created a standardized format for presenting data by developing standard file structures. Nathan Baker, Ph.D., laboratory fellow and technical group manager for the Applied Statistics and Computational Modeling Group at the Pacific Northwest National Laboratory — and co-leader of the effort — explains that the need to rationalize data and conduct data mining and simulations made it vital to develop a standard. Baker notes that further ISA-TAB-Nano development, which specifies the format for representing and sharing information about nanomaterials, small molecules and biological specimens (including metadata and summary data) using spreadsheet or TAB-delimited files continues to be a community-driven effort that welcomes new contributions and collaborations.

BEYOND THE LABORATORY

Another new subcommittee led by Aleks Stefaniak, Ph.D., from NIOSH, has generated great interest and excitement, Kaiser explains. Named Subcommittee E56.06 on Nano-Enabled Consumer Products, it reacts to the growing concerns of both consumers and regulators about the use of nanotech products. "There are currently some 1,600 products labeled or self-described by producers as containing nanomaterials. So there is concern about nanomaterials in these products being released by various means and then causing people to be exposed to potentially unsafe nanomaterials. So far, Subcommittee E56.06 has one standard work item in the release area that is of great interest to regulators and to industry," says Kaiser.

Indeed, according to Hackley, in recent years, environmental and health concerns — including those related to consumers — have actually tended to eclipse the technical aspects of nanotechnology. Many in industry are concerned that they could create a nanomaterial that could turn out to be problematic down the road, especially given the current lack of clear regulatory guidance. To underscore the point, Kaiser cites concerns that have been expressed

Committee E56 on Nanotechnology has developed two standards to outline **minimum requirements for nanotech education at the undergraduate level**:

E2996

Guide For Nanotechnology Workforce Education in Health and Safety

E3001

Practice For Workforce Education in Nanotechnology Characterization

within an interagency group. "People from industry shared anecdotal information about insurance companies that, upon learning a company was involved in nanotechnology, either dropped the company's coverage entirely or sharply raised their rates. So this is an area of very active concern," she says.

Because of the lack of standards and regulatory guidance, it is in fact difficult for anyone to say unambiguously what is or isn't safe. "The EU issued a regulatory policy about two years ago which considers the size, number and concentration of nanomaterials. However, industry has been struggling ever since to figure out how to comply — and how to turn the EU policy into practical guidance. Because of these issues, E56 has a real opportunity to have an impact, especially in our engagement with regulatory agencies," says Hackley.

"We think that E56.06 will become a very active subcommittee," adds Hackley.

Also eyeing the growth of the industry and the critical need for properly trained personnel, E56 has staked out additional territory. "We were approached three to four years ago by a group that is part of the Nanotechnology Applications and Career Knowledge network, which is the NSF National Advanced Technological Education Center for Nanotechnology Workforce Development.

"They told us they would like to work on developing standards to outline minimum requirements for nanotech education at the undergraduate level, whether students are looking to move into technician positions or are looking to acquire further advanced education in the field. In either case, there was a perceived need to define basic, core skills," Hackley explains. The result has been standards E2996, Guide for Nanotechnology Workforce Education in Health and Safety, and E3001, Practice for Workforce Education in Nanotechnology Characterization.

"We have also talked about forming a separate education subcommittee, and I think I will propose that to the executive subcommittee," Kaiser adds.

AN INVITATION

For those interested in learning more about E56, the committee's next meeting will be held April 9-10 at NIST in Gaithersburg, Maryland. Registration for the meeting is available on the ASTM website.

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