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Shorts on Standards

The CAP has 30 official liaisons to various organizations who attend scientific meetings or designate others to do so. They report to the Standards Committee, which reports to the Council on Scientific Affairs. We periodically publish bits of what the CAP's outbound liaisons hear and see in their liaison roles.

Nanotechnology in the clinical laboratory

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In December 2015, the International Organization for Standardization published the technical report (ISO/TR 17302) on "Nanotechnologies—Framework for Identifying Vocabulary Development for Nanotechnology Applications in Human Healthcare." This technical report is designed to standardize the descriptions of clinical applications of nanotechnologies in health care. It signals the overall maturation of nanotechnology in health care and, of particular importance to pathologists and laboratory professionals, the use of nanotechnology in the clinical laboratory.

ISO began in 1947 as an international organization to establish standards for products and services. ISO standards not only facilitate international trade but also set minimum specifications for health care products including quality in the clinical laboratory. The CAP 15189 quality management program is an example of the adoption of an ISO standard in the clinical laboratory. In 2005, ISO established a technical committee on nanotechnologies (ISO/TC 229); this committee has produced multiple technical reports and standards including the recent ISO report on nanotechnologies in health care (ISO/TR 17302).

Nanotechnology is a broad term that encompasses technologies that manipulate or exist in the scale of 0.1 to 100 nanometers. As a reference, a single base pair of DNA is 0.3 nanometer. For several decades, technologies at the nanoscale have demonstrated promise for clinical analytical technologies. Nanoscale objects not only have the potential for measuring more analytes in parallel within densely packed arrays, but nanoscale methods exploit novel physical or chemical properties that do not occur at micro or bulk dimensions. Examples of nanotechnology currently used in clinical laboratories include nanoparticle (colloidal gold)-based lateral flow immunoassays, electrochemical sensors, and DNA sequencers. The latest generation DNA sequencer from Illumina (HiSeq 4000) has etched wells of about 400 nm in diameter where clusters of DNA sequence are generated. Similarly, DNA sequencing devices from PacBio (RSII) and Oxford (MinION) have critical analytical components with manufactured features of less than 100 nm and 5 nm, respectively.

As the use of nanotechnology in the clinical laboratory grows, the safe use and disposal of nanoscale reagents need to be considered. The features of nanoscale materials that make them attractive for analytical purposes (for example, high surface area to volume ratio and increased reactivity) also result in potential greater toxicity. For instance, carbon nanotubes are thin tubes with diameters in the nanometer dimension. These thin tubes may induce chronic inflammation and cause pulmonary fibrosis in mice. Some researchers speculate there may be similarities in fibrotic potential between nanotubes and asbestos crystals. There are already existing standards for personal protection (that is, nanoparticulate safety) when handling nanoparticles as well as standards for environmental disposal.

Although there are environmental and personal safety concerns with nanotechnology, it is important to remember that manufactured nanoparticles are ubiquitous in U.S. consumer goods. The Woodrow Wilson Project on Emerging Nanotechnologies has identified more than 1,600 consumer products that have nanoparticles or nanocoatings. Indeed, titanium dioxide nanoparticles are frequently used as a whitening agent for candies and baked goods. In 2014, the FDA issued a draft guidance for the use of nanomaterials in animal feed and a separate draft guidance for nanomaterials in cosmetic products. Most pertinent to clinical laboratories, the FDA also in 2014 issued a final guidance for manufacturers to determine whether an FDA-regulated product is considered to have nanotechnology and require additional scrutiny. This final guidance may have particular relevance to in vitro diagnostic manufacturers that use nanotechnology for better analytical performance.

Nanotechnology is already present in everyday life from clothing to candies. In the clinical laboratory, nanotechnology is fundamental to innovative analytical tools such as DNA sequencers. Standards and regulations are emerging to promote health, safety, and minimal standards to meet the proliferation of nanotechnology-enriched or -enabled devices and products.

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