NANOTECHNOLOGY CHARACTERIZATION LABORATORY

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ASTM Standards for Nanoparticle Biocompatability Testing

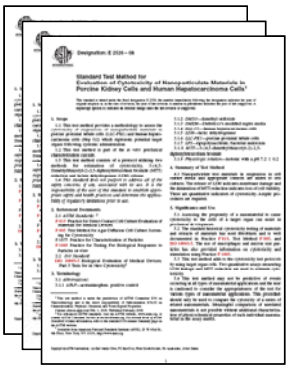
The Nanotechnology Characterization Laboratory (NCL), part of the National Cancer Institute's Alliance for Nanotechnology in Cancer, announced today that three of its methods for biocompatibility-testing of nanomaterials have been incorporated into American Society for Testing and Materials (ASTM International) standards. These are the first formal standards for biocompatability-testing of nanomaterials intended for medical applications.

ASTM voluntary consensus standards contribute to making the development, manufacturing, and supply of products and services safer, cleaner, and more efficient. In the medical and pharmaceutical fields, ASTM International standards have been used for several decades throughout the world for quality control and regulatory evaluation. Nanoparticle developers and manufacturers leverage these well-established methodologies whenever possible, but the unique properties of nanomaterials frequently limit the applicability of traditional pharmaceutical methods. For example, nanomaterials may invalidate colorimetric assays which rely on absorbance measurements. Other nanoparticles have catalytic properties that interfere with enzymatic tests or contain surfactants which may affect assay reagents. Such difficulties have necessitated the development of standards specifically for biocompatability evaluation of nanomaterials, such as the three new ASTM standards, designated E2524, E2525, and E2526.

E2526 is a method for evaluation of nanomaterial toxicity by examining effects on kidney and cancerous liver cells. Several studies indicate that many nanoparticles are cleared from the body through the kidney or liver, making these organs good choices for target organ toxicity evaluation. In this standard, two separate assays provide complementary data, so that cross-validation can be used to identify interference.

E2524 is a protocol for examining destruction of red blood cells (hemolysis). Hemolysis can lead to anemia, jaundice and other problems, so all intravenously administered pharmaceuticals must be examined in regards to their hemolytic potential.

E2525 is a method for evaluating nanoparticle stimulation or inhibition of certain bone marrow cells (macrophages). Inhibition of these cells is a common side effect of anti-cancer drugs, and these cells may be particularly sensitive to nano-scale materials.



All three of the new standards evaluate aspects of nanomaterial toxicity. Whether or not nanomaterials are more toxic than their macro-scale counterparts has been a matter of extensive debate. The scientific literature contains a wide range of findings due to the variety of assays used. Arriving at a definitive answer to this question depends on the use of standard methods, such as E2524, E2525, and E2526. These ASTM standards are being used in an ASTM-sponsored interlaboratory study involving over 100 laboratories, beginning in spring 2008. Such interlaboratory comparison and standards for nanoparticle characterization will help alleviate confusion, help dispel ambiguity, and speed the regulatory process and the translation of nanotech drugs from discovery to development.

For more information, please contact ncl@mail.nih.gov or visit http://ncl.cancer.gov/. E2524-E2526 are under the jurisdiction of ASTM Committee E56 on Nanotechnology, and its subcommittee E56.02 on Characterization: Physical, Chemical, and Toxicological Properties. For information on ASTM Committee E56 on Nanotechnology, contact Pat Picariello at ASTM International (phone: 610/832-9720; ppicarie@astm.org). ASTM International standards are available from the ASTM website, www.astm.org or from ASTM Customer Service (phone: 610/832-9585; service@astm.org).

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