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White Paper: Guidance for Evaluating Nanotechnology Risk

By George W. Pearson, CSP, ARM, Jeffery C. Camplin, CSP, CPEA, and Jolinda Cappello

Nanomaterials are engineered structures with at least one dimension of 100 nanometers or less. These materials are increasingly used for commercial purposes such as fillers, opacifiers, catalysts, semiconductors, cosmetics, microelectronics and drug carriers. Materials in this size range may approach the length scale at which some specific physical or chemical interactions with their environment can occur.

As a result, their properties differ substantially from those bulk materials of the same composition, allowing them to perform exceptional feats of conductivity, reactivity and optical sensitivity. Possible undesirable results of these capabilities are harmful interactions with biological systems and the environment, with the potential to generate toxicity. This article identifies the known or potential hazards and controls associated with various forms of nanomaterials.

Risks associated with current nanosized materials are currently undefined. At this point in time, risk from current materials appears to be manageable. However, predicted evolution and refinement of nanotechnology in the near future will require the establishment of principles and test procedures to ensure safe research, manufacture, use and disposal of nanomaterials. Evaluating these current and future risks of nanotechnology is necessary and achievable.

This article presents an overview of nanotechnology, a discussion of why there is cause for concern and a detailed review of methods to characterize the known hazards and to evaluate the potential risks

associated with operations using nanotechnology. Based on what is currently known, suggestions are offered from agencies such as NIOSH on how to control hazards in the processing and use of nano-engineered materials.

Overview of Nanotechnology

Nanotechnology is said to be the key driver of a new industrial revolution producing new business opportunities and growth. Nanotechnologists have developed industrial processes that exploit the ability to work with materials at the molecular and supra-molecular (more complex than a molecule; composed of many molecules levels, Merriam Webster) level. Engineered nanoparticles of a size less than 100 nm (0.1 μ m) include:

- carbon lattices and nanotubes;
- metal oxides;
- liposomes;
- micelles;
- polymers.

Figures 1 and 2 (p. 14 and p. 15) present additional information on the hazards of nanomaterials and their uses and properties.

What Are Nanoengineered Materials?

Nanomaterials are engineered materials that have at least one dimension between 1 and 100 nanometers (NIOSH, 2007).

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What Is Nanotechnology?

Based on ASTM's definition, nanotechnology refers to a wide range of technologies that measure, manipulate, or incorporate materials and/or features with at least one dimension between approximately 1 and 100 nanometers (nm). Such applications exploit the properties, distinct from bulk/macroscale systems, of nanoscale components (ASTM Standard E 2456-06, Terminology for Nanotechnology).

The Scale of Reference for Particles at the Nanoscale

A nanometer is equal to one billionth of a meter or 10^{-9} .

- a flea is 10^{-3} or 1 mm;
- a human hair is 10^{-4} or 80 μm ;
- a red blood cell is 10^{-5} or 7 μm ;
- a strand of DNA is 10^{-8} or 2 nm;
- a bundle of carbon nanotubes is approximately 1.4 nm wide;
- a carbon 60 fullerene (sometimes called a buckyball) is 0.7 nm.

A significant point to derive from this comparison is that a nanoparticle is considerably smaller than a red blood cell and that red blood cells move freely throughout the circulatory system of the human body from the arteries to the capillaries (Aftanski, 2005).

Cause for Concern or a Boon to Society?

Nanotechnology is used in paints and coatings, medical imaging, electronics and cosmetics as well as in other consumer products. Because of their very small size and large surface area, engineered nanomaterials present certain SH&E hazards, which are unknown with non-nanomaterials. The concern is that nanomaterials are being used in products or are being considered for other uses without a clear perspective on the SH&E impact of such uses (Knowles, 2006). At the nanoscale, the laws of physics, biology and chemistry merge and the behavior of these small particles changes, such as their mobility in the environment, reactivity, toxicity and ability to enter the human body (Hett, 2004).

Because of their small size and large surface area, nanoparticles may have

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Practice Specialty Fees to Increase

The Council on Practices and Standards (CoPS) would like to inform you that effective January 2008, the cost to join a practice specialty will increase from \$15 to \$20 (per practice specialty).

In the nearly 14 years since the last price increase, ASSE and CoPS have worked hard to keep practice specialty membership fees affordable, even during several postage rate hikes and increasing printing and publication costs. The minor \$5 increase will be used to address rising printing and postage costs as well as the additional labor and personnel needed to publish each of the 13 different technical publications and to provide our current high-caliber products

and services. It will also position the practice specialties for future growth and improvement.

Thanks to practice specialty members' article contributions, we are pleased to see that the technical publications have increased in quality and page length. Most of the technical publications now average between 16 and 24 pages of content, compared to the average length of four to six pages in 1995. And, since it is CoPS' mission to give practice specialty members only the best product possible, the small change in price will allow us to continue to offer you the superior resources you depend on and deserve. We appreciate your support and understanding.

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chemical, physical and biological properties distinctly different than larger particles of similar chemical composition. These properties may include the ability to reach the gas exchange regions of the lung, travel from the lung throughout the body, penetrate dermal barriers, cross cell membranes and interact at the molecular level.

NIOSH is investigating these properties, as it would with any new technology or material in the workplace, to provide the necessary guidance to ensure a safe and healthy workplace (NIOSH, 2007).

... nanoparticle production processes may potentially result in exposure by inhalation, dermal or ingestion routes and that little is known about current levels of exposure (Nano IH Review HSE). Several studies have shown that some of them can pass through the various protective barriers of living organisms. The inhaled nanoparticles can end up in the bloodstream after passing through all the respiratory or gastrointestinal protective mechanisms. They are then distributed in the various organs and accumulate at specific sites. They can travel along the olfactory nerves and penetrate directly into the brain, just as they can pass through cell barriers. These properties, extensively studied in pharmacology, could allow organic nanoparticles to be used as vectors to carry medications to targeted body sites. The corollary is that undesirable nanoparticles could be distributed throughout the body of exposed workers. Some of these nanoparticles have shown major toxic effects (IRSST).

Nanotechnology is too new and no large body of knowledge or experience exists. Regulatory agencies are struggling to understand how to assess the risk and to establish protocols (Aftanski, 2005).

How Did We Get Here?

Nanotechnology is advancing faster than the SH&E sciences. They have unique physical and chemical properties and they promise to drive the next industrial revolution with a limitless range of applications, from biomedical imaging, drug delivery and therapeutics to materials manufacturing, optics, electronics, energy production and quantum computing.

The unique physicochemical properties of nanomaterials also mean that they may have unique bio-availabilities and other characteristics that make them potentially toxic to humans. While the industrial applications of nanoparticles are increasing

The properties of nanosized particles present many challenges to both the medical community and to regulatory agencies in undertaking risk assessment and risk management evaluations. There have been several key environmental and worker safety issues that must be addressed in the near future.

daily, less attention has been paid to occupational safety and health concerns, possible environmental effects from workplaces manufacturing and using nanoengineered particles, or to considerations of possible health effects in the community at large. There is an urgent need to tackle these issues—many consumer products already contain nanomaterials (e.g., cosmetics, sunscreens, paints and textiles)—and many more are in development.

Today, more than 475 consumer products are on the market that range from nanoscale coatings to computer devices, sunscreens, sporting goods and medical devices (Wilson International Center for Scholars). (For a current inventory of products, visit www.nanotechproject.org.)

Governmental & Scientific Organizations Playing Catch Up

NIOSH is engaged in an aggressive research program. As the lead federal agency charged with fully understanding the hazards, human health risks and appropriate risk controls to protect the American worker, NIOSH has formed the Nanotechnology Research Center (NTRC). This is where NIOSH engineers and scientist work to unravel the mysteries associated with nanotechnology.

NIOSH has redirected funds to support NTRC by providing \$3 million in 2005, \$3.7 million in 2006 and \$4.6 million in 2007. NIOSH boasts a comprehensive research agenda targeting 10 topical focus areas they believe will help them understand potential health risks and deliver and disseminate hazard control remedies. This 10-point program covers the following topics:

- 1) toxicity and internal dose;
- 2) risk assessment;
- 3) epidemiology and surveillance;
- 4) engineering controls;
- 5) measurement methods;
- 6) exposure assessment;
- 7) fire and explosion safety;
- 8) recommendations and guidance;
- 9) communications and education;
- 10) applications.

Additional information can be found in NIOSH 2007-123 and on the NIOSH website at www.cdc.gov/niosh.

Risk Management Challenges of Nanotechnology

Nanotechnology continues to advance. Currently, risk associated with engineered nanomaterials is assumed to be relatively low because broad-scale industrial production and environmental release have yet to occur. However, as production of nanomaterials expands, the potential for human exposure and adverse health effects is also likely to increase. It is, therefore, imperative that appropriate regulatory regimens be put in place as soon as possible to provide adequate protection for workers and the community.

Many organizations other than NIOSH are seeking collaborations and partnerships to study the issue and to learn more about the SH&E hazards of engineered nanomaterials. These include governmental agencies in Canada, the U.K. and the European Union. Private institutions include the International Council on Nanotechnology

(ICON) and universities such as the University of California, Santa Barbara and Rice University in Houston, TX.

The properties of nanosized particles present many challenges to both the medical community and to regulatory agencies in undertaking risk assessment and risk management evaluations. There have been several key environmental and worker safety issues that must be addressed in the near future. Several reports have highlighted the lack of information concerning the toxicology of nanoparticles and their behavior in air, water and soil. They recommended that gaps in the data be filled in immediately to allow risk assessments to be conducted, beginning with occupational scenarios where exposures already occur.

Hazard Characterization & Control

Carefully examining the safety and health issues associated with nanomaterials and nanoparticles should help identify any differences in risks posed by manufactured nanoparticles compared with materials based on the same chemical composition. This will assist the framing of appropriate regulatory models to deal with any new risks.

The National Nanotechnology Initiative (NNI) in the U.S. has begun to systematically investigate some SH&E issues of nanotechnologies and allocated \$1.2 billion to nanotechnology research in 2006, yet as little as \$11 million was spent on safety research. A larger percentage of the NNI budget should probably be spent on safety and health.

NIOSH calls for interim precautionary measures to be implemented until more definitive measures are available. The agency reports that processes that generate nanomaterials in the gas phase or that use or produce nanomaterials as powders or slurries/suspensions/solutions (i.e., in liquid media) pose the greatest risk for releasing nanoparticles.

In addition, maintenance on production systems (including cleaning and disposal of materials from dust collection systems) is likely to result in exposure to nanoparticles if it involves disturbing deposited nanomaterials. Exposures associated with waste streams containing nanomaterials may also occur. Devices comprised of solid nanostructures, such as integrated circuits, pose a minimal risk of exposure to nanoparticles during handling except in some processes.

Formulating and processing coatings could also lead to exposure to nanoparticles. Nanomaterials that are processed by cutting and grinding can generate nanostructured particles that undergo degradation processes, which can lead to exposure by inhalation, ingestion and/or dermal penetration (NIOSH, 2006).

NIOSH & Interim Hazard Controls

The control of airborne exposure to nanoparticles can likely be accomplished by using a wide variety of existing engineering control techniques similar to those used in reducing exposures to general aerosols (NIOSH, 2006).

Nanomaterials have the greatest potential for entering the human body if they are in the form of airborne aerosols of if they come into contact with the skin. Airborne nanomaterials can become inhaled and deposited in the lungs; they can enter the blood stream and translocate to other organs.

Pulmonary inflammation and lung tumors have been observed in animal studies. Studies of exposed workers indicate a decrease in lung function and other adverse respiratory symptoms; however, these results could have been confounded by other chemicals in the same work environment. Safety concerns include powder and combustible nanoengineered materials. It is also believed there is an increased risk to dust ignition due to its increased particle surface area over more coarse materials with similar mass. Some nanomaterials can initiate catalytic reactions that would otherwise not likely be based only on their chemical composition (NIOSH, 2007).

NIOSH-Recommended Engineering Controls

Using the NIOSH interim guidelines (NIOSH, 2006), following is a summary of the suggested engineering controls. The first step in the classic hierarchy of hazard control:

- Dust collection with high-efficiency particulate air (HEPA) filters can be effective in removing nanomaterials.
- Keep work areas clean using either a HEPA-filtered vacuum cleaner or wet wiping methods.
- Do not dry-sweep or air-hose work areas.
- Use cleanup methods that prevent worker contact with wastes.
- Prohibit the storage and consumption

of food or beverages in workplaces where nanomaterials are handled.

- Provide hand-washing facilities and encourage workers to use them before eating, smoking or leaving the worksite.

- Provide quick-drenching facilities, showers and clothes-changing areas to prevent contamination (including take-home).

- No standards exist for nanomaterial penetration of apparel to prevent dermal exposure. However, test standards for clothing incorporate testing with nanosized particles and offer an indication of effectiveness (i.e., ASTM F1671-03 for penetration of bloodborne pathogens).

- Several types of respirators can provide different levels of protection when properly fit-tested on the worker:

- 1) filtering facepiece-disposable PF=10
- 2) electrometric half-facepiece PF=10
- 3) powered with loose-fitting facepiece PF=25
- 4) electrometric full-facepiece with N-100 or R-100 filters PF=25
- 5) powered with tight-fitting half-facepiece or full-facepiece PF=50 (NIOSH, 2004).

Following a public comment period, NIOSH published additional information to include specifics to help understand the control of human exposure potential (NIOSH, 2007).

It is believed that nanomaterials used in composites, surface coatings and integrated circuits may not pose a risk of exposure during handling and use; however, formulating and applying nanoscale coatings could lead to exposure. Processes developing nanomaterials in the gas phase as powders in slurries, suspensions, or solutions are likely to pose the greatest risk for releasing nanoparticles.

Tasks that may increase exposure potential are:

- working with liquid media while pouring mixing and agitating;
- nanomaterials processed in a gas phase that is not enclosed;
- handling these materials in powder form, which could be come aerosolized;
- maintaining equipment and processes that produce spills or waste;
- cleaning dust collection systems used to collect nanoparticles;
- machining, grinding, sanding and drilling are processes that could create dusts and airborne aerosols.

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NIOSH-Suggested Precautions

Implementing engineering controls as indicated is the initial step in controlling physical hazards presented by nanoparticles. Formulate and implement a risk management program to control the risk. As NIOSH suggests, the following are key elements for a risk management program applied to the processing, handling and use of nanomaterials.

- Evaluate the hazard.
 - Assess worker exposure.
 - Educate and train employees.
 - Establish methods to evaluate the effectiveness of engineering controls.
 - Develop procedures for the use of PPE, including the use of clothing, gloves and respiratory protection.
 - Follow up with a systemic evaluation of exposures and control measures to be sure risk control interventions are effective.
 - According to NIOSH, current knowledge indicates that a well-designed exhaust ventilation system with HEPA filters should be effective in removing nanoparticles.
 - Good work practices are also essential in achieving risk controls that mitigate exposure. This includes cleaning work areas with HEPA vacuums, using wet methods, preventing employees from eating food in work areas and providing adequate hand-washing facilities.
- The need for occupational health surveillance and medical monitoring is underscored by the uncertainty and the lack of available information about human health effects. NIOSH strongly suggests that every workplace involved in processing, handling and using nanoengineered materials consider the need for an occupational health and medical surveillance program (NIOSH, 2007).

Other Suggested Control Methods

- Recommend a conservative approach to the new processes (Aftanski, 2005):
- Do not accept exposure levels for non-nanosized materials as sufficient protection from nanosized materials.
 - Isolate the worker from any contact with the nanoparticles until safe exposure levels can be established. Supplied breathing apparatus and Level 3 laboratory conditions should be considered.
 - Set up a monitoring and recordkeeping system to track effected workers' health.
- Based on review of relevant docu-

Figure 1 Potential Hazards of Nanomaterials

Type of Exposure	Exposure Pathways	Potential Health Hazards
Respiratory	Inhalation	Alzheimer's disease Asthma Breathing problems Cardiovascular disease Disease similar to asbestosis Entry into bloodstream (bloodstream can carry nanoparticles to spleen, endothelium, liver and heart) Entry into brain through nasal mucous membrane (bypassing blood-brain barrier) Lung cancer Lung fibrosis Lung inflammation Nanoparticle accumulation of nanoparticles in olfactory lobe of brain
Ingestion	Atmospheric dust on food Dental fillings and implants Drinking water Food additives Toothpaste	Entry into bloodstream (bloodstream can carry nanoparticles to spleen, endothelium, liver and heart) Impaired biological, structural and metabolic processes Impaired immunity Nanoparticle absorption through intestinal tissue Nanoparticle accumulation in organs
Dermal	Penetration through skin	Entry into bloodstream (bloodstream can carry nanoparticles to spleen, endothelium, liver and heart)
Environmental	Air Groundwater Soil Waste streams Water	Cardiovascular and respiratory disease through air pollution Contamination of human and animal food chain through crop consumption Crop contamination Global pollution through water cycle Soil and groundwater contamination

ments and limited web searches, the following risk control measures are suggested (Cappello, 2005):

- Consider the lifecycle and quantity of nanomaterials produced.
- Interrupt/block pathways by which nanoparticles can enter the body.
- Limit release of nanomaterials into air, water and soil.
- Number, size and surface area of nanoparticles are factors in toxicity.
- Understand methods used in disposal of nanomaterials.
- Understand the possible interactions between nanomaterials and people/environment.
- Understand the processes and materials used in the manufacture of nanomaterials.

Best Practices

- The following best practices are provided for informational purposes. It is recognized that research is ongoing concerning health effects, engineering controls and air monitoring techniques.
- worker baseline medical surveillance;
 - effective air monitoring;
 - in-house toxicology studies;
 - design and implementation of effective control technologies;
 - capture of potential discharges to the environment;

- transparency with stakeholders (McShane, 2006).

Precautionary Perception

One of the dangers associated with introducing new technologies while safety and health knowledge gaps remain is a loss of faith in government regulatory systems and the possible triggering of a community backlash. Such resistance to technological innovation has been evident in other sectors (e.g., with genetically modified organisms) and could prove to be economically disastrous for fledgling nanotechnology industries (anon).

Guidance for the Future

As a community, we should support more research to better understand the risks of nanoengineered materials. NIOSH is off to a good start, but they are actively seeking partners to help advance their research program.

- It is suggested that those who use and process nanoengineered materials employ a conservative approach to hazard control and employ precautionary principles based on known or predictive hazards.
- When determining the nature and extent of controls, stress the hierarchy of hazard controls regarding nanohazards.
- Hedge the potential negative backlash

Figure 2 Types of Nanomaterials, Their Properties & Uses

Types of Nanomaterials	Where Found/Derived	Properties	Current Uses	Potential Uses
Biopolymers	Living cells	Complex molecules		Biocompatible sensors Simple motors
Carbon nanotubes	Graphite	Small, thin, hollow cylinders Can be multi-wall or single-wall Manufactured in various lengths and diameters Metallic Semi-conducting		Nano-electronic devices, circuits and computers
Dendrimers		Spherical molecules Can trap metal ions	Coatings and Inks Carrier molecules in drug delivery	Environmental applications
Fullerenes	Graphite Interstellar dust Geological formations on Earth	Hollow spheres Extremely stable Can withstand very high temperatures and pressures		Medical applications Creating new molecules Trapping molecules
Inorganic nanotubes		Lubricating Resistant to shockwave and impact. Catalytic reactivity High capacity for lithium and hydrogen storage		
Nanocapsules, nanospheres and nanoshells		Composed of insoluble organic polymers Capable of integration with other substances Can circulate in a living organism	Medications	Further medical applications
Nanoparticles	In nature	Particles less than 100 nm in diameter Manufactured as metal oxides	Cosmetics, Textiles Paints, Drug delivery, and Sunscreens	
Nanowires		Ultra fine wires or linear arrays Made of silicon, gallium nitrate	Semiconductor applications High-density data storage	
Quantum dots		Nanoparticles of semiconductors	Composites Solar cells Fluorescent biological labels	
Thin films, layers and surfaces		One-dimensional	Integrated circuits	

caused from knowledge gaps from such a fast-growing technology through the development of ethical use guidelines, toxicological evaluations, safe work practices and waste stream analysis. ■

Resources for Figures 1 & 2

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 George W. Pearson, CSP, ARM, is the immediate past administrator of the Risk Management/Insurance Practice Specialty and has led its discussion/research concerning the need for risk assessments of nanotechnology.
 Jeffery C. Camplin, CSP, CPEA, is the Administrator of the Environmental Practice Specialty and has led that practice specialty's concerns, discussions and research on a myriad of environmental issues.
 Jolinda Cappello is a communications specialist in ASSE's Practices and Standards Department.

Correction

In the Vol. 7, No. 1 issue of *RM/Insight*, the following sentence (page 6, column 3) in George Pearson's article "The Cost of Uncertainty" should have read: "According to NIOSH, current knowledge indicates a well-designed exhaust ventilation system with high-efficiency air (HEPA) filters should be effective in removing nanoparticles in use today." We apologize for the error.