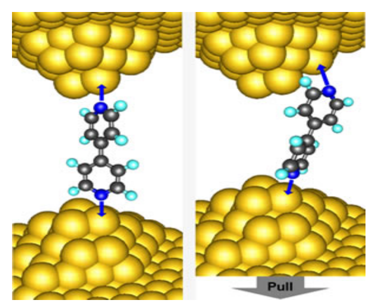
OTA Technology Guidance Document: Nanotechnology — Considerations for Safe Development

August 2010

The Concept of Safe Development

The Massachusetts Office of Technical Assistance (OTA) is responsible for helping entities in the state achieve superior environmental, health and safety performance while also improving economic sustainability. Nanotechnology is a very promising set of industries. It creates a wide range of opportunity for innovation in areas such as biomedical devices, improved electronic devices, clean energy technology, and materials engineering[1]. There is vast potential for environmental improvement, along with the economic benefits of new products of higher quality and greater variety. At the same time, there are indications of potential harm from certain exposures and releases of engineered nanoparticles (ENPs), and it is essential to recognize, reduce and control these risks when they are present. An effective program for reducing or eliminating potential risks would be premised on adequate recognition of where those risks might arise, and a continuous effort to apply preventive strategies.

Because there is much uncertainty about the potential impacts of nanomaterials, it is necessary to be attentive to new information as it develops. There is little uncertainty, however, about the current availability of means for enhancing safety for workers, waste handlers, consumers, and for protecting the environment. Good practices exist for preventing exposures and releases, and those who use or create nanomaterials should carefully consider learning about them and implementing them. The following are recommendations for enhancing the safety of this developing technology, drawn from existing resources and discussions with relevant experts. This guidance is provided for the express purpose of assisting in the development of this technology, as failure to prevent exposures or releases will not just risk harm to health or the environment – it will also impede the common interest in realizing the benefits that nanotechnology can provide.

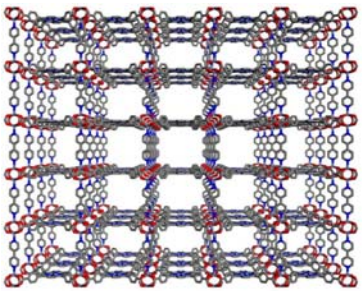


Single molecule junction switch between two nanowires (Lawrence Berkeley National Laboratory)

Recommendations for good management practices for facilities (companies, public and private research institutions, including educational facilities) handling engineered nanoparticles (ENPs) have been developed by several organizations. (See *Further Reading* at the end of this document). There are many varieties of ENPs, which differ from each other in many respects, and much remains to be understood about their interactions with biological organisms. But because studies have shown that engineering the size and

[1] Although "Most current applications of nanotechnology are evolutionary in nature, offering incremental improvements in existing products and generally modest economic and societal benefits…in the longer term, nanotechnology may deliver revolutionary advances with profound economic and societal implications." *Nanotechnology: A Policy Primer*, Congressional Research Service, 3/12/2010, p. 1. http://assets.opencrs.com/rpts/RL34511_20100312.pdf. The report's summary notes: "Since the launch of the National Nanotechnology Initiative (NNI) in 2000 through FY2010, Congress has appropriated approximately $12.4 billion for nanotechnology R&D. In addition, the President requested an additional $1.8 billion in funding for nanotechnology R&D for FY2011. More than 60 nations have established similar programs. In 2006 alone, total global public R&D investments reached an estimated $6.4 billion, complemented by an estimated private sector investment of $6.0 billion."

surface area of materials on the nanoscale[2] can alter reactivity and create other new characteristics, caution is required. Some studies have associated some inhaled nanoparticles (engineered or incidental[3]) with deleterious biological effects. These include respiratory ailments, absorption into the bloodstream, and translocation to other organs and organ systems[4] (see *Further Reading*). There is also evidence of certain particles passing the blood-brain barrier and potentially harming the neurological system.[5] A recent study measured DNA damage due to exposure to titanium dioxide nanoparticles.[6] To address gaps in knowledge, in 2008 the National Science and Technology Council of the U.S. National Nanotechnology Initiative published a strategy to accelerate progress in environmental, health and safety (EHS) research; spending on nanotechnology EHS by federal agencies since 2005 now approaches one-half billion dollars.[7] Sufficient research has already been published to establish that material risks may accompany the development of nanotechnologies.[8] Until further research is completed to understand better the toxicity and pathways of exposure for engineered nanomaterials, an assumption that there is no need to implement preventive management would be difficult to justify. The National Institute for Occupational Safety and Health (NIOSH) notes in recent guidance: "Until the results from research studies can fully elucidate the characteristics of nanoparticles that may pose a health risk, precautionary measures are warranted.[9]" A risk reduction program should be developed at facilities that are handling ENPs with the goal of preventing exposures and releases that may cause harm, even if we do not yet fully understand that risk.



Porphyrin paddlewheel framework (University of Nebraska-Lincoln)

Managers, supervisors, health and safety officers should consider the importance of communicating commitment and fostering the awareness that implements the requisite caution. Surveys of nanosafety practices have found that most companies working with nanomaterials in industrial settings have implemented some "measures aimed at reducing hazards at their source and other exposures" - however, not all have done so.[10] Establishing a risk reduction plan communicates that some risk may be present

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[2] Generally defined as from 1-100 nanometers (nm). At this level new properties emerge in many materials. For example, carbon in the form of nanotubes becomes an excellent conductor of electricity; aluminum can become explosive; normally white zinc oxide can become transparent, and catalysts can become more effective. This is the scale "at which proteins are copies and assembled, enzymes catalyze reactions, energy is transferred in and out of cells, bonds are made and broken…DNA…has a diameter of only a few nanometers". (Sean O'Donnell and Jacqueline Isaacs, "A World of Its Own", in *Governing Uncertainty, Environmental Regulation in the Age of Nanotechnology*, Ed., C. Bosso, 2010, p. 14).

[3] Incidental nanoparticles occur as byproducts of natural or industrial processes such as incineration. Although the specific concern of this guidance is with engineered nanoscale materials, (materials deliberately designed to consist of or contain structures that exploit unique properties at the nanoscale), studies of incidental nanoscale particles and other ultrafine airborne particulates are useful to provide some guidance. Epidemiological studies have shown associations between fine and ultrafine particulate air pollution and increased morbidity and mortality from respiratory and cardiopulmonary disease.

[4] See, for example, Oberdorster, et al., "Extrapulmonary translocation of ultrafine carbon particles following whole-body inhalation exposure of rats", 2002, *J. Toxicology and Environmental Health*, 65 Part A (20): 1531-1543; Donaldson et al., "Carbon Nanotubes, A Review of their Properties in Relation to Pulmonary Toxicology and Workplace Safety", *Toxicological Sciences* 2006, 92(1): 5-22; Ma-Hock, Treumann, et al., "Inhalation Toxicity of Multiwall Carbon Nanotubes in Rats Exposed for 3 Months", *Toxicological Sciences* 112(2), 468-481 (2009); Powers, Wrench, et al., "Silver Impairs Neurodevelopment: Studies in PC12 Cells", *Environmental Health Perspectives*, 10.1289/ehp.0901149.

[5] For example, Borm et al., "Potential Risks of Nanomaterials: a Review carried out for ECETOC", *Particle and Fiber Toxicology,* 2006, 3:11. For a review of the relevant literature, see *Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials, CDC/NIOSH, 2009, pp. 11-20;* the bibliography in *CDC Current Intelligence Bulletin 60*, pp. 8-12.

[6] Trouiller, et al, "Titanium dioxide nanoparticles induce DNA damage and genetic instability *in vivo* in mice", *Cancer Research,* 69, 8784, November 15, 2009.

[7] http://www.nano.gov/html/society/EHS.html; *Strategy for Nanotechnology-Related Environmental, Health and Safety Research,* Executive Office of the President, 2/08.

[8] Also see the bibliography of studies provided by the recently formed Nanosafety Consortium, consisting of "12 leading companies involved in the commercialization of carbon nanomaterials" and concerned with "responsible commercialization" of their products: http://www.nanosafetyconsortium.com/invivobibliography.html.

[9] *Approaches to Safe Nanotechnology*, 3/09, v, at: http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf.

[10] Balas, Arruebo, Urrutia, Santamaria, "Reported nanosafety practices in research laboratories worldwide", *Nature Nanotechnology,* Vol. 5, p. 93, February 2010. In research facilities, however, only about ten percent of researchers reported using nano-enabled hoods. About thirty

whenever nanoparticles are used, calling for constant attention to the need for care in handling. This precautionary approach is justified both by indications that harm can result from unintended exposure, and by uncertainties concerning how nanoparticles may interact with biological processes.

A risk reduction plan for your facility can be thought of as having two contextual levels: one, the direct and immediate, which protects personnel in the workplace where ENPs are handled, and prevents the release of ENPs from the workplace into the environment. The second level of context is the eventual potential impact of ENPs, after they have left the facility, considering possible releases during transport, use, and disposal. Strategies for preventing harm should address both contexts. The first strategic effort should be to consider design options to render products safer, and the next focus should be on containment. An effective ENP risk reduction program will not just avoid harm to workers, neighbors, consumers, sensitive species, and others, but also liabilities and business risks from actual, potential and perceived hazards. Acting to avoid harm to others is evidence of good faith, which results in a better legal position than not actively anticipating and preparing for such contingencies.[11] An effective plan will designate responsible parties, specify reporting and corrective actions to ensure that protocols are followed, and continuously evaluate effectiveness through monitoring, to achieve standards that protect people, the environment, and business goals. Safer product and process design will consider alternatives to hazardous inputs, and examine potential impacts from the generation of raw materials to the ultimate fate of materials disseminated in commerce or dispersed into the environment.

At the Facility: A program for worker safety begins with an evaluation of the potential exposures to ENPs, focusing on where they might become free to be inhaled or otherwise absorbed during synthesis, transfer, delivery of pre-manufactured ENPs, storage or use. NIOSH recommends a hierarchy of exposure control, beginning with elimination or substitution of risks at the source - potentially the least expensive and most efficient approach to safety. Next is engineering controls - removing a hazard or placing a barrier between the worker and the hazard. If well-designed, engineering controls "can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection." If hazards are still present facilities should use administrative controls and personal protective equipment.[12] Because of uncertainty, it is prudent to presume some risk is present without waiting for proof of harm, and to take action to avoid potential exposure and ensure safety. Included in this assessment should be ENP residues in equipment, used filters, and unintended releases. Because free ENPs have the potential for enhanced mobility in air, it is critical to evaluate air movement near potential release points. NIOSH recommends several methods for measuring and characterizing nanomaterial air concentrations including aerosol sampling, airborne surface area analysis, and particle number measurement.[13]

Preventive Materials Selection and Process Design If ENPs are not necessary for the process, consider substituting other materials, and consider ENPs that have lower inherent toxicity. Reducing nanotoxicity is a developing field and new findings can inform materials selection. For example, the U.S. Environmental Protection Agency funded research at Brown University exploring "methods for detoxifying nanotubes through targeted removal of the bioavailable portion of the total metal, making use of new

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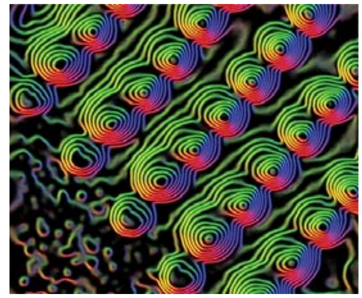
percent of researchers who stated that the materials they made could become airborne did not use any type of personal respiratory protection. "Furthermore, many research laboratories dispose of nanomaterials in the same way they dispose of other chemicals."

[11] In addition to the legal protection afforded by adequate warning, increasing confidence and trust can enhance commercial prospects. A recent survey by Michael Cobb at North Carolina State University "on public attitudes toward medical applications and physical enhancements that rely on nanotechnology shows that support for the technology increases when the public is informed of the technology's risks as well as its benefits." http://news.ncsu.edu/releases/wmscobbnanorisks/.

[12] NIOSH Topic: Engineering Controls, at http://www.cdc.gov/niosh/topics/engcontrols/.

[13] A summary of instruments and measurement methods can be found in *Approaches to Safe Nanotechnology*, p. 25 (Table 7-1). ENPs are likely to agglomerate into larger particles, making it feasible in many settings to use established air filtration technologies.

understanding of metal location, form, and release behavior in physiological fluids”[14]. The researchers also found that carbon nanotube toxicity may be reduced by modifying fiber length[15]. Others have found it may be mitigated by dispersion to prevent aggregation[16]. Researchers have noted that biological oxidative stress may be correlated with specific surface area and certain metal ions[17]. Hydrophilicity and neutral charge have been found to be “conducive to low cytotoxicity and reduced inflammation”.[18] Researchers have reduced toxicity by modifying surfaces and using coatings.[19] Addition of molecular groups to nanoparticles can significantly alter bioimpact.[20] Enrico Burello and Andrew Worth of the systems toxicology unit at the European Commission's Joint Research Centre in Ispra, Italy have created a model for estimating oxidative stress—using the expected electronic energy levels in the nanoparticle structure to assess whether the materials will likely remove antioxidants from cells or generate reactive oxygen species[21]. Product designers should familiarize themselves with this new and rapidly developing literature.



Magnetic fields around nickel nanoparticles (Courtesy of Brookhaven National Laboratory)

In addition to considering changes in input materials, safety can be enhanced by evaluating processing steps. For example, a recent investigation of airborne exposures to nano particles and fibers generated during dry and wet abrasive machining showed that “Wet cutting, the usual procedure for such composites, did not produce exposures significantly different than background whereas dry cutting, without any emissions controls, provided a worst-case exposure”[22].

<u>Containment</u> Design engineering controls for potential release points, including containment and local ventilation to prevent release of the ENPs into the workplace, using High Efficiency Particulate Air filters. Use the se filters as well at all environmental air emission points, to prevent release to the environment. NIOSH expects that “for most processes and job tasks, the control of airborne exposure to nano-aerosols can be accomplished using a variety of engineering control techniques similar to those used in reducing exposure to general aerosols”.[23]

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[14] Hurt, Kane, “Physical and Chemical Determinants of Nanofiber/Nanotube Toxicity”, 2007, at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7386/report/F.

[15] Liu, Kulaots, Kane, and Hurt, “Progress in the Design of Carbon Nanotubes for Environmental Health and Safety”, (Brown University), presented at Environmental Implication and Applications of Nanotechnology, 6/9-11, 2009, UMass Amherst.

[16] Mutlu, Budinger, Green, et al., “Biocompatible Nanoscale Dispersion of Single-Walled Carbon Nanotubes Minimizes in vivo Pulmonary Toxicity”, Nano Letters, 2010, Articles ASAP, DOI: 10.1021/nl9042483.

[17] Bello, Hsieh, Schmidt, and Roger, “Using Biological Oxidative Stress to Understand and Characterize Exposures to Nanomaterials”, (University of Massachusetts at Lowell), presented at Environmental Implication and Applications of Nanotechnology, 6/9-11, 2009, UMass Amherst.

[18] Reijnders, “Hazard Reduction in Nanotechnology”, *Journal of Industrial Ecology*, 6/08, p. 301, citing Vonarbourg, et al., “Parameters influencing the stealthiness of colloidal drug delivery systems, *Biomaterials* 27(24), 4356-4373, 2006.

[19] Ibid.

[20] Gao, Wang, “Fullerene Derivatives Induce Premature Senescence”, ***Toxicology and Applied Pharmacology*** Volume 244, Issue 2, 15 April 2010, Pages 130-143. Chemically modified fullerenes have impacts on cells that pristine fullerenes do not.

[21] E Burello and A P Worth, Nanotoxicology, 2010, DOI: 10.3109/17435390.2010.502980 . Philip Broadwith writes on the Royal Society of Chemistry’s Chemistry World blog (http://www.rsc.org/chemistryworld/News/2010/July/26071001.asp#): “The team's results correlate well with known toxicity data, for example titanium dioxide nanoparticles are known to produce oxidative stress and the model predicted them to have the right energy levels to do so. However, Burello stresses that so far the model only incorporates one mechanism of toxicity. 'We focused on oxidative stress because it's quite well known and an important mechanism of action,' he says, adding that they are now trying to build in other factors such as ions leaching from the particles, interactions with proteins and lipid membranes. 'For each one we're starting to identify the correlated properties and build up a mechanism of action.'” See also: *Review of computational approaches for predicting the physicochemical and biological properties of nanoparticle*s, Saliner, Burello, Worth, Joint Research Center Scientific and Technical Reports, 2009, http://ecb.jrc.ec.europa.eu/documents/QSAR/EUR_23974_EN.pdf.

[22] Bello, Wardle, et al. “Exposure to nanoscale particles and fibers during machining of hybrid advanced composites containing carbon nanotubes”, *Journal of Nanoparticle Research,* 11 (1). pp. 231-249, http://dx.doi.org/10.1007/s11051-008-9499-4.

[23] *Approaches to Safe Nanotechnology*, p. vii.

Consider fixation for dry powders, which pose the greatest threat for inhalation. Bind free ENPs in liquids, gels, solids, or slurries, and avoid the creation of aerosols. [24] Work with nanomaterials can be performed in a contained environment such as a directionalized laminar flow fume hood or a glove box. (Note that research has shown particles may escape from conventional fume hoods).[25] Local exhaust at emission points has been effective in the pharmaceutical industry for handling very small, hazardous particles[26]. Handling of materials should also be confined to an isolated workspace or one that is reasonably distanced from other workers. Capture ENPs that could adhere to workclothes or other transportable items. Note the possibility for resuspension of settled particles. The various means to prevent exposure should be tailored to the circumstances of handling and use. Mike Ellenbecker and Candace Tsai of the University of Massachusetts at Lowell's Work Environment Program conducted evaluations of exposures in laboratories handling nanomaterials, and found that significant exposures were measured in some laboratories, engineering and administrative controls are effective to reduce exposures, fume hoods may not offer adequate protection, and proper design and operation of ventilation are required for effective control.[27]

Proper Personal Protective Equipment (PPE) should be required when containment cannot prevent exposure to ENPs. Accurate determination of particle penetration in skin may be difficult, and may be influenced by chemical carriers. NIOSH is currently conducting research in this area, and recommends that current industrial hygiene best practices (such as paying particular attention to abraded or lacerated skin) should be followed until more specific data exists.[28] Use clothing appropriate for wet-chemistry laboratory operations (closed-toed shoes, long pants without cuffs and long sleeved shirt, laboratory coats, proper eye protection, and nitrile or latex gloves).[29] To select appropriate respirators, see NIOSH Respirator Selection Logic at www.cdc.gov/niosh/docs/2005-100/default.html)[30], and institute a program including training, fit testing, evaluating respirator impact on ability to perform work, monitoring, and respirator maintenance. In cases where respirators are not required but precaution suggests their use, dust masks or disposable respirators with an N95 or higher filter rating are recommended.[31] Note that when respirators are necessary to protect worker health, OSHA's respiratory protection standard (29 CFR 1910.134) triggers medical evaluation requirements.[32]

Beyond the Facility: Preventing facility releases should be an integral part of the program, and evaluated along with worker safety. Areas to be evaluated include contaminated waste, disposal of liquids, and potential air releases. For example, unbound engineered nanoparticles could leave the facility when items or equipment are washed. Consider whether waste water systems will capture ENPs, and if they will remain safely bound in treatment residues such as sludge, filters, or absorption media. Consider where drains go, as research has shown some ENPs are toxic in aquatic biological systems.[33] Best practice would aim to prevent any drain discharge of ENPs. Implement safe-change procedures for used HEPA

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[24] The British Standards Institute recommends binding powder nanomaterials in liquid or solid media. "Dispersions, pastes or pelletized forms should be used instead of powder substances wherever this is technically feasible." *Part 2: Guide to safe handling and disposal of manufactured nanomaterials,* BSI, p. 12, at http://www.bsigroup.com/en/sectorsandservices/Forms/PD-6699-2/Download-PD6699-2-2007/.

[25] Tsai, Barry, Ellenbecker, "Assessment and Characterization of Exposures to Airborne Nanoparticles Associated with Typical Industrial Processes", (University of Massachusetts Lowell), presented at Nanotech Conference and Expo, Houston Texas, 5/3-7, 2009. A Fast Mobility Particle Sizer (FMPS) found elevated concentrations compared to the background in most laboratories.

[26] Geraci, "Good Current Practices for Managing Nanomaterials", CDC and NIOSH, 2nd Annual Massachusetts Nanotechnology Workshop, 1/29 2009, Boston, Massachusetts.

[27] Presentation, Toxics Use Reduction Act 20th Anniversary Symposium and Conference November 4, 2009.

[28] *Approaches,* p. 44.

[29] Ellenbecker, *Interim Best Practices for Working with Nanoparticles,* Center for High Rate Nanomanufacturing, Draft 3, 10/12/07.

[30] And consult *Approaches*, pp. 44 – 51.

[31] Ellenbecker, Mike. 2007. *Interim Best Practices for Working with Nanoparticles: Center for High-Rate Nanomanufacturing.* DRAFT-November.

[32] NIOSH,*Current Intelligence Bulletin: Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles.* 2009, p. 4

[33] For example, Laban, Nies, et al., "The effects of silver nanoparticles on fathead minnow (Pimephales promelas) embryos". *Ecotoxicology*, 2010; 19 (1).

filters in ventilation systems. Make sure that facility comfort heating, ventilation and air conditioning systems are also evaluated for their capacity to transfer ENPs and keep "clean room" work areas under negative air pressure.[34]

Cleanup, Storage, Transfer Prohibit cleaning with dry methods, such as sweeping or blowing air, and consider the fate of particles captured by wet cleaning. Consider nonroutine activities, such as equipment cleaning or decommissioning. Consider using enclosed vacuum systems to transfer materials, and "clean-in-place" systems that do not require dismantling of the equipment where ENPs are used. Establish protocols to ensure the proper handling of wastes contaminated by ENPs, such as wipes, PPE, workclothing, and any material in which ENPs have become trapped, could break free, or leach out[35]. Enclose all ENP containers, including waste, with secure caps or covers, and instruct handlers, through appropriate labeling, in preserving containment controls.

Waste Shipments Ensure waste transporters are aware that they are carrying waste containing ENPs, and include in waste management contracts assurances that the waste material from your facility will be handled and disposed of safely, such as that the ENPs will be fixed in solid media or enclosed until destruction or permanent isolation (in order to protect waste management workers as well as to prevent releases to the environment). Before sending for incineration, determine if that method will effectively destroy the waste. The hazardous waste management system presents a comparatively secure option; however, if the waste is not regulated as hazardous, waste companies will not be required to handle it with requisite precaution once they take possession. Therefore, contracts should contain sufficient specificity to ensure continuous proper management.

Employee Involvement Educate all employees handling engineered nanomaterials in facility protocols for waste disposal, waste management and cleaning, including incidents of mismanagement discovered through assertive monitoring. Ask for suggestions as part of an effort for continuous improvement.

Beyond Immediate Application: Evaluate impacts of use and post-use disposition in order to protect consumers and others, and your organization from potential product, contract, tort, or other liability. Will the use of the product, or its disposal, result in the release of ENPs? Consider that products end up in landfills, incinerators, compacters, can become degraded through exposure to the elements, and can potentially reach all environmental media. Those facing such possible exposures, or faced with cleanup costs, may argue that they had a right to know about the presence of ENPs. Liability is most likely to apply in civil litigation to risks that are reasonably foreseeable. Thinking through the life cycle of the product, and who faces risks of exposure down the line, is a starting point for assessing where disclosure may be advisable. Place yourself in the context of the product recipient and ask, "would I wish to be informed of the presence of this material?" Keeping up to date on the information about potential risks is key to making this judgment. Consider that it is not always information that you know about, but information that you should have known about, that determines the standard to which you may be held.

Labeling The British Standards Institute's labeling guidance recommends providing labeling on the product itself or its packaging, when "any different handling, maintenance, cleaning, storage or disposal of the product is advised as a consequence of nanoparticle content".[36] The Guidance conforms to the General Product Safety Directive of the European Union that consumer products should not be sold with

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[34] *Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings*, ASTM Standard E 2535-07.

[35] *BSI Guide to Safe Handling and Disposal* recommends that "Any material that has come into contact with dispersible manufactured nanoparticles (that has not been decontaminated) should be considered as belonging to a nanomaterial-bearing waste stream." (p. 22).

[36] British Standards Institute, *Guidance on the labeling of manufactured nanoparticles and products containing manufactured nanoparticles,* 12/07, p. 7.

"known irreducible risks inherent in their use unless consumers are provided with appropriate information (i.e. warnings or instructions) enabling them to assess the risks and protect themselves from harm."[37]

Potentially Affected Entities Consider consumers, workers who use materials containing ENPs, and workers who will come in contact with wastes containing ENPs. Review Material Safety Data Sheets and consider whether their statement of physical characteristics is sufficiently comprehensive, and if new protective recommendations need to be added. Consider whether the release of ENPs during use or post-use disposition will be toxic to any receptors in the environment, such as aquatic organisms. If these considerations suggest the need for warnings, reconsider the product make-up as well, investigating whether the inherent hazard can be designed out. It may also be possible to mitigate any harm by establishing a post-use product recovery system.

Proactive Compliance Communicate with agencies that have regulatory authority over the risks the product could cause. For example, a new nanoform of an existing chemical can trigger the Significant New Use Rule of the Toxic Substance Control Act. Consulting with the U.S. Environmental Protection Agency on regulatory status at the outset will avoid penalties for not complying with reporting requirements that turn out to be applicable.

Transparency An open and transparent program for testing can provide useful information for safe design and handling, and disclosure, including the evaluation of releases or impacts in use, after disposal, and the durability of products under various scenarios. Good faith attempts to address harm before it manifests are generally a good means of guarding against the potential for legal liability.

Recognizing the Value of Prevention Preventing harm has long been shown to be the most cost-effective means of addressing risk, but its value is often unrecognized because when costs are prevented from manifesting, they are not visible. A program of risk reduction that encompasses the life cycle of products and materials containing engineered nanoparticles will pay for itself by establishing the firm foundation of trust necessary for new nanotechnologies to gain full acceptance and thrive. Indications of risk are sufficient to warrant a strong commitment to prevention. Failing to prevent these risks from having impacts will likely create obstacles to further technological development.

Realizing the Value of Nanotechnology There is no doubt that nanotechnologies hold great promise of societal benefit, in many fields, including health and the environment.[38] For this promise to be realized, preventive EHS management must be a core value of the enterprise.

Further Reading: Available Guidance on ENP Risk Reduction

Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials, NIOSH, 2009. http://www.cdc.gov/niosh/topics/nanotech/safenano/

Current Intelligence Bulletin: Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles, NIOSH, 2009

Good Nano Guide (Interactive Forum): http://www.goodnanoguide.org

[37] Ibid, p. 6

[38] "The world of the future will be defined by how we use this mastery…The benefits of nanotechnology, both current and future, are hard to exaggerate." J. Clarence (Terry) Davis, "Nanotechnology, Risk and Governance," in foreword to *Governing Uncertainty*, *supra*, n. 2, at xii.

Guidance for Handling and Use of Nanomaterials at the Workplace, BAUA, 2007

Guide to Safe Handling and Disposal of Manufactured Nanomaterials, British Standards Institute, SAFENANO, and the Institute of Occupational Medicine, 2008.

Interim Best Practices for Working with Nanoparticles: Center for High-Rate Nanomanufacturing, Ellenbecker, 2007.

International Council on Nanotechnology at Rice University: http://icon.rice.edu/

Nano Risk Framework, Dupont, Environmental Defense Fund, 2007: http://www.nanoriskframework.com.

Nanotechnology Environmental, Health and Safety: A Guide for Small Businesses, NanoSafe, Inc.

Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupation Settings, ASTM International, 2007.

For Assistance:

Contact the Massachusetts Office of Technical Assistance and Technology (OTA), a confidential service, for assistance with compliance or performance improvements relating to the safe development of nanotechnology (http://www.mass.gov/eea/ota/, Rick Reibstein, (617) 626 1062).

Contact the Massachusetts Division of Occupational Safety, the state's OSHA consultation program, for assistance with workplace safety (http://www.mass.gov/dos, *(*617) 626-2975).

Contact the Massachusetts Department of Environmental Protection if you are interested in participating in open meetings on nanotechnology, or require clarification of regulatory requirements (http://www.mass.gov/dep/, (617) 292-5500).

Contact the University of Massachusetts Work Environment program for assistance with measuring or preventing exposures in the workplace (http://www.uml.edu/college/she/WE/, (978) 934-3250).

The Office of Technical Assistance and Technology (OTA) has developed several guidance documents. To see the other guidance documents please visit: http://www.mass.gov/eea/ota. OTA is a non-regulatory office within the Executive Office of Energy and Environmental Affairs (EEA) that provides a range of non-regulatory assistance services to help businesses cut costs, improve chemical use and energy efficiency, and reduce environmental impact in Massachusetts. For further information about energy efficiency and renewable energy, or about OTA's technical assistance services, contact:

Office of Technical Assistance and Technology, 100 Cambridge St., Suite 900, Boston, MA 02114

Phone: (617) 626-1060 Fax: (617) 626-1095 Website: http://www.mass.gov/eea/ota