Nanotechnology Environmental, Health and Safety: A Guide for Small Business

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The opinions expressed in this report are those of the author and do not necessarily reflect views of the Woodrow Wilson International Center for Scholars or The Pew Charitable Trusts.

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Preface

At least 600 businesses work on nanotechnology in the United States,[i] of which small firms or startups make up the majority. Small and medium-sized businesses and laboratories face unique challenges; in particular, many indicate that they lack the resources and the necessary information to deal with nanotechnology environmental, health and safety (EHS) issues in the workplace.[ii] Studies continue to show that nanobusinesses need information and guidance in order to adequately manage potential EHS risks associated with nanotechnology.[iii, iv]

It's understood that dealing with uncertain risks from engineered nanomaterials to human health and the environment is not an easy task. However, it is an important and critical one given that some of the properties of materials at the nanoscale may present harm to human health and the environment.[v] As nanomaterial manufacturing expands, and companies—particularly small businesses—seek guidance to help them ensure their processes and products are safe, this report helps with the development of EHS risk management approaches and practices.

This report was written by Matt Hull, who in 2003 initiated the concept of an integrated EHS approach for nanobusiness operations and in 2005 persuaded his employer (a manufacturer of carbon nanomaterials) to pursue research to proactively minimize worker exposure to nanomaterials and consider life cycle impacts of nanomanufacturing. That effort resulted in the NanoSafe five-point program, a practical near-term risk management approach developed at the interface between industry, academia, and authoritative agencies such as the National Institute for Occupational Safety and Health (NIOSH). It encourages proactive engagement on environmental safety issues in the nanotechnology workplace within five components: (1) facility management, (2) product stewardship, (3) workforce protection, (4) environmental management, and (5) emerging technologies and strategies.

This report describes the NanoSafe framework and presents resources and information that can aid nanobusinesses. It is intended to serve as an information resource for small businesses and laboratories that are interested in developing their own proactive approaches for managing nanotechnology EHS risks. Managing risks earlier rather than later will not only protect workers and users of nanomaterials and nanoproducts, but will help protect firms from potential liability or regulatory risks. In addition, proactive EHS programs enhance the public image of nanobusinesses to consumers (both individuals and other firms).

This report serves as a useful source of information for small businesses and laboratories interested in assuring the safety of their workers and users of their products.

--David Rejeski
Director, Project on Emerging Nanotechnologies

[i] Based on *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, May 2007, Available at: http://www.penmedia.org/maps/mappage.html (accessed November 16, 2007). Numbers are drawn from publicly available lists; the actual number of companies working in nanotechnology is likely to be much higher.

[ii] Lekas, D., R. Lifset and D. Rejeski. "Nanotech Startup Concerns, Information Needs, and Opportunities to Proactively Address Environmental, Health, and Social Issues: Focus on Firms in Connecticut and New York." Master's-degree project completed at the School of Forestry and Environmental Studies, Yale University. Available at www.nanotechproject.org/file_download/87. July 2006.

[iii] Lindberg, J. and M. Quinn. A Survey of Environmental, Health and Safety Risk Management Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region, Department of Work Environment and the Lowell Center for Sustainable Production, University of Massachusetts Lowell, Prepared for the Project on Emerging Nanotechnologies. December. 2007.

[iv] Gerritzen, G., L. Huang, K. Killpack, M. Mircheva and J. Conti. A Survey of Current Practices in the Nanotechnology Workplace. Produced for the International Council on Nanotechnology by the University of California Santa Barbara. November 13, 2006.

[v] Maynard, A. D., Aitken, R. J., Butz, T., Colvin, V., Donaldson, K., Oberdörster, G., Philbert, M. A., Ryan, J., Seaton, A., Stone, V., Tinkle, S. S., Tran, L., Walker, N. J. and Warheit, D. B. Safe Handling of Nanotechnology. *Nature* 444:267-269. 2006.

About the Author

Matthew Hull has led research programs exploring applications and implications of engineered nanomaterials in environmental systems for agencies such as the US Department of Defense, US Environmental Protection Agency, National Aeronautics and Space Administration, and the UK Department of Environment Food and Rural Affairs. He has written and presented extensively on the environmental applications and implications of nanotechnology in international forums and in 2007 was appointed to the US Nanotechnology Technical Advisory Group (nTAG) and to the President's Council of Advisors on Science and Technology (PCAST).

Mr. Hull served as Principal Investigator at Luna Innovations Incorporated (Blacksburg, VA) from 2003 to 2007, where his research focused on developing technologies and strategies to protect human and environmental health. In 2003, Mr. Hull developed the concept for the NanoSafe™ framework, which provides a practical and integrated approach for proactively addressing nanotechnology environmental health and safety issues in nanotechnology facilities (particularly small and medium-sized enterprises). To advance and validate all aspects of the integrated framework, he initiated and sustains an active program of communication and collaboration with other EHS experts in industry, academia, and government.

Currently, Mr. Hull serves as President of NanoSafe, Inc., a start-up company headquartered in Blacksburg, VA, which is focused on providing products and services for the safe development, manufacturing, and application of emerging nanotechnologies. In addition to his role with NanoSafe, Inc., Mr. Hull is a National Science Foundation doctoral fellow in the Department of Civil and Environmental Engineering at Virginia Tech (Blacksburg, VA) where his research is focused on understanding the applications and implications of engineered nanomaterials in environmental systems. He has an M.S. in Biology from Virginia Tech and a B.S. in Environmental Science from Ferrum College (Ferrum, VA).

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Overview

Recent studies have shown that information gaps pose the greatest challenge to nanotechnology firms' identification and successful management of nanotechnology environmental health and safety (EHS) risks. This guide will help nanotechnology entities, particularly small businesses, to close these gaps.

As summarized below, each section of the report presents key points and resources associated with the five elements of the NanoSafe approach[1,2]: (1) facility management, (2) product stewardship, (3) workforce protection, (4) environmental management, and (5) emerging technologies and strategies. Each section contains information that will help the reader better understand:

- Federal agency involvement
- Definitive (or Credible) EHS reports and publications
- How to keep abreast of best practices for the management of risks

The remainder of this overview defines these elements and highlights key points and resources covered in each section.

FACILITY MANAGEMENT

Summary: Uncertain risks place unique demands on facilities and facility managers. Specialized equipment, monitoring strategies, updated organizational structures, and revised working practices may be required.

Key Points:

- Start by consulting the 'OSHA [Occupational Safety and Health Administration] Handbook for Small Businesses,' available at www.osha.gov/Publications/osha2209.pdf. The OSHA handbook contains a useful 'Hazard Assessment Checklist' that addresses a broad range of potential hazards in the workplace. While the checklist is not intended to be 'nano-specific', readers will find that many elements of the list are useful for uncovering emerging nanotechnology EHS risks in the workplace.

- Consult references such as 'Approaches to Safe Nanotechnology: An

[1] Hull, M.S., S.R. Wilson, M.D. Hoover, 2005. Understanding and assessing an emerging technology in practice: an innovative industry/government partnership. Poster presentation at the Second International Symposium on Nanotechnology and Occupational Health. Minneapolis, MN.
[2] Hull, M.S., M.D. Hoover, C.L. Geraci, 2006. Update on understanding and assessing an emerging technology in practice: continuation of an innovative industry/government partnership. Poster presentation at the International Conference on Nanotechnology Occupational and Environmental Health and Safety: Research to Practice. Cincinnati, OH.

Information Exchange with NIOSH [the National Institute for Occupational Safety and Health],' which is available at www.cdc.gov/niosh/topics/nanotech/safenano, and the Environmental Defense-DuPont Nano Risk Framework, which is available at www.nanoriskframework.com. Both resources provide comprehensive and specific information to assist EHS personnel with making informed decisions regarding the management of emerging nanotechnology EHS risks. More recent resources provided by ASTM International and the British Standards Institute will also contain useful information.

- In areas where significant questions remain, establish partnerships with groups such as the NIOSH Field Team (see http://www.cdc.gov/niosh/docs/2008-121/) and/or university and government laboratories or qualified EHS consultants.

PRODUCT STEWARDSHIP

Summary: Any product poses an inherent risk to consumers and the environment. Ultimately, generators of these products are responsible for testing these materials to ensure their safety to consumers. Generators are also responsible for communicating possible hazards through accurate product labels and material safety data sheets (MSDS).

Key Points:

- Resources are available to assist entities with taking steps to identify, quantify, and manage potential risks of products to employees, consumers, and the environment. Some of these resources include the Nanoparticle Information Library maintained by NIOSH (www.cdc.gov/niosh/topics/nanotech/NIL.html); collaborations with universities and government laboratories; the National Nanotechnology Initiative (NNI)-mandated National Nanotechnology Characterization Centers (www.nano.gov/html/centers/home_centers.html); and the International Council on Nanotechnology (ICON) Nanotech EHS Reference Database (icon.rice.edu/research.cfm).

- Entities developing and commercializing nanotechnology products should consider 'Product Stewardship' approaches integrating Life Cycle Assessment. These strategies may help developers identify and manage risks from the earliest stages of product conceptualization to disposal and/or recovery/reuse.

- Comprehensive stewardship efforts assist generators with characterizing their products and ultimately, determining possible hazards to consumers and the natural environment. Information obtained by the generator and/or third parties can then be conveyed to workers and consumers through MSDS and product labels. Care should be taken to avoid characterizing the properties of a given nanoscale material simply based on the properties of the same material at the bulk-scale. Any such claims should be supported by data.

- According to U.S. federal agencies such as the Consumer Product Safety Commission (CPSC) and OSHA, generators of nanotechnology-based products are ultimately responsible for determining and communicating potential hazards associated with their products. Resources and guidelines are available to assist generators with this process.

- Voluntary stewardship programs are one approach that has been taken by Federal governments in the UK and US to address emerging nanotechnology EHS risks.

WORKFORCE PROTECTION

Summary: Employees are on the 'front lines' for exposures. Routine health surveillance may help identify and mitigate possible health risks to employees at the earliest stages. Workplace monitoring programs may be useful for characterizing exposures. New strategies and tools for health surveillance and workplace monitoring may be needed.

Key Points:

- The nanotechnology workforce is growing and thus opportunities for exposure to engineered nanomaterials are increasing—particularly in workplaces where these materials are generated and handled. To ensure worker safety amidst uncertain nanotechnology EHS risks, health surveillance strategies should be considered in order to identify and track health problems attributable to workplace operations. Since its inception, NIOSH has played an important role in the development and refinement of occupational health surveillance programs.

- Workplace monitoring typically is incorporated into an employee health surveillance program. Monitoring helps quantify and track physio-chemical parameters that may be linked to employee health outcomes.

- Quantifying employee health before the employee begins a particular job function provides a baseline health profile to which future health screens may be compared. In this regard, the coupling of baseline and periodic health screens may help identify potential health hazards at their earliest and most correctable stages.

- The specific elements of an employee health surveillance and/or monitoring program for the nanotechnology workplace have not yet been defined.

ENVIRONMENTAL MANAGEMENT

Summary: Environmental emissions (i.e., air, wastewater, solid wastes) from nanotechnology facilities may contain engineered nanomaterials. It is currently unclear what environmental risks are posed by such emissions. Proactive approaches to evaluating the properties of these emissions and/or managing them may be important for protecting public health and the natural environment. In the US, environmental regulatory policies are in place that applies to products and emissions containing engineered nanomaterials.

Key Points:

- While initial safety concerns focus primarily on potential human health hazards in the workplace, it is important for nanotechnology facility operators to consider downstream implications of emerging nanotechnologies on the natural environment. Facility managers may consider mapping their manufacturing processes and/or laboratory handling procedures to identify potential release scenarios in air emissions, process water, and/or solid waste streams. For organizations with sufficient resources, efforts may be taken to modify processing steps and/or implement control technologies to reduce or eliminate unintended environmental emissions.

- Many nanotechnology organizations are unclear as to how current state and federal environmental regulations relate specifically to nanotechnology. Studies have shown that many existing environmental statutes (the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Clean Air Act, and the Federal Insecticide, Fungicide, and Rodenticide Act) apply to nanomanufacturing and associated products and/or wastes. Other environmental statutes may apply or may soon apply to nanomanufacturing. These include the Comprehensive Environmental Response, Compensation and Liability Act, the Clean Water Act, and other new approaches (Environmental Management Systems/Innovative Regulatory Approaches) customized specifically for nanomanufacturing facilities.

- Comprehensive life cycle assessment approaches (i.e., cradle to grave) may help identify, mitigate, and communicate possible environmental hazards associated with engineered nanomaterials and nano-enabled products.

EMERGING TECHNOLOGIES AND STRATEGIES

Summary: Given the frequent emergence of new findings and differing opinions on nanotechnology EHS issues, organizations may consider participating in forums that facilitate the exchange of 'lessons learned' and new information.

Key Points:

- A group of international experts recently published a paper in *Nature* describing ‘Five Grand Challenges’ for nanotechnology EHS research.[3] These challenges represent key areas where information is limited, yet especially critical. Given the significance of emerging technologies and strategies in these five areas, EHS professionals may wish to familiarize themselves with the current status, trends, and implications of research underway in these areas.

- Many organizations, particularly small laboratories and start-up companies, lack the resources to effectively implement robust and forward-looking EHS management approaches. For these organizations, technology development partnerships may be an effective means for accessing expertise and equipment. Moreover, at this early stage of development, new strategies and tools developed through such partnerships may improve the safety of emerging nanotechnologies and thereby possess marketable value.

- Nano entities may also wish to take advantage of a number of key resources and activities (such as those presented in this guide) that can provide emerging and practical information on managing EHS issues.

[3] Maynard, A. et al., 2006. Safe handling of nanotechnology. *Nature* 4444: 267-269.

Introduction

Near-Term Management of Emerging Nanotechnology EHS Risks

The availability of proven approaches to effectively manage workplace and environmental exposures to engineered nanoparticles is understandably limited due to the relative novelty of this emerging technology—*there is simply not enough information currently available to justify either the need for or exclusion of specialized management strategies*. Nevertheless, growth of the nanotechnology industry and associated manufacturing and application of engineered nanoparticles has surged in recent years. Nanotechnology was incorporated into more than $50 billion in manufactured goods in 2006[4] and is projected to reach $2.6 trillion, or about 15 percent of total global output, by 2014.[5] This growth, coupled with emerging studies cautioning that some engineered nanomaterials may have toxicological properties stemming from their small size, has created human and environmental health risks—either actual or perceived—that must be managed. Consequently, some have reasoned that until a scientifically-founded and thoroughly documented nanotechnology health and safety management paradigm is developed, it is prudent for nanotechnology-related enterprises to adopt proactive 'good practices' approaches to minimize any potential health and safety risks to employees, surrounding communities, and end-users of nanotechnology-based products.[6]

In spite of the obvious need for a long-term management plan for emerging nanotechnology environmental health and safety (EHS) risks, practical strategies that can be readily implemented in a range of facilities are needed in the *near-term* to manage the most pressing potential risks to human health and the environment. Without effective near-term strategies, the uncertainty of EHS risks associated with some engineered nanomaterials may pose challenges to widespread acceptance of emerging nanotechnologies, many of which address important societal needs, such as next-generation cancer therapeutics, modulation of the human immune system, improved materials for energy storage, and advanced treatment systems for purification of drinking water.

As the field of nanotechnology continues to advance, stakeholders such as the companies that create and market nanomaterials have an unprecedented opportunity to proactively address and minimize risks, engage and educate the public, and ultimately, effectively develop and commercialize nanotechnologies

[4] Lux Research, 2007. Profiting from International Nanotechnology, Report Press Release: Top nations see their lead erode. Lux Research Inc., New York, NY.
[5] Lux Research, 2006. *The Nanotech Report™: Investment Overview and Market Research for Nanotechnology*. 4th edition, volume 1. Lux Research Inc., New York, NY.
[6] The Royal Society and The Royal Academy of Engineering (London), 2004. Nanoscience and nanotechnologies: opportunities and uncertainties. Available at: www.royalsoc.ac.uk/policy.

whose societal benefits are found to outweigh their associated risks. In order to accomplish this, however, corporate stakeholders, particularly small and start-up businesses must be convinced that they can address emerging EHS concerns without sinking their business in the process. Small companies and young start-ups teetering on the brink of major product discoveries are highly limited with respect to the resources they can dedicate to proactive EHS management strategies. Thus, the purpose of this document is to provide an information resource primarily for those organizations as they attempt to navigate the complex and emerging nanotechnology EHS landscape.

Uncovering EHS Information Gaps

The 'Survey of Current Practices in the Nanotechnology Workplace'[7] produced by the International Council on Nanotechnology (ICON) in collaboration with researchers from the University of California at Santa Barbara (UCSB) provides the most comprehensive information to date on the EHS management concerns expressed by key stakeholders working with nanomaterials. The report states that organizations cite a "lack of information" as the primary barrier to implementation of effective risk management strategies for emerging nanotechnology EHS risks. Consequently, these organizations seek "new information from scientific literature and governmental guidelines for help in assessing the risks related to their nanomaterials and the appropriate steps that should be taken to address them." The survey further declares that there is strong demand for "additional industry and governmental guidance in risk assessment and EHS practices."

In addition to the general need for more guidance and information, below is a list of several examples of specific EHS issues faced by companies and laboratories identified by the ICON/UCSB survey:

1. Basing safety strategies on properties of bulk materials;
2. Failure to monitor the workplace or environment for fugitive particle emissions; and
3. Failure to provide formal guidance to downstream users on the safe handling and disposal of nanomaterials.

Other surveys have yielded results similar to those obtained through the ICON/UCSB work. For example, a survey of nano startup firms in Connecticut and New York in 2006 revealed that a lack of information is a major barrier to implementing EHS approaches dealing with nanomaterials.[8] However, firms'

[7] Gerritzen, G., L. Huang, K. Killpack, M. Mircheva and J. Conti. A Survey of Current Practices in the Nanotechnology Workplace. Produced for the International Council on Nanotechnology by the University of California Santa Barbara. November 13, 2006.
[8] Lekas, D., Lifset, R, and D. Rejeski, 2006. Nanotech Startup Concerns, Information Needs, and Opportunities to Proactively Address Environmental, Health, and Social Issues: Focus on firms in

perceived ability to proactively manage potential risks varied depending on company size, resources, and internal leadership on EHS issues. Overall, firms indicated a strong preference for receiving information on nanomaterial precautionary measures electronically and from a government source. Findings from a more recent survey, including in-depth interviews, of nano firms in New England states show that firms (both large and small) want technical environmental management assistance.[9] In addition, this study found that 80 percent of the large firms (as compared to 33 percent of the small and micro-sized firms) were taking steps to manage potential risks in their materials and processes.

EHS Management and Small Businesses

One of the areas where the development of EHS management approaches may be both especially useful *and* challenging, is the nanotechnology community comprised primarily of small and medium-sized businesses. These businesses comprise "some 90% of all the businesses in the world" and are "responsible for 50-60% of total employment."[10] They also represent a large and growing segment of the commercial nanotechnology landscape.[11] In fact, among nanotechnology businesses, small startups or university-led initiatives account for the majority of companies.[12] Despite their significant contribution to global economies, small businesses are often overlooked when it comes to the development of initiatives and strategies that specifically address their unique EHS management needs. In 2003, a publication of the United Nations Environment Programme entitled, '*Big challenge for small business: sustainability and SMEs,*' highlighted some of the challenges that small businesses face with respect to development of proactive EHS approaches. Some of these challenges are summarized in Table 1, which is re-created from the UN document. The same challenges encountered by small businesses with respect to managing EHS issues in conventional industries may also influence their ability to manage emerging nanotechnology EHS issues.

Connecticut and New York. Master's Project completed at Yale's School of Forestry and Environmental Studies. Available at: www.nanotechproject.org/file_download/87. July.

[9] Lindberg, J. and M. Quinn. 2007. A Survey of Environmental, Health and Safety Risk Management Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region, Department of Work Environment and the Lowell Center for Sustainable Production, University of Massachusetts Lowell, Prepared for the Project on Emerging Nanotechnologies. December.

[10] United Nations Environment Programme, 2003. Big challenge for small business: sustainability and SMEs. Industry and Environment, 26 (4), 52 pp.

[11] Gerritzen, G., L. Huang, K. Killpack, M. Mircheva and J. Conti. A Survey of Current Practices in the Nanotechnology Workplace. Produced for the International Council on Nanotechnology by the University of California Santa Barbara. November 13, 2006.

[12] Garrett, D., 2005. "Opinion: Stars Aligning for Nano Offerings." *Small Times*. October 28. www.smalltimes.com/document_display.cfm?section_id=76&document_id=10238.

Table 1. Barriers to adoption of environmental and social responsibility in small to medium-sized businesses.[13]

- **Insufficient technology, expertise, training and capital**
- **Lack of initiatives tailored for small companies**
- **Inadequate understanding of what the business case is for environmental and social responsibility**
- **The need to deal with more pressing matters such as upgrading the quality of technology, management and marketing**
- **Price competition**
- **Limited consumer pressure**

Given the unique challenges facing smaller organizations, some stakeholders have indicated that the development of management frameworks with specific provisions to assist small nanotechnology businesses with addressing emerging nanotechnology EHS issues may be especially useful.[14,15]

In 2005, the European NanoBusiness Association (ENA) released its survey of 142 European businesses (of which 18% were small- to medium-sized businesses) on their attitudes of the impact of nanotechnologies on their businesses, the role of regulation, and perceptions of nanotechnologies. When asked what needs to be studied in regards to nanotechnologies, the vast majority of respondents answered with health and environmental impacts.[16] Despite the clear support for additional work in this area, an extensive European survey of small nanotechnology businesses and startup concerns revealed that environmental and social impacts of nanotechnology rank *low* among companies' concerns amidst other challenges.[17] The authors of this study concluded that "this shows that there is a lack of conscience/awareness on the potential risks of such aspects for the nanomaterial branch among [small- to medium-sized businesses]." However, this may also indicate that with lack of information and so many uncertainties about risk, firms are focusing their efforts on other more certain aspects of business.

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[13] United Nations Environment Programme, 2003. Big challenge for small business: sustainability and SMEs. Industry and Environment, 26 (4), 52 pp.

[14] Small Times Magazine, 2007. SOCMA's new coalition represents SME nano developers to government. Published May 25, 2007 at www.smalltimes.com/articles/.

[15] Maynard, A. D., 2006. Testimony to the U.S. House of Representatives Committee on Science. Hearing on: "Research on Environmental Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?" September 21, 2006.

[16] European NanoBusiness Association (ENA), 2005. "The 2005 European NanoBusiness Survey." The European NanoBusiness Association.

[17] European Commission, 2005. European Survey on Success Factors, Barriers and Needs for the Industrial Uptake of Nanomaterials in SMEs. Report funded by European Commission, Nanoroad SME, Sixth Framework Programme. July.

A Practical Small Business Approach

To address the need for a near-term nanotechnology EHS management paradigm designed specifically with small business concerns in mind, this report describes a five-point management program focused on proactive minimization of nanotechnology EHS risks. This approach—referred to as NanoSafe—was developed at the interface between small business, academia, and NIOSH, and was first presented in 2005 at the International Conference on Nanotechnology Occupational Safety and Health in Minneapolis, MN (Figure 1).[18] While several frameworks,[19] principles,[20] standards,[21] and codes of conduct[22] have recently been proposed for addressing emerging nanotechnology EHS risks, NanoSafe is unique in that aspects of the program were researched and developed within an actual small business nanomanufacturing facility, and thus were found to have practical relevance to a real-world setting. Other companies, particularly small- to medium-sized businesses and laboratories, may find this information helpful as they prepare to balance the requirements of bringing nano-inspired products to market with ensuring the safety of their workforce, the general public, and the natural environment.

[18] Hull, M.S., M. Hoover, S. Wilson, 2005. Assessing an emerging technology in practice. Poster presentation at the Second International Symposium on Nanotechnology and Occupational Health. Minneapolis, MN.

[19] Environmental Defense – DuPont Nano Partnership, 2007. NANO Risk Framework. 100 pp. Available at: www.nanoriskframework.com

[20] Coalition, 2007. Principles for the Oversight of Nanotechnologies and Nanomaterials. Coalition led by the International Center for Technology Assessment. July 31. Available at: www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_final.pdf (accessed November 27, 2007).

[21] ASTM International, *Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings* (initiated August 23, 2005); and ISO, *Technical Report ISO/TR 27628, Workplace Atmospheres – Ultrafine, Nanoparticle and Nano-structured Aerosols – Inhalation Exposure Characterization and Assessment* (February 1, 2007).

[22] See Responsible NanoCode at www.responsiblenanocode.org/.

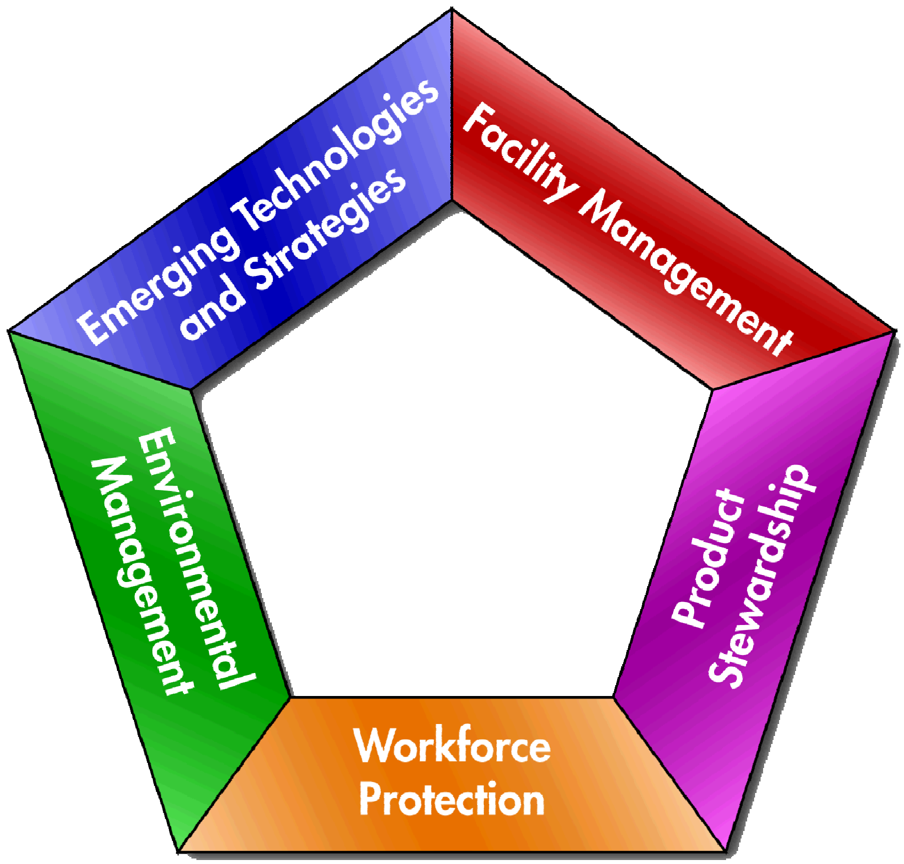


Figure 1. NanoSafe: Conceptual five-point nanomaterials safety management approach stemming from collaboration among small business, government, and academia.

Table 2 summarizes the five elements of the NanoSafe framework, which arose from experience in working with engineered nanomaterials, as well as through discussions with federal and academic researchers investigating nanotechnology EHS issues. In a general sense, these five elements are thought to encompass many of the questions likely to face representatives of nanotechnology companies and research laboratories as they construct new manufacturing or R&D facilities, develop or launch new nanotechnology-based products, protect employees, manage releases of engineered nanoparticles to the natural environment, and finally, take steps to stay ahead of the nanotechnology EHS curve given the frequent emergence of new findings.

Table 2. Five primary elements of the NanoSafe approach developed for managing nanotechnology EHS risks in one small company.

No.	Element	Rationale
1	Facility Management	Uncertain risks place unique demands on facilities and facility managers. Specialized equipment, monitoring strategies, updated organizational structures, and revised working practices may be required.
2	Product Stewardship	Any product poses an inherent risk to consumers and the environment. Ultimately, generators of these products are responsible for testing these materials to ensure their safety to consumers. Generators are also responsible for communicating possible hazards through accurate product labels and MSDS.
3	Workforce Protection	Employees are on the 'front lines' for exposures. Routine health surveillance may help identify and mitigate possible health risks to employees at the earliest stages. Workplace monitoring programs may be useful for characterizing exposures. New surveillance strategies and tools may be needed.
4	Environmental Management	Environmental emissions (i.e., air, wastewater, solid wastes) from nanotechnology facilities may contain engineered nanomaterials. It is currently unclear what environmental risks are posed by such emissions. Proactive approaches to evaluating the properties of these emissions and/or managing them may be important for protecting public health and the natural environment. In the US, environmental regulatory policies are in place that applies to products and emissions containing engineered nanomaterials.
5	Emerging Technologies and Strategies	Given the frequent emergence of new findings and differing opinions on nanotechnology EHS issues, nanotechnology-related enterprises may consider participating in forums that facilitate the exchange of 'lessons learned' and new information. In some instances, these lessons or even new tools created may have marketable value to others.

The sections that follow focus on key aspects of these five core elements of the NanoSafe management framework. These elements are intended to demonstrate a general organizational approach for how entities engaged in nanotechnology-related enterprises, particularly small- to medium-sized businesses, can take practical steps to proactively manage human and environmental health and safety risks. The information contained in this report is intended to provide other organizations, particularly small businesses and labs, with a first-tier information resource that may be of assistance as they develop their own nanotechnology-specific EHS risk management programs.

FACILITY MANAGEMENT

In This Section

- **A Starting Point for Risk Assessment: The OSHA Handbook for Small Businesses**
- **Comprehensive Information on Nano-Specific Risks and Management Strategies**
- **Meeting Resource Needs through Innovative Partnerships and Obtaining Third Party Validation**
- **Calling on Consultants**

The emerging nature of research findings and regulations pertinent to nanotechnology EHS may present unique challenges to safety managers of facilities where nanoscale materials are developed or otherwise handled. This is likely to remain the case until a universal 'best practices' model or equivalent approach to facility management emerges. As evidenced by recent publications at the forefront of this dialogue,[23,24,25,26,27,28,29,30] the establishment of such a model is a top priority on the agendas of many international organizations, including government agencies, and representatives from industry, academia, and non-government organizations (NGOs). As these international organizations continue to progress towards developing management practices based on sound

[23] ASTM International. 2007. Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings. Document ASTM E2535-07 available for purchase at: www.astm.org/Standards/E2535.htm

[24] British Standards Institute, 2007. Nanotechnologies –Part 2: Guide to Safe Handling and Disposal of Manufactured Nanomaterials. Document BSI-PD6699-2 available for free download at: www.bsiglobal.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/

[25] National Institute for Occupational Safety and Health (NIOSH), 2006. Approaches to Safe Nanotechnology: An Information Exchange with NIOSH (Version 1.1). Department of Health and Human Services, Centers for Disease Control and Prevention. 60 pp.

[26] U.S. Environmental Protection Agency (EPA), 2007. Nanotechnology white paper. 136 pp.

[27] Maynard et al., 2006. Safe handling of nanotechnology. Nature 4444: 267-269.

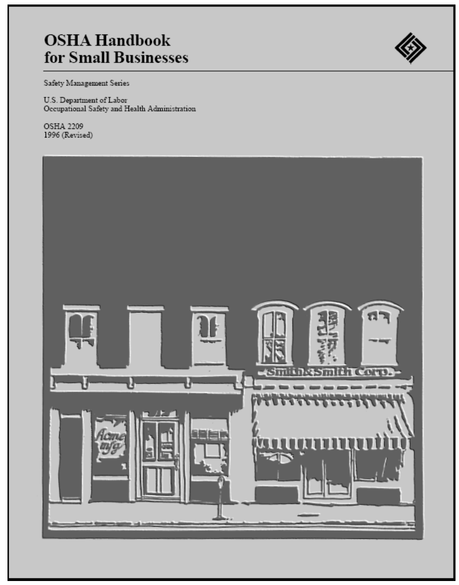
[28] The Royal Society & The Royal Academy of Engineering (London), 2004. Nanoscience and nanotechnologies: opportunities and uncertainties. Available at: www.royalsoc.ac.uk/policy.

[29] Environmental Defense – DuPont Nano Partnership, 2007. NANO Risk Framework. 100 pp. Available at: www.nanoriskframework.com

[30] Gerritzen, G., L. Huang, K. Killpack, M. Mircheva and J. Conti. A Survey of Current Practices in the Nanotechnology Workplace. Produced for the International Council on Nanotechnology by the University of California Santa Barbara. November 13, 2006.

science and thoughtful assessments of *actual* risks, individual entities engaged in nanotechnology-related activities have been encouraged to adopt their own practical strategies for identifying and managing EHS risks associated with their respective facilities and material handling practices.

A Starting Point for Risk Assessment: The OSHA Handbook for Small Business



The Occupational Safety and Health Administration (OSHA) developed the *OSHA Handbook for Small Businesses*[31] to assist small business employers with meeting the legal requirements imposed by, and under, the authority of the Occupational Safety and Health Act of 1970 (P.L.91-596) and to achieve an in-compliance status voluntarily prior to an inspection performed pursuant to the Act. The handbook is available online at www.osha.gov/Publications/osha2209.pdf.

Materials contained in the handbook are based upon the federal OSHA standards and other requirements in effect at the time of publication, and upon generally accepted principles and activities within the job safety and health field. [*Disclaimer:* The booklet is not intended to be a legal interpretation of the provisions of the Occupational Safety and Health Act of 1970 or to place any additional requirements on employers or employees, but the material contained therein is expected to be useful to small business owners or managers and can be adapted easily to individual establishments. All employers should be aware that there are certain states (and similar jurisdictions) which operate their own programs under agreement with the U.S. Department of Labor, pursuant to section 18 of the Act. The programs in these jurisdictions may differ in some details from the federal program.]

One component of the *OSHA Handbook for Small Businesses* that may be particularly helpful to small- to medium-sized businesses engaged in nanotechnology-related activities as they start preparing a comprehensive management plan for their nanotechnology facility is the OSHA Hazard Assessment Checklist. This checklist is designed to serve as a generic framework through which hazards associated with virtually any industrial process

[31] Occupational Health and Safety Administration (OSHA), 1996. OSHA Handbook for Small Businesses. Safety Management Series, U.S. Department of Labor, OSHA 2209. Available at: www.osha.gov/Publications/osha2209.pdf. For a copy of this publication, write to the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402, or call (202) 512-1800, (202) 512-2250 (fax) for ordering information.

may be identified. In its current form, the checklist may not necessarily identify any new workplace hazards created by manufacturing and handling of engineered nanomaterials. However, with careful review, discussion among, and input from EHS professionals and individuals engaged in specific nanotechnology-related activities, the checklist may be helpful in identifying areas where additional considerations may be warranted for nanomaterials. Some example questions from the checklist are provided in Table 3. These questions were selected given their particular relevance to nanotechnology EHS information gaps. For example, how can a safety manager or employer answer 'yes' to questions regarding the adequacy of personal protective equipment (PPE), overall awareness of possible nanomaterials hazards, Threshold Limit Value (TLV) and/or Permissible Exposure Limit (PEL) values for airborne contaminants given the current limited status of information industry-wide?

Table 3. Example of questions from the OSHA Hazard Assessment Checklist.

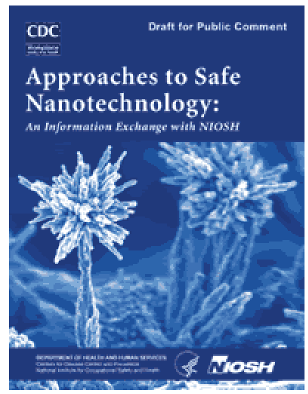
Current Checklist Questions
Do you have a safety committee or group made up of management and labor representatives that meets regularly and report in writing on its activities?
Are you keeping your employees advised of the successful effort and accomplishments you and/or your safety committee have made in assuring they will have a workplace that is safe and healthful?
Has the employer been trained on personal protective equipment (ppe) procedures, i.e. what ppe is necessary for job tasks, when they need it, and how to properly adjust it?
Are employees aware of the hazards involved with the various chemicals they may be exposed to in their work environment, such as ammonia, chlorine, epoxies, caustics, etc.?
Are you familiar with the Threshold Limit Values or Permissible Exposure Limits of airborne contaminants and physical agents used in your workplace?

Comprehensive Information on Nano-Specific Risks and Management Strategies

Approaches to Safe Nanotechnology: An Information Exchange with NIOSH: One of the resources available for addressing emerging nanotechnology EHS issues at the facility level is the report: *Approaches to Safe Nanotechnology: An Information Exchange with NIOSH*, which is available online at www.cdc.gov/niosh/topics/nanotech/safenano/. As stated on the NIOSH Web page, the purpose of this document is as follows:

> *"This document reviews what is currently known about nanoparticle toxicity and control, but it is only a starting point. The document serves as a request from NIOSH to occupational safety and health practitioners, researchers, product innovators and manufacturers, employers, workers, interest group members, and the general public to exchange information that will ensure that no worker suffers material impairment of safety or health as nanotechnology develops. Opportunities to provide feedback and information are available throughout this document."*

While NIOSH's *Approaches to Safe Nanotechnology* report does not provide mandated nanomaterial-specific recommendations for facility management, it does serve as one of the most trusted information resources currently available to assist safety managers with making rational decisions about risk minimization in their respective facilities.



To briefly demonstrate the utility of the *Approaches to Safe Nanotechnology* document, consider the following example question taken from the OSHA Hazard Assessment Checklist, as listed in the previous table. In this particular example, the checklist addresses TLVs or PELs of certain workplace contaminants.

Are you familiar with the Threshold Limit Values or Permissible Exposure Limits of airborne contaminants and physical agents used in your workplace?

In most instances, TLVs or PELs have not been specifically determined for nanoscale materials as this is a time-consuming and resource-intensive process that cannot be readily undertaken by a small business. Nevertheless, these values are important for determining the effectiveness of engineering controls or the need for specific ppe in the workplace. To address this information gap, NIOSH states the following on pg. 23 of its *Approaches to Safe Nanotechnology*:

> *"In determining the effectiveness of controls or the need for respirators, it would therefore be prudent to consider both the current exposure limits or guidelines (e.g., PELs, RELs, TLVs) and*

the increase in surface area of the nanoparticles relative to that of particles for which the exposure limits or guides were developed."

As this example illustrates, facility safety managers may benefit from using the *OSHA Handbook for Small Businesses* and *Approaches to Safe Nanotechnology* documents together as complementing sources of information for instituting appropriate precautionary measures to deal with nanomaterial exposure within facilities.

While professional judgment remains a critical element of EHS decision-making, the general guidance issued by NIOSH through its *Approaches to Safe Nanotechnology* provides an important resource to facility safety managers tasked with ensuring the safety of workers in facilities where engineered nanomaterials are manufactured or otherwise handled. With this information along with those that follow, well-trained facility safety managers can make better informed EHS decisions in the workplace.

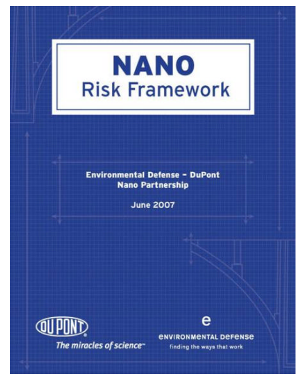
American Society for Testing and Materials (ASTM) Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings:
The ASTM recently published ASTM E2535-07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings. According to ASTM, this guide "*describes actions that could be taken by the user to minimize human exposures to unbound, engineered nanoscale particles (UNP) in research, manufacturing, laboratory and other occupational settings where UNP may reasonably be expected to be present.*" ASTM states that the intent of this document is to "*provide guidance for controlling such exposures as a cautionary measure where neither relevant exposure standards nor definitive hazard and exposure information exist*." The document can be obtained in print or electronic form at the link provided below: www.astm.org/Standards/E2535.htm.

British Standards Institute (BSI) Guide to Safe Handling and Disposal of Manufactured Nanomaterials:
In January 2008, a UK-based team comprised of SAFENANO, the Institute of Occupational Medicine, and the British Standards Institute (the UK National Standards body) published PD 6699-2:2007 Nanotechnologies - Part 2: Guide to Safe Handling and Disposal of Manufactured Nanomaterials. According to a press release on the guide, "*This document provides step-by-step guidance through the general approach to management of risks, information needs, hazard assessment, measurement of exposure, methods of control and disposal.*" The document is available for free download from the BSI site at the link below: http://www.bsigroup.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/

In addition to the guide described above, BSI published eight other documents offering guidance on nanotechnology-related issues. These documents are available at the following website:

www.bsigroup.com/nano

Environmental Defense-DuPont NANO Risk Framework:
Environmental Defense and DuPont teamed up to develop a "comprehensive, practical, and flexible" framework intended for companies and organizations to evaluate and address potential nanomaterial risks. This *Nano Risk Framework* report, released in June 2007, is available for download online at www.nanoriskframework.com.



Some have argued that the framework may delay governments from establishing needed mandatory nanotechnology regulation[32] or sets the EHS bar too high, especially for small companies; however, few can argue with the value of the comprehensive information, strategies, and case studies offered in this document. The framework is meant to guide a broad range of users working with nanomaterials on data gathering, assessing EHS risks, decision-making to reduce potential risks, and communicating that information.

Meeting Resource Needs through Innovative Partnerships

Throughout the process of developing a specific facility management strategy, it is likely that smaller entities will encounter situations where they require resources beyond what they can readily provide on their own. These resources generally include access to expertise or equipment. In these situations, innovative partnerships may help provide necessary resources. The following sections describe the forms that some of these partnerships may take.

[32] Civil Society-Labor Coalition, 2007. "Civil Society-Labor Coalition Rejects Fundamentally Flawed DuPont-ED Proposed Framework." An Open Letter to the International Nanotechnology Community at Large. April 12.

NIOSH Field Team[33]

> ***"Through this approach, NIOSH can better respond to requests from industry and other stakeholders for practical, effective guidance in designing and maintaining safe nanotechnology operations, based on first-hand collaborative observations and sound research data."[33]***
>
> NIOSH Director John Howard, M.D.

As part of its strategic research program on the occupational safety and health applications and implications of nanotechnology, NIOSH has formed an interdisciplinary field team of NIOSH researchers specifically focused on the area of nanotechnology. Key information about working with the NIOSH Field Team is available online[34,35] and quoted below:

- **Background:** *"The National Institute for Occupational Safety and Health (NIOSH), part of the Centers for Disease Control and Prevention (CDC), is the leading federal agency conducting research and providing guidance on the occupational safety and health implications of exposure to engineered nanomaterials. As part of its nanotechnology research agenda, NIOSH created a field research team to assess workplace processes, materials, and control technologies associated with nanotechnology and conduct on-site assessments of potential occupational exposure to a variety of nanomaterials."*

- **Funding:** *"This field research effort is fully funded by NIOSH; therefore, there is no monetary cost to the participant. In addition, there are federal laws and regulations that provide protection for the proprietary and trade secret information of the participating companies."*

- **Participants:** *"Research laboratories, producers, and manufacturers working with engineered nanomaterials (1 to 100nm) are invited and encouraged to collaborate with NIOSH. Those who are interested, or unsure of whether they qualify, should contact NIOSH [see 'Contact' section below]."*

- **Requirements to Participate:** "*The investment of the participants' time, availability, and access to participating worksites is required. Someone from the field research team will contact those who express*

[33] Material from NIOSH Topic Page on Nanotechnology: www.cdc.gov/niosh/topics/nanotech/newsarchive.html#fieldteam
[34] NIOSH document 121: www.cdc.gov/niosh/docs/2008-121/
[35] NIOSH document 120: www.cdc.gov/niosh/docs/2008-120/

interest in participating to determine if they meet the necessary qualifications. For those who qualify, a site visit will be scheduled. If new work practices or engineering control suggestions are implemented, or if modifications of existing practices or controls are made, then a return visit by NIOSH may occur to examine the effectiveness of those changes."

- **Use of Data:** "*The data collected by the field research team will be communicated back to the participant. It may then be used in a general manner by NIOSH to update its guidance on occupational safety and health implications of exposure to nanomaterials, and made available in technical documents, scientific presentations, or on the NIOSH Web site. Participants will not be identified in any NIOSH documents that are disseminated publicly without their permission."*

- **Contact:** Interested participants can obtain more information by contacting Charles Geraci of the NIOSH Field Team at:

Charles L. Geraci, Ph.D., CIH
Branch Chief
Education and Information Division and Nanotechnology Research Center
NIOSH, MS C-32
4676 Columbia Parkway
Cincinnati, OH 45336
Ph: 513-533-8339
Fax: 513-533-8230
Email: CGeraci@cde.gov

Universities, Government Laboratories

In addition to the NIOSH field team, a number of research groups from academia, government laboratories, and even industry may be interested in partnering with organizations engaged in nanotechnology R&D and/or manufacturing, to help fulfill obligations on research grants pertinent to EHS, or to enhance their service-providing capabilities to the emerging nanotechnology industry (in the case of some environmental consulting firms). These types of partnerships offer unique risks and rewards, but still may offer improved access to expertise and equipment resources needed to identify and manage EHS risks in nanotechnology facilities. Initiating an effective collaboration is usually a three-step process requiring:

i. some up-front groundwork to identify suitable collaborators,
ii. contacting potential collaborators, and
iii. actually working with the collaborator on a project of mutual benefit.

A good resource for identifying potential collaborators at university and government laboratories is the Project on Emerging Nanotechnologies' federal grants database, which identifies research teams who have obtained federal funding for nanotech EHS research. This inventory is available online at: http://www.nanotechproject.org/inventories/ehs/

Other useful resources for identifying university or government research centers include:

- Chemical & Engineering News' nanoproliferation diagram, which identifies the over 60 university centers, networks, and other facilities funded by U.S. agencies reporting to the NNI;[36]
- Small Times' feature story "Educating Small Tech Revolutionaries;[37] and
- Project on Emerging Nanotechnologies' interactive map of U.S. nanotechnology entities, which pinpoints the locations of academic and government research centers for nanotechnology.[38]

Understanding the Risks and Rewards of Partnering

Entities interested in partnering may wish to note the risks and rewards involved with doing so. As with any partnership, tradeoffs must be made to ensure that each party benefits from the relationship.

For example, partnerships with academic organizations may require agreements that enable the academic partner to publish the results of their work. In many instances, the industry partner is given the opportunity to review and comment on these results prior to publication.

Partnerships also involve increased efforts by both parties at the onset of the collaboration. Representatives of small nanobusinesses will need to take the initiative to reap the benefits of working with NIOSH, universities, other organizations, and government lab partners.

Calling on Consultants

Inevitably, some EHS challenges in the nanotechnology workplace will be too complex for some organizations to manage internally, even with highly effective partnerships in place. In general, this occurs in situations where the judgment of a trained professional (e.g., Certified Industrial Hygienist) is required to interpret data or make recommendations regarding modification of specific manufacturing and/or handling procedures. Hiring specialized consultants may be difficult for

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[36] Thayer, A., 2007. Nanoproliferation. Chemical & Engineering News. 85(15). April 9.
[37] Small Times, 2007. Educating Small Tech Revolutionaries. Small Times. May/June. pp 18-38.
[38] *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, May 2007, Available at: www.penmedia.org/maps/mappage.html

some small companies to afford, but in some cases, this may ultimately be the most economical and technically sound way to work through especially challenging EHS issues.

A number of existing EHS consulting firms have added nanotechnology capabilities to their overall service offerings, and a handful of new firms have emerged that focus exclusively on EHS concerns linked to development and handling of engineered nanomaterials. Services offered by a sampling of companies include quantitative risk analysis, testing services, and Web-based worker medical surveillance. An important point for organizations to remember when purchasing services from these firms, however, is that while firms inherently differ in the cost, availability, and general nature of their services, *all* are currently limited by the small (albeit growing) body of peer-reviewed literature nanotechnology EHS issues. Thus, organizations seeking specialized nanotechnology EHS services should carefully evaluate firms to determine their experience with engineered nanomaterials and in nanotechnology facilities. In addition, organizations should maintain realistic expectations of the conclusions.

PRODUCT STEWARDSHIP

In This Section

- **'Product Stewardship' Defined**
- **Resources to Assist with Voluntary Testing of Products**
- **Communicating Product Information Effectively**
- **Voluntary Reporting Schemes**

'Product Stewardship' Defined

As defined by the US EPA, 'Product Stewardship' is:

> *"a product-centered approach to environmental protection. Also known as extended product responsibility (EPR), product stewardship calls on those in the product life cycle—manufacturers, retailers, users, and disposers—to share responsibility for reducing the environmental impacts of products."*[39]

The Product Stewardship Institute reiterates the need for this shared responsibility by "all participants involved in the life cycle of a product."[40]

The concept of product stewardship is especially critical to emerging nanotechnologies given that these engineered nanomaterials are new and information is limited about how they will behave in the environment and affect human health at different stages of the material or product's life span. It is important for producers of nanomaterials and nanoproducts to consider the upstream and downstream effects of their products and byproducts. Through such a holistic approach, producers may ask – Can my product be recycled? How will the nanomaterials break down? What effect may that have on workers' or users' health? What will happen if my product is disposed in a landfill or washed off and makes its way to a wastewater treatment facility? What types of inputs and wastes will the production, use, and disposal of my product create? By asking such questions proactively during product design and development, producers may help reduce downstream risks and costs to workers, consumers, disposers, and the environment.

[39] www.epa.gov/epr/about/index.htm
[40] www.productstewardship.us/

Resources to Assist with Voluntary Testing of Products

While comprehensive testing of products is essential to ensuring the safety of consumers, the general public, and the environment, this process requires significant capital investment that in some cases, may exceed the operating budgets of small companies with limited resources. While companies may not circumvent costs associated with obtaining FDA or EPA approval of products, they may be able to reduce overall testing expenses associated with early-stage product formulations by referring to available nanomaterial EHS databases or by partnering with researchers in academia or federal laboratories who are interested in evaluating the EHS issues associated with emerging nanotechnologies. Three of these resources are described below.

NIOSH Nanoparticle Information Library

In collaboration with its national and international partners, NIOSH has developed and released in prototype form a Web-based Nanoparticle Information Library (Figure 2). The purpose of the library is "to help occupational health professionals, industrial users, worker groups, and researchers organize and share information on nanomaterials, including their health and safety-associated properties." For each nanomaterial entered into the searchable online database, the following information is provided:

- Nanomaterial composition;
- Method of production;
- Particle size, surface area, and morphology (included scanning, transmission, or other electron micrographic images);
- Demonstrated or intended applications of the nanomaterial;
- Availability for research or commercial applications;
- Associated or relevant publications; and
- Points of contact for additional details or partnering.

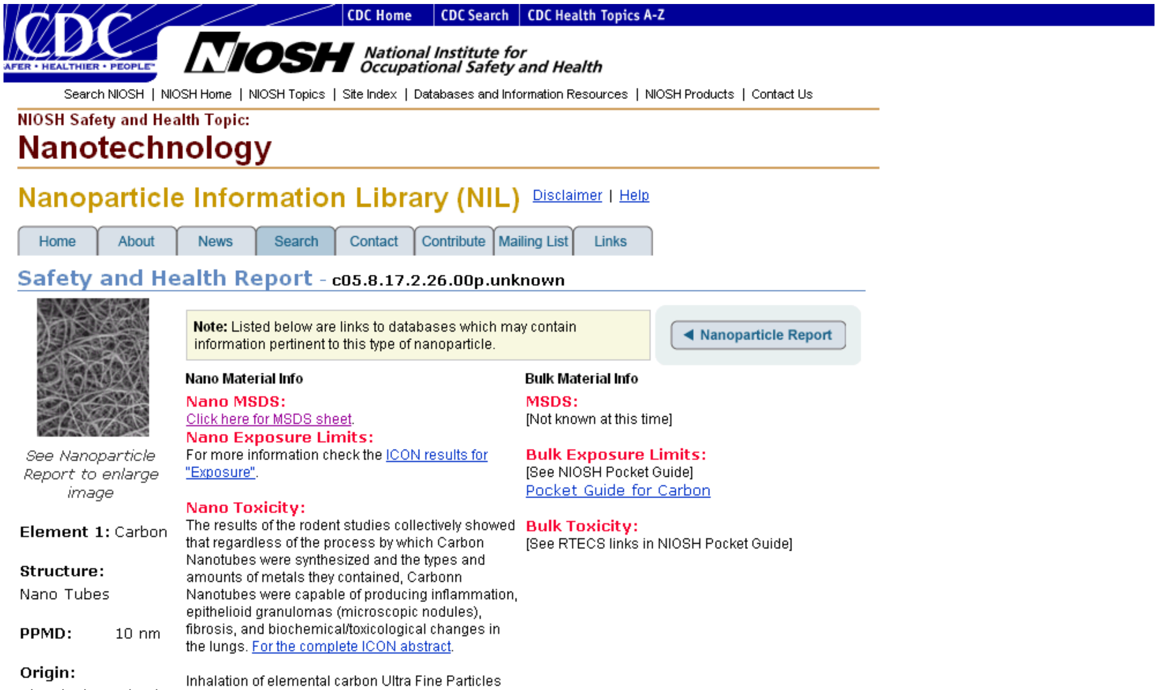

Figure 2. Screen-shot of the NIOSH Nanoparticle Information Library. This resource may be helpful for finding current information on EHS issues relevant to a particular nanoscale product.[41]

Universities, Government Laboratories

There are many universities and government laboratories currently engaged in research focused on developing testing procedures and toxicological profiles for engineered nanomaterials. In many instances, these groups are looking for industry partners to supply them with relevant nanoscale materials for testing purposes. Thus, it may be beneficial to explore partnerships whereby engineered nanomaterials are transferred under appropriate mutual agreements in exchange for access to expert testing resources and test results.

NNI Centers, Networks, and Facilities

One of the goals of the U.S. National Nanotechnology Initiative (NNI) was to "develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology." One component of achieving this goal was the creation of a vast and growing infrastructure of centers, networks, and facilities designed to "provide opportunities and support for multidisciplinary research among investigators from a variety of disciplines and from different research sectors, including academia,

[41] The NIOSH Nanoparticle Information Library can be accessed freely online at: www.cdc.gov/niosh/topics/nanotech/NIL.html

industry and government laboratories." More information on the multidisciplinary centers is available at: www.nano.gov/html/centers/home_centers.html.[42]

ICON EHS Database

One tool that may be especially useful for locating literature pertinent to EHS implications of engineered nanomaterials is the ICON Environmental, Health and Safety (EHS) database. The database contains summaries and citations for research papers that have specific relevance to nanotechnology and EHS. Users may also access full papers, but site registration or payment may be required for the majority of these articles. The ICON EHS database may be accessed at the following link: icon.rice.edu/research.cfm.

Communicating Product Information Effectively

In order to extract maximum value from voluntary product testing, producers must be able to communicate information about their products to consumers (as well as their own employees) in a clear and efficient manner. In general, chemical information is communicated in two primary forms: the material safety data sheets (MSDS) and product labels. According to the ICON/UCSB survey, "MSDS and personal interactions were the most commonly described methods for transmitting information of product stewardship. For safe use, manufacturers tended to provide MSDS as guidance."[43]

Not even the best labels or MSDS can communicate information you do not have.

Given the novelty or 'prototype' form of many emerging nanotechnologies, as well as the questionable adequacy of some techniques used to quantify the physio-chemical and/or toxicological properties of engineered nanomaterials, it is no small task for generators to obtain the information required to communicate information about their products and prototypes—not even the best labels or MSDS can communicate information you do not have. In response, some generators have created MSDS for their nanoscale products based on the properties of the bulk materials from which they were created (e.g., properties of graphite are used to describe single wall carbon nanotubes). The public does not appear to embrace this approach and some stakeholders have spoken out in clear opposition to it.[44]

[42] www.nano.gov/html/centers/nnicenters.html

[43] International Council on Nanotechnology (ICON), 2006. A survey of current practices in the nanotechnology workplace. Prepared by the University of California, Santa Barbara.

[44] Balbus, J., 2005. Protecting Workers and the Environment: an Environmental NGO's Perspective. Platform presentation at the 2nd International Symposium on Nanotechnology and Occupational Safety and Health. October 3-6, 2005. Minneapolis, MN.

In spite of the increased challenges facing generators of nanotechnology-based products, generators ultimately remain responsible for both determining and communicating any hazardous properties of their products to end-users. The sections immediately following summarize perspectives of two U.S. federal agencies involved in evaluating and communicating product hazards as well as some of the tools and guidelines applied during this process.

The CPSC and Nanotechnology Products

The Consumer Product Safety Commission (CPSC) is the U.S. federal agency "charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency's jurisdiction." The CPSC protects consumers primarily from products that pose fire, electrical, chemical, or mechanical hazards.

A recent report authored by a CPSC staff member concluded that "if a substance is considered 'hazardous', then the Federal Hazardous Substances Act (FHSA) requires cautionary labeling to address the principal hazard presented by the product and instructions for safe use, handling and storage of the product." If a substance is determined to be hazardous and the label is deemed inadequate to protect public health and safety, then the CPSC can ban the substance.

According to the CPSC, manufacturers are responsible for determining whether their products are "hazardous substances" and for ensuring that such products are labeled as required by the FHSA. The CPSC report states the following regarding the definition of a product as a "hazardous substance":

[45] Thomas, T., K. Thomas, N. Sadrieh, N. Savage, P. Adair, & R. Bronaugh et al. 2006. Research Strategies for Safety Evaluation of Nanomaterials, Part VII: Evaluating Consumer Exposures to Nanoscale Materials. Toxicological Sciences. 91(1):14-19

Defining a Product as a "Hazardous Substance"
(Adapted from Thomas et al., 2006)

The definition of a hazardous substance under the FHSA is risk-based and the regulation addresses both acute and chronic hazards. To be considered a "hazardous substance" under the FHSA (15 U.S.C. § 1261 (f)(1)(A)), a consumer product must satisfy a two-part definition:

- ☑ *First, the substance (or mixture of substances) must be toxic under the FHSA, or present one of the other hazards enumerated in the statute.*

- ☑ *Second, it must have the potential to cause "substantial illness or substantial personal injury during or as a proximate result of any customary or reasonably foreseeable handling or use." Therefore, exposure and the likelihood of risk must be considered in addition to inherent toxicity when assessing whether a product meets the definition of a hazardous substance under the FHSA.*

OSHA and the Hazard Communication Standard

OSHA is the foremost regulatory body in the United States charged with ensuring that safe working conditions are provided for American workers. A major component of OSHA's efforts on this front are focused on ensuring that hazards are communicated clearly to the individuals who may be affected by them. The following statement regarding 'hazard communication' was taken from the OSHA Web site and summarizes requirements under OSHA's Hazard Communication Standard.

Hazard Communication Standard[46]

"In order to ensure chemical safety in the workplace, information must be available about the identities and hazards of the chemicals. OSHA's Hazard Communication Standard (HCS) requires the development and dissemination of such information:

- ☑ *Chemical manufacturers and importers are required to evaluate the hazards of the chemicals they produce or import, and*
- ☑ *Prepare labels and material safety data sheets (MSDSs) to convey the hazard information to their downstream customers.*
- ☑ *All employers with hazardous chemicals in their workplaces must have labels and MSDSs for their exposed workers, and train them to handle the chemicals appropriately."*

MSDSs and Product Labels

The OSHA Hazard Communication Standard (HCS) incorporates a 3-pronged approach to communicating hazards posed by materials:

- Labels on containers,
- Development of material safety data sheets (MSDS), and
- Employee training.

While employee training is usually limited to communicating information along the manufacturing chain, the importance of product labels and MSDS frequently transcend the boundaries of the workplace.

Product labels, though brief, are the most immediate source of information. Nevertheless, since the label is attached to the product container, it is typically accessible whenever the product is being used. Labels are snapshots used to remind product users of any potential hazards and to point out resources for more information (e.g., MSDS, Web sites).

MSDS are typically as comprehensive as a product label is brief. They provide a "one-stop shopping source for everything you might need or want to know about a chemical." Given the diversity of the audience for which MSDS are intended, they must provide a broad array of information. In particular, MSDS "must be useful to the safety and health professionals

[46] www.osha.gov/SLTC/hazardcommunications/index.html

deciding what controls to use, the first aid or medical treatment to provide, and the precautionary measures to follow."[47]

As noted above, OSHA requires chemical manufacturers and importers to obtain or create a MSDS for each hazardous chemical they produce or import and maintain those MSDS in workplace.[48] OSHA also points out that "producers of chemicals may be subject to 'failure to warn' suits that can have significant financial implications."

More information on MSDS can be found at www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099#1910.1200(g).

Voluntary Reporting Schemes

Currently, it is unclear whether and to what extent nanotechnology businesses and laboratories should report the nature of their nanotechnology-specific activities (e.g., types and quantities of nanomaterials generated, working practices, etc.) to state or federal regulatory agencies. One approach that has been considered is the implementation of voluntary reporting schemes that permit the exchange of information between regulators and entities engaged in nanotechnology activities. In general, these programs do not replace existing legislation; rather, they are intended to offer flexibility in the nature of information exchanged so that a moderate level of oversight can occur without unnecessarily hindering nanotechnology research. Two of these programs—the UK Voluntary Reporting Scheme for Engineered Nanoscale Materials and the US EPA Nanoscale Materials Stewardship Program—are summarized below:

UK Voluntary Reporting Scheme for Engineered Nanoscale Materials

The UK Voluntary Reporting Scheme for Engineered Nanoscale Materials program was initiated in September 2006 and is intended to run until September 2008. The program is run by the UK Department for Environment, Food and Rural Affairs (DEFRA), in conjunction with other government departments and agencies. The aim of the program is to obtain from UK businesses involved in the manufacture or use of engineered nanomaterials information that provides *"an indication of those nanomaterials which are currently in development or production"*. This information is expected to assist legislators with aligning resource allocation and policy-making with relevant industry and consumer needs. The program recognizes the potential sensitivity of certain commercial

[47] OSHA, 2004. Hazard Communication in the 21st Century Workplace. Available online at: www.osha.gov/dsg/hazcom/finalmsdsreport.html
[48] www.osha.gov/

business information and thus offers flexibility in the types of information that can be provided under the voluntary scheme.[49]

More information on the UK Voluntary Reporting Scheme for Engineered Nanoscale Materials is available at the following web-link: http://www.defra.gov.uk/environment/nanotech/policy/.

EPA Nanoscale Materials Stewardship Program

EPA implemented its voluntary Nanoscale Materials Stewardship Program (NMSP) under the Toxic Substances Control Act (TSCA) in January of 2008, which is intended to "*complement and support its efforts on new and existing nanoscale materials.*" The general components of the Stewardship Program are designed to:

- *Help the Agency gather existing data and information from manufacturers, importers, processors, and users of existing chemical nanoscale materials to build EPA's knowledge base in this area;*
- *Identify and encourage use of risk management practices in developing and commercializing nanoscale materials;*
- *Encourage the development of additional test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions;*
- *Encourage responsible development of nanoscale materials.*

In July 2007, the agency solicited comments on its latest concept paper for the development of the NMSP,[50] on information collection activities for the voluntary program,[51] and on the inventory status of nanoscale substances under TSCA.[52] These documents and forms are posted at: www.epa.gov/oppt/nano/nmspfr.htm.

EPA intends to encourage participation in the NMSP by individuals or entities that manufacture, import, modify, or use engineered nanoscale materials in the manufacture of a product. EPA indicates that information gathered through the Stewardship Program will be used to support further development of TSCA, specifically as it relates to nanoscale materials.

[49] DEFRA, 2008. UK Voluntary Reporting Scheme for Engineered Nanoscale Materials www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-nanoscale.pdf

[50] EPA, 2007. Concept Paper for the Nanoscale Materials Voluntary Program under TSCA. Office of Pollution Prevention and Toxics, Environmental Protection Agency.

[51] EPA, 2007. Supporting Statement for an Information Collection Request. Office of Pollution Prevention and Toxics, Environmental Protection Agency.

[52] EPA, 2007. TSCA Inventory Status of Nanoscale Substances - General Approach. Office of Pollution Prevention and Toxics, Environmental Protection Agency.

This includes determining "any regulatory actions that may be needed to protect human health and the environment."[53]

[53] Nanoscale Materials Stewardship Program www.epa.gov/oppt/nano/

In This Section

- **Occupational Health Surveillance Overview**
- **Elements of Baseline and Routine Health Surveillance in Nanotechnology Facilities**
- **Workplace Monitoring**

Occupational Health Surveillance Overview

Currently, over 800 entities engaged in nanotechnology research and development or manufacturing currently exist in the U.S. alone.[54] This includes commercial firms as well as government and university laboratories. In addition, it is currently estimated that there are at least 20,000 individuals working worldwide in nanotechnology today.[55]

One approach for preventing adverse health effects to workers is occupational health surveillance. According to NIOSH, occupational health surveillance involves the "tracking of occupational injuries, illnesses, hazards, and exposures." Surveillance approaches include assessments of both individual- and group/population-based activities. Data obtained from health surveillance programs are used to "guide efforts to improve worker safety and health, and to monitor trends and progress over time."

Tracking occupational injuries, illnesses, hazards and exposures has been an integral part of NIOSH since its creation by the Occupational Safety and Health Act in 1970. NIOSH complements important statistical or surveillance activities carried out by other federal agencies (including the Bureau of Labor Statistics, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and the National Center for Health Statistics), state governments, and private sector groups.[56] NIOSH's surveillance efforts include:

[54] *Putting Nanotechnology on the Map*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, (May 2007), Available at: www.penmedia.org/maps/mappage.html. Note, these numbers are drawn from publicly available lists compiled by the Project on Emerging Nanotechnologies; the actual number of entities working in nanotechnology is likely to be much higher.
[55] NNI. 2007. Frequently Asked Questions, National Nanotechnology Initiative. www.nano.gov/html/res/faqs.html Accessed November 26, 2007.
[56] www.cdc.gov/niosh/topics/surveillance

- Analyzing and interpreting existing data;
- Undertaking data collection efforts to fill gaps in surveillance data;
- Provides support to state agencies to conduct occupational surveillance and associated prevention efforts;
- Funds and conducts research on surveillance methods; and
- Works with federal, state, and private sector partners to improve occupational health surveillance.

Elements of Baseline and Routine Health Surveillance in Nanotechnology Facilities

Health surveillance programs are carried out to prevent illness when there is knowledge about both the possibility of an exposure to a health hazard and the health effects caused by that exposure, and tests available to detect those effects.[57] Successful surveillance programs involve assessing needs, setting program goals and defining the target population, choosing testing modalities, collecting and interpreting data to benefit individuals and groups of workers, intervening based on results, communicating results, and evaluating the program.[58]

Currently, it is unclear whether employee health surveillance strategies geared specifically for nanotechnology workers are necessary. Some have argued in favor of some form of proactive health surveillance program, while others have questioned whether the need and costs associated with such a program are justified. Still, others are unclear exactly what components would comprise such a program since there are no clear biomarkers and/or health outcomes established around which to base an exposure assessment specific for engineered nanomaterials. The uncertainties about adverse effects from nanomaterial exposure present a challenge to designing and implementing a health or medical surveillance program in the nanotechnology workplace.[59]

Much the same as with establishing effective parameters for workplace monitoring programs, researchers are investigating candidate indicators of human health impacts associated with engineered nanomaterials for surveillance purposes.[60,61] Testing parameters discussed in the literature and at recent

[57] Nasterlack, M. Zober, A., and C. Oberlinner. 2007. Considerations on occupational medical surveillance in employees handling nanoparticles. Int Arch Occup Environ Health, Published Online September 12Accepted August 31.
[58] Harber, P., Conlon, C., and R.J. McCunney, 2003. *Occupational medical surveillance.* In: McCunney RJ, ed. A Practical Approach to Occupational and Environmental Medicine. Philadelphia, PA: Lippincott, Williams, and Wilkins.
[59] Kosnett, M.J. and L.S. Newman, 2007. Medical Surveillance for Nanomaterials. Presentation given at 2007 American Public Health Association 135th Annual Meeting, Washington, DC.
[60] Nasterlack, M. Zober, A., and C. Oberlinner. 2007. Considerations on occupational medical surveillance in employees handling nanoparticles. Int Arch Occup Environ Health, Accepted Published Online September 12August 31.

conferences present a number of pros and cons. Nasterlack et al. 2007[62] concluded that none of the effect parameters proposed for nanoparticle-exposed employees, including heart rate variability, blood-clotting parameters, pro-inflammatory cytokines, are specific or sufficiently validated as individual health risk indicators. Some also require equipment that is not routinely available. Other parameters (e.g., ECG, chest X-ray and pulmonary function) are useful diagnostic tools, but only when health effects are known, which is not yet the case for nanomaterial exposure.[63]

Kosnett and Newman 2007[64] point out the limitations of applying other parameters (e.g., spirometry, chest x-ray) in the nanotechnology workplace; however, they suggest that other parameters (e.g., serum biomarkers, imaging, and exercise oximetry) may serve as potential future modalities for pulmonary testing. This report does not intend to comment on which of these measurements are most appropriate for nanotechnology facilities. Given the existing constraints in developing surveillance programs and potential ethical issues of employee screening (as highlighted by Schulte and Salamanca-Buentello 2007[65]), some researchers have proposed the development of nanotechnology worker exposure registries.

As noted in its *Approaches to Safe Nanotechnology* report, NIOSH is currently developing guidance for occupational health surveillance for nanotechnology, which should serve as a useful resource for workplaces.[66]

Workplace Monitoring

Workplace monitoring typically accompanies health surveillance programs and is intended to relate certain parameters measured at a facility with observed human health outcomes (e.g., particulate levels measured relative to worker respiratory function). While many monitoring programs have been instituted at workplaces around the world, it is currently unclear as to which measurements are most critical in facilities where engineered nanomaterials are manufactured or otherwise handled. Researchers are actively working to identify these parameters (e.g., Maynard and Kuempel 2005,[67] Oberdörster et al. 2007,[68]

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[61] Kosnett, M.J. and L.S. Newman, 2007. Medical Surveillance for Nanomaterials. Presentation given at 2007 American Public Health Association 135th Annual Meeting, Washington, DC.
[62] Nasterlack, M. Zober, A., and C. Oberlinner. 2007. Considerations on occupational medical surveillance in employees handling nanoparticles. Int Arch Occup Environ Health, Published Online September 12.
[63] *Ibid.*
[64] Kosnett, M.J. and L.S. Newman, 2007. Medical Surveillance for Nanomaterials. Presentation given at 2007 American Public Health Association 135th Annual Meeting, Washington, DC.
[65] Schulte, P.A. and F. Salamanca-Buentello, 2007. Ethical and Scientific Issues of Nanotechnology in the Workplace, Environmental Health Perspectives. 115(1): 5:12. January.
[66] Available at www.cdc.gov/niosh/topics/nanotech/safenano/.
[67] Maynard, A.D. and E.D. Kuempel. 2005. "Airborne nanostructured particles and occupational health." *Journal of Nanoparticle Research* 7(6): 587-614, December.

Maynard 2007,[69] Maynard and Aitken 2007,[70] Wittmaack 2007[71]), but a global consensus on these parameters has not yet been reached. In the meantime, resources are available to assist nanotechnology developers with establishing their own workplace monitoring programs. Perhaps the most well known of these resources is the NIOSH field team (see Section 4.1), given their extensive background in workplace monitoring programs in general, and particulate/aerosol measurements in particular.

While the world awaits a standardized workplace monitoring program, some of the nanomaterial parameters to consider monitoring in the workplace—as reported in the literature and at recent conferences—include particle number, particle size distribution, surface area, chemistry or reactivity, solubility, shape, mass concentration. This report does not intend to comment on which of these measurements are most appropriate for nanotechnology facilities.

As discussed in Maynard and Aitken 2007, different situations will require different material attributes—whether surface area, mass or particle number concentration—to be measured; the paper recommends measuring all three where possible. The idea of a universal aerosol sampler enabling the collection of personal exposure to all three of these metrics is explored in this paper and in the recent *Nature* paper on the safe handling of nanotechnology written by fourteen distinguished nanotechnology experts.[72]

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[68] Oberdörster, G., V. Stone, and K. Donaldson. 2007. "Toxicology of nanoparticles: A historical perspective." *Nanotoxicology* 1(1): 2-25. March.
[69] Maynard, A.D. 2007. "Nanotechnology: The next big thing, or much ado about nothing?" *Ann. Occup. Hyg.* 51:1-12.
[70] Maynard, A. D. and R. J. Aitken. 2007. Assessing exposure to airborne nanomaterials: Current abilities and future requirements. Nanotoxicology 1(1): 26-41.
[71] Wittmaack K., 2007. In search of the most relevant parameter for quantifying lung inflammatory response to nanoparticle exposure: particle number, surface area, or what? Environ Health Perspectives. 115:187–194.
[72] Maynard, A. D., Aitken, R. J., Butz, T., Colvin, V., Donaldson, K., Oberdörster, G., Philbert, M. A., Ryan, J., Seaton, A., Stone, V., Tinkle, S. S., Tran, L., Walker, N. J. and Warheit, D. B. 2006. Safe handling of nanotechnology. Nature 444:267-269.

ENVIRONMENTAL MANAGEMENT

In This Section

- **Environmental Emissions Overview**
- **Thinking Beyond the Workplace**
- **The Concept of Life Cycle Assessment**
- **U.S. Environmental Regulatory Policy**

Environmental Emissions Overview

Knowledge of engineered nanoparticles and their interaction with the natural environment is deficient.[73] Researchers have acknowledged that nanoscale contaminants dispersed in air, sediment, and aqueous media may possess unique physical and chemical properties that ultimately could influence their fate, transport, transformation, and bioavailability in the environment.[74] Despite the general lack of information regarding nanoparticle interaction with the environment, several recent studies have suggested that some engineered nanomaterials are toxic in aquatic[75] and biological systems[76,77] and some have enhanced mobility in simulated groundwater systems.[78] These initial findings coupled with the rapid growth of the nanotechnology industry have stimulated further research into the human and environmental effects of engineered nanoparticles.

Thinking beyond the Workplace

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73 Colvin, V., 2003. The potential environmental impacts of engineered nanomaterials. Nature Biotech. 21, 1166-1170.

74 Masciangoli, T. & W.X. Zhang., 2003. Environmental technologies at the nanoscale. Environ. Sci. Tech. March 1, 2003. 102A.

75 Oberdörster, E., 2004. Manufactured nanomaterials (Fullerenes, C_{60}) induce oxidative stress in brain of juvenile largemouth bass. Environ. Health. Perspect. 112, 1058. Published online at http;//dx.doi.org (doi:10.1289/ehp.7021).

76 Derfus, A., W. Chan & S. Bhatia, 2004. Probing the Cytotoxicity of Semiconductor Quantum Dots, Nano Letters, 4(1), 11-18.

77 Warheit et al., 2004. Comparative pulmonary toxicity assessment of SWNTs in rats, Toxicol. Sci., 77, 117-125.

78 Lecoanet et al., 2004. Laboratory assessment of the mobility of nanomaterials in porous media. Environ. Sci. Tech. 38, 5164-5169.

Beyond the EHS issues encountered in the nanotechnology workplace, the potential exists for some nanomanufacturing processes to inadvertently release free nanoparticles into the environment through air emissions, discharged process water, commercial use, or disposal in solid waste streams. However, it remains unclear whether environmental releases of nanomaterials pose any actual EHS risks. This uncertainty has created challenges for federal agencies, such as the U.S. Environmental Protection Agency (EPA), charged with protecting human health and the environment. As indicated from the following statements issued on the EPA nanotechnology topic Web page,[79] the lack of conclusive information has hindered the development of specific regulatory policies pertinent to nanotechnology EHS:

- *"At this early stage of development of nanotechnology, there are few detailed studies on the effects of nanoscale materials in the body or the environment. Early results are also inconclusive, and it is clear that it is not yet possible to make broad conclusions about which nanoscale substances may pose risks. "*

- *"There is a need for more information to assess the potential environmental, health, and safety impacts for most engineered nanoscale materials. Such information is important because EPA needs a sound scientific basis for assessing and managing unreasonable risks that may result from the introduction of nanoscale materials into the environment."*

Despite current data gaps, some environmental agencies may have existing laws and regulations, such as noted below by EPA, that provide them with authority to regulate engineered nanomaterials.

> *"Many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). This law provides EPA with a strong framework for ensuring that new and existing chemical substances are manufactured and used in a manner that protects against unreasonable risks to human health and the environment. For example, EPA requires manufacturers of new chemical substances to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can require reporting or development of information to assess existing chemicals already in the marketplace. Additionally, EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled*."[80]

[79] Environmental, Health and Safety Implications of Nanoscale Materials www.epa.gov/oppt/nano/nano-facts.htm
[80] Nanotechnology under the Toxic Substances Control Act www.epa.gov/oppt/nano/ (accessed November 27, 2007)

The Concept of 'Life Cycle Assessment'

Life-cycle-based assessment practices have been proposed as a means for helping to identify and manage unique EHS issues occurring throughout the product life cycle—from research and development, through production, commercial application, and ultimately, to disposal.

Recently, a report issued by the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies and the European Commission reviewed the topic of nanotechnology and life cycle assessment.[81] That document noted the following:

> *"One approach that can improve our understanding of the possible impacts of nanotechnology is Life Cycle Assessment (LCA). This comprehensive analysis tool can be used to evaluate how a product or material—from the start of production through end-of-life—affects ecosystems and human health. LCA is already widely used internationally by scientists, engineers, and product designers in universities and businesses. If applied in the nanotechnology realm, the tool has the potential to guide researchers, policymakers, and companies as they seek to realize the commercial and practical benefits of a nanoproduct, while avoiding potential risks."*

The UK Royal Society also stressed the importance of using LCA as a tool to better understand the tradeoffs in environmental benefits and risks from nanotechnologies in its seminal 2004 report.[82]

A lengthy discussion of LCA is beyond the scope of this report. Rather, the intent is to introduce nanotechnology developers to the concept of examining the full impact potential of their products and to search for appropriate alternatives where possible. Even if a full LCA is not completed for each product, life cycle thinking (similar to product stewardship) about potential impacts should be incorporated into product design.

For more information on LCA, a few useful resources include:

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[81] Woodrow Wilson International Center for Scholars and European Commission, 2007. Nanotechnology and Life Cycle Assessment: A Systems Approach to Nanotechnology and the Environment. Synthesis of results obtained at a workshop in Washington, DC, October 2006. www.nanotechproject.org/111/32007-life-cycle-assessment-essential-to-nanotech-commercial-development

[82] The Royal Society. 2004. "Nanoscience and nanotechnologies: opportunities and uncertainties." The Royal Society and The Royal Academy of Engineering. London, UK. July 29. www.nanotec.org.uk/finalReport.htm

EPA, 2006. “Life Cycle Assessment: Principles and Practice.” Prepared by Scientific Applications International Corporation for the National Risk Management Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency. EPA/600/R-06/060. May 2006. Available at: www.epa.gov/nrmrl/lcaccess/lca101.html

Graedel, T.E. and B.R. Allenby, 2003. Industrial Ecology. Second Edition. Pearson Education, Inc.: Upper Saddle River, New Jersey. Chapters 15-17.

ISO 14040:2006: Environmental management - Life cycle assessment - Principles and framework. International Organization for Standardization (ISO). Available at: www.iso.org/iso/catalogue_detail?csnumber=37456

ISO 14044:2006: Environmental management - Life cycle assessment - Requirements and guidelines. International Organization for Standardization (ISO). Available at: www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=38498

U.S. Environmental Regulatory Policy

On July 25, 2006, the American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) released a comprehensive review of the core federal environmental statutes pertinent to nanotechnology.[83] The review resulted in detailed briefing documents on six environmental statutes and a briefing document on innovative governance mechanisms that identify key legal and regulatory issues EPA can be expected to encounter as it considers how best to address issues likely to arise in connection with nanotechnology. EHS personnel as well as legal counsels involved with nanotechnology facilities may find it helpful to review the briefing documents to determine initial applicability to their respective organizations. When necessary, specialized legal perspectives may be needed to help further assess compliance with applicable as well as emerging regulations.

The ABA SEER briefing documents provide the first comprehensive, scholarly review of the core federal environmental statutes with a view toward assessing the utility of each in addressing the legal and regulatory issues pertinent to EPA's jurisdiction presented by nanotechnology. In general, the papers concluded that the core environmental statutes were found to provide EPA with sufficient legal authority to address adequately the challenges EPA is expected to encounter as it assesses the enormous benefits of and potential risks associated with

[83] American Bar Association, Section of Environment, Energy, and Resources, 2006. Section Nanotechnology Project, Papers available at www.abanet.org/environ/nanotech/ (accessed November 28, 2007).

nanotechnology. Specifically, the ABA SEER briefing papers found the following:[84]

- The existing environmental statutes of TSCA, RCRA, CAA, and FIFRA apply to nanomanufacturing and associated products and/or wastes.
- Other environmental statutes may apply or may soon apply to nanomanufacturing. These include CERCLA, CWA, and other new approaches customized specifically for nanomanufacturing facilities (EMS/Innovative Regulatory Approaches).
- Under TSCA, EPA has expansive authority to regulate nanomaterials, including the authority to require health and environmental testing; collect production, health, and environmental information about nanomaterials; and promulgate rules regulating, and even prohibiting, the manufacture, processing, distribution, and use of nanomaterials.
- Under RCRA, EPA has authority to regulate discarded wastes that might include nanoscale materials.
- Under CAA, EPA has authority to regulate air emissions.

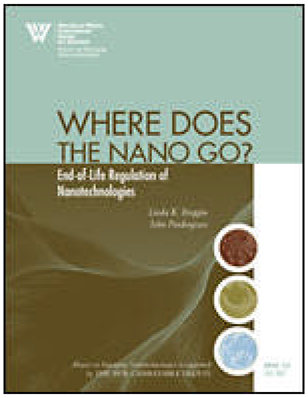
The Project on Emerging Nanotechnologies has also produced comprehensive analyses of the environmental statutes and their ability to deal with nanotechnology.

For instance, in *EPA and Nanotechnology: Oversight for the 21st Century*, former EPA assistant administrator for policy J. Clarence Davies sets out an agenda for creating an effective oversight system as nanotechnology advances. He also suggests ways that the EPA can improve its ability to provide adequate oversight for nanotechnology and other emerging 21st century challenges.[85] The nanotechnology industry also has an important role to play in this process. Davies recommends that industry members take part in dialogues with other stakeholders to discuss the optimal form of nano oversight.

The report, *Where Does the Nano Go? End-of-Life Regulation of Nanotechnologies*, by Linda K. Breggin and John Pendergrass of the Environmental Law Institute explores nanomaterial and nanoproduct end-of-life

[84] DISCLAIMER: These papers are solely the product of the ABA SEER, and do not purport to represent the opinions of EPA. SEER's efforts in undertaking and completing this ambitious project are extraordinary. The Section lawyers who devoted considerable time, energy, and scholarly attention to preparing the briefing documents have provided a unique and immensely useful service. The briefing documents are well written and comprehensive resources that the Section hopes lawyers, regulators, and stakeholders in the nanotechnology area will find useful and that will facilitate further discussion on the topics each considers.

[85] Davies, J. C., 2007. *EPA and nanotechnology: Oversight for the 21st century*. PEN 09. Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, May. Available at: www.nanotechproject.org/file_download/197 (accessed November 28, 2007).



issues within the existing regulatory frameworks of the RCRA and the CERCLA.[86] They authors point out that EPA must make key decisions about how to apply these statutes to nanotechnology waste in order to ensure adequate oversight for these technologies. However, the report notes that the agency lacks much of the data on human health and eco-toxicity that form the basis for such determinations, creating some tough challenges ahead in EPA's decision-making process. The report also calls on firms that manufacture nanomaterials, investors, and insurers to consider the new kinds of liabilities and environmental risks that may emerge as a result of the release and disposal of waste nanomaterials into the environment.

[86] Breggin, L. K. and J. Pendergrass, 2007. *Where Does the Nano Go? End-of-Life Regulation of Nanotechnologies*. PEN 10. Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at: www.nanotechproject.org/file_download/208. (accessed November 28, 2007).

In This Section

- **Five Grand Challenges**
- **Technology Development Partnerships**
- **Nanotechnology EHS Meetings**
- **Key Organizations**
- **Resources for Emerging Information**

The fifth element of the NanoSafe framework provides an overarching perspective and strategy for conducting business in the face of both uncertainty and change. Given the dynamic and evolving nature of the nanotechnology EHS landscape, tools and strategies created to address risks identified and/or perceived today may require considerable modification in the future. Certainly, this is true of any rapidly advancing high-technology field, but as the research community has only recently begun to focus specifically on nanotechnology EHS issues, it is likely that new research findings could propel risk management approaches into unanticipated directions spanning from strict regulation to no regulation. The more probable scenario, however, is likely somewhere in between. Maintaining links to emerging information either on the Web or through conference attendance may help nanotechnology entities remain updated on the most recent findings.

Five Grand Challenges

A 2006 article published in *Nature* by Maynard et al.[87] summarizes five grand challenges for research on nanotechnology risk that the authors—an assemblage of international experts on the subject—believe must be met if the technology is to reach its full promise. Table 6 lists these grand challenges. This article is particularly valuable in that it describes key areas where nanotechnology EHS information is either currently limited or where new tools and approaches are needed (see article for a list of important target dates for meeting these challenges). These areas are listed below and provide insight into at least a few areas where developments may be especially critical. Thus, stakeholders may wish to pay careful attention to developments in these areas. For example, a nanotech company undertaking workplace monitoring for nano-scale particles

[87] Maynard, A. et al., 2006. Safe handling of nanotechnology. *Nature* 444: 267-269.

may need to ask themselves periodically: “am I using the latest and most effective instruments to perform my workplace exposure measurements?”

Table 6. Five Grand Challenges identified by international experts in nanotech EHS. Stakeholders may wish to watch these areas closely for emerging information and new strategies.

1. **Instruments to assess environmental exposure to nanomaterials;**
2. **Methods to evaluate the toxicity of nanomaterials;**
3. **Models for predicting the potential impact of new, engineered nanomaterials;**
4. **Way of evaluating the impact of nanomaterials across their life cycle; and**
5. **Strategic programs to enable risk-focused research.**

Technology Development Partnerships

As indicated in the Maynard et al. 2006[88] publication, progress in nanotechnology is pushing the limits of instrumentation available to assess environmental exposure to nanomaterials. Thus, in certain instances nanotechnology facility managers may find that they require tools or strategies not addressed by existing safety technologies or approaches. In these situations, technology development partnerships between organizations requiring new tools and strategies to manage emerging nanotechnology EHS risks and developers of advanced instrumentation technologies may help marry possible solutions with specific needs. As mentioned previously in this document, there are many risks and rewards associated with such partnerships, but when managed appropriately, they may yield important advancements in developing next-generation EHS management tools.

Nanotechnology EHS Meetings

Attending and participating in conferences, seminars, and workshops is one way to learn about and share strategies for managing nanotechnology-specific EHS risks. Over the past few years, there have been a number of key meetings that have fostered the dialogue required to catalyze partnerships among key stakeholders. Ultimately, this type of dialogue may help facilitate management practices that are both effective and attainable. Conferences and symposia on

[88] *Ibid.*

nanotechnology in general and nanotechnology EHS in particular emerge frequently. Below are some resources to consult to obtain the latest information on meetings and events that may be of interest to your organization:

- **Nanowerk: Nanotechnology Conferences and Events**
  - **Link:** www.nanowerk.com/phpscripts/n_events.php
  - **About:** This resource provides a hyper-linked database of upcoming nanotechnology conferences and symposia. The database is searchable by month and city.
  - .
- **ICON Events Page**
  - **Link:** http://icon.rice.edu/eventsother.cfm
  - **About:** This resource offers a database of current and archived events with an emphasis on nanotechnology EHS. The database is searchable by date. Additional coverage of events specific to the International Council on Nanotechnology is provided.
- **The Project on Emerging Nanotechnologies Events Page**
  - **Link**: http://www.nanotechproject.org/events/
  - **About:** This resource provides links to upcoming PEN events and major international activities with a strong emphasis on EHS.

Key Organizations

Several organizations have been established to address emerging nanotechnology EHS issues. Nanobusinesses may wish to take part in one or more of these groups as a way of sharing best practices and staying abreast of new nanomaterial information. A few examples of these organizations are provided below:

- **SOCMA (Synthetic Organic Chemical Manufacturers Association)**
  - **Link:** http://www.socma.com/
  - **About:** The Synthetic Organic Chemical Manufacturers Association is a preeminent trade organization that caters to industrial scale manufacturers. SOCMA has nearly 275 members across several industries that include small specialty suppliers to large multinational corporations. The organization serves to promote innovative, yet safe and environmentally responsible chemical production methodologies. Recently, SOCMA formed a new coalition for start-ups and small businesses developing and manufacturing nanoscale materials. The goals of the coalition are to:
    - Promote a positive public perception of nanotech;

- Advocate the needs and interests of start-ups, small and medium-sized enterprises;
- Establish consistency and accuracy in developing standards, definitions and nomenclature;
- Secure fair treatment in trade; and
- Share best practices.

- **ANSI (American National Standards Institute)**
  - **Link:** http://www.ansi.org/
  - **About:** The American National Standards Institute serves as the collective governing body with regard to product or service standardization. The institute is responsible for the oversight, development, and implementation of thousands of guidelines and accepted norms across countless businesses ranging from electronic devices, to energy delivery systems, to dairy and livestock products. ANSI has a Nanotechnology Standards Steering Panel, as well as the U.S. Technical Advisory Committee (TAG) for participation in development of international standards at the level of the International Organization for Standardization (ISO).

- **ASTM International**
  - **Link:** http://www.astm.org
  - **About:** ASTM International (formerly known as the American Society for Testing and Materials) is a voluntary standards development organization that assists in the guidance and quality of product development and integration. The organization functions on a global scale and addresses the standardization needs of the global economy. ASTM technical committee E56 addresses nanotechnology issues.

- **BSI (British Standards Institute)**
  - **Link:http://www.bsigroup.com/en/Standards-and-Publications/About-BSI-British-Standards/**
  - **About:** BSI British Standards is the UK's National Standards Body, recognized globally for its independence, integrity and innovation in the production of standards and information products that promote and share best practice. BSI works with businesses, consumers and government to represent UK interests and to make sure that British, European and international standards are useful, relevant and authoritative.

- **ILSI (International Life Sciences Institute)**
  - **Link:** http://www.ilsi.org
  - **About:** The International Life Sciences Institute serves as a global forum in which issues pertaining to food safety, consumer health, and bodily nutrition are addressed by individuals from the

academic, government, and scientific communities. The ILSI mission is to improve the understanding of the aforementioned issues by fostering area-specific programs and building collective information resources on these issues.

- **ISO (International Organization for Standardization)**
  - **Link:** http://www.iso.org
  - **About:** The International Organization for Standardization is a global standard-setting body that is comprised of nearly 198 countries, and establishes industrial and commercial standards. These standards are used in manufacturing, products, and services to ensure efficiency, safety, and quality. Additionally, ISO standards serve to ensure consumer and environmental product safety. ISO Technical Committee 229 address issues for nanotechnologies.

- **NanoBusiness Alliance**
  - **Link:** **http://**www.nanobusiness.org
  - **About:** The NanoBusiness Alliance is the industry association for the emerging nanotechnology industry. Through its extensive network of leading startups, Fortune 500 companies, research institutions, NGOs and public-private partnerships, the Alliance shapes nanotechnology policy and helps accelerate the commercialization of nanotechnology innovations. The NanoBusiness Alliance has offices in New York, Chicago, Washington, DC, and Connecticut.

Resources for Emerging Information

A number of newsletters and publications are available to provide the latest findings on nanotechnology EHS issues. A few examples of these publications are provided below:

- **NIOSH Safety and Health Topic: Nanotechnology**
  - **Link:** www.cdc.gov/niosh/topics/nanotech/
  - **About:** NIOSH is the leading federal agency conducting research and providing guidance on the occupational safety and health implications and applications of nanotechnology. This research focuses NIOSH's scientific expertise, and its efforts, on answering the questions that are essential to understanding these implications and applications: The website includes details of the NIOSH nanotechnology research program strategy and accomplishments, the Nanoparticle Information Library, and the web-based Approaches to Safe Nanotechnology: A Information Exchange with NIOSH.

- **Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies**
    - **Link:** www.nanotechproject.org
    - **About:** The Project on Emerging Nanotechnologies, an initiative of the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts, collaborates with researchers, government, industry, NGOs, policymakers, and others to look long term, to identify gaps in knowledge and regulatory processes, and to develop strategies for closing them. The Project provides independent, objective knowledge and analysis that can inform critical decisions affecting the development and commercialization of nanotechnologies.

- **International Council on Nanotechnology (ICON)**
    - **Link:** icon.rice.edu
    - **About:** ICON is an international, multi-stakeholder organization whose mission is to develop and communicate information regarding potential environmental and health risks of nanotechnology, thereby fostering risk reduction while maximizing societal benefit. ICON activities include an online journal, an EHS bibliography, reports and user surveys, and also a new GoodWiki pilot initiative to share ideas about good handling practices for nanotechnologies.

- **Nanowerk**
    - **Link:** www.nanowerk.com
    - **About:** Nanowerk.com is a nanotechnology and nanosciences portal developed and maintained by Honolulu-based Nanowerk LLC.

- **SAFENANO**
    - **Link:** www.safenano.org
    - **About:** The Safenano Initiative is a venture by the Institute of Occupational Medicine (IOM). The initiative was designed to help industrial and academic communities to quantify and control the risks to their workforce, as well as to consumers, the general population and the environment, through both information provision and consultancy services.

- **NANOSAFE2**
    - **Link:** www.nanosafe.org
    - **About:** The overall aim of NANOSAFE2 is to develop risk assessment and management for secure industrial production of nanoparticles.

- **NanoSafe Australia**
  - **Link:** www.rmit.com.au/NANOSAFE
  - **About:** The NanoSafe Australia network is a group of Australian toxicologists and risk assessors, who have formed a research network to address the issues concerning the occupational and environmental health and safety of nanomaterials.

- **NanoRegNews**
  - **Link:** www.nanoregnews.com
  - **About:** NanoReg is a professional services firm specializing in the regulation of the products of nanotechnology. The NanoReg Report is published by NanoReg to provide current information on government regulations and environmental health and safety issues related to the production and use of nanoscale materials throughout the nanotechnology value chain.

- **Nanotechwire**
  - **Link:** www.nanotechwire.com
  - **About:** Nanotechwire provides nanotechnology news from various global sources.

- **Nanotechnology Law Report**
  - **Link:** www.nanolawreport.com
  - **About:** Nanotechnology Law Report is produced by Porter Wright Morris & Arthur LLP's nanotechnology practice group. The blog is dedicated to providing up-to-date information and commentary on the intersection of nanotechnology and the law.

- **Nanoforum**
  - **Link:** www.nanoforum.org
  - **About:** Nanoforum is a pan-European nanotechnology network funded by the European Union (EU) under the Fifth Framework Programme (FP5) to provide information on European nanotechnology efforts and support to the European nanotechnology community. On the Nanoforum Web site, all users (whether they are members of the public, industry, R&D, government or business communities) can freely access and search a comprehensive database of European nanoscience and nanotechnology (N&N) organisations, and find out the latest on news, events and other relevant information (including education tools, further training, jobs, and other EU projects). In addition, Nanoforum publishes its own specially commissioned reports on nanotechnology and key market sectors, the economical and societal impacts of nanotechnology, as well as organizing events

throughout the EU to inform, network and support European expertise.

- **InterNano**
  - **Link:** www.internano.org
  - **About:** InterNano is an open-source online information clearinghouse for the nanomanufacturing research and development (R&D) community in the United States. It is an initiative of the National Nanomanufacturing Network (NNN). InterNano that is supported by the Center for Hierarchical Manufacturing through a grant from the National Science Foundation. It is designed to provide the nanomanufacturing community with an array of tools and collections relevant to its work and to the development of viable nanomanufacturing applications, including descriptions of nanomanufacturing processes and features for describing EHS controls and good practices.

Acronyms

ABA	American Bar Association
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CPSC	U.S. Consumer Product Safety Commission
CWA	Clean Water Act
EHS	environmental, health and safety
EMS	Environmental Management System
EPA	U.S. Environmental Protection Agency
EPR	extended product responsibility
EU	European Union
FDA	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
ICON	International Council on Nanotechnology
ILSI	International Life Sciences Institute
ISO	International Organization for Standardization
LCA	life cycle assessment
MSDS	material safety data sheet
NGO	non-governmental organization
NIOSH	National Institute for Occupational Safety and Health
NNI	National Nanotechnology Initiative
OSHA	U.S. Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
PPE	personal protective equipment
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Limit
SEER	Section of Environment, Energy, and Resources of the ABA
SME	small and medium sized enterprise
SOCMA	Synthetic Organic Chemical Manufacturers Association
TLV	Threshold Limit Value
TSCA	Toxic Substances Control Act
UCSB	University of California at Santa Barbara