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CONFERENCE PROCEEDINGS

Nanomaterials in the Workplace

Policy and Planning Workshop on Occupational Safety and Health

James T. Bartis, Eric Landree

Prepared for the National Institute for Occupational Safety and Health

RAND INFRASTRUCTURE, SAFETY, AND ENVIRONMENT

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1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138
1200 South Hayes Street, Arlington, VA 22202-5050
4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213
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Preface

How do the National Institute for Occupational Safety and Health (NIOSH) and related federal agencies allocate limited resources so that worker health and safety go hand in hand with innovation and technical progress? This was the central issue addressed at a workshop on nanotechnology and occupational safety and health hosted by the RAND Corporation on October 17, 2005. This document draws on the discussions during that workshop and places them within a policy framework for further consideration by NIOSH. This report should also be useful to other federal agencies responsible for protecting health and safety (such as the U.S. Environmental Protection Agency, the Occupational Safety and Health Administration, and the U.S. Food and Drug Administration) and to those agencies sponsoring the development of or planning to use nanomaterials (such as the National Science Foundation, the Department of Energy, the Department of Defense, and the Department of Commerce). Industries and other organizations engaged in the development, manufacture, or use of products based on nanotechnology may find this report of interest in planning nanotechnology development and use.

This workshop was conducted as part of an ongoing program of research and analysis in support of and sponsored by NIOSH, which is part of the Centers for Disease Control and Prevention within the Department of Health and Human Services.

The RAND Safety and Justice Program

This research was conducted under the auspices of the Safety and Justice Program within RAND Infrastructure, Safety, and Environment (ISE). The mission of ISE is to improve the development, operation, use, and protection of society's essential physical assets and natural resources and to enhance the related social assets of safety and security of individuals in transit and in their workplaces and communities. Safety and Justice Program research addresses occupational safety, transportation safety, food safety, and public safety—including violence, policing, corrections, substance abuse, and public integrity.

Questions or comments about this report should be sent to the project leader, Eric Landree (Eric_Landree@rand.org). Information about the Safety and Justice Program is available online (www.rand.org/ise/safety). Inquiries about research projects should be sent to the following address:

Andrew Morral, Director
Safety and Justice Program, ISE
RAND Corporation
1200 South Hayes Street
Arlington, VA 22202-5050
703-413-1100, x5119
Andrew_Morral@rand.org

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Summary

Over the past few years, various organizations inside and outside of government have focused attention on the lack of understanding of the human health and environmental consequences of nanomaterials. Reports on the human health risks of nanotechnology frequently mention the importance of managing the occupational health risks associated with exposure to nanomaterials. Workers involved with the manufacture or handling of nanomaterials are viewed as being especially susceptible to receiving high exposures to those materials.

The chemical and physical properties of engineered nanomaterials can vary dramatically from those of the bulk forms of the same materials. Nanomaterials represent new substances that require research, analysis, and testing to determine whether they pose health risks and, if so, how those risks can be managed.

On October 17, 2005, the RAND Corporation hosted a workshop on nanotechnology and occupational safety and health. The workshop focused on the policy and planning issues (as opposed to scientific issues) required to understand the options available to NIOSH in formulating and implementing its strategic objectives to protect the safety and health of workers exposed to nanoscale materials. While the workshop discussions ranged over a broad series of topics, there were four problem areas that were repeatedly raised during the course of the meeting:

1. Knowledge gaps related to health risks and worker protections are raising concerns regarding liability that may stymie the development and introduction of new nanomaterials.
2. Efforts to address the occupational risks associated with specific nanomaterials are being impeded by shortfalls in fundamental scientific knowledge common to broad classes of nanomaterials.
3. Public and private resources and funds being allocated to understanding the occupational, health, and environmental risks of emerging nanomaterials are not commensurate with the pace of development of new nanomaterials.
4. Cooperation among federal agencies and between the public and private sectors is essential for progress.

Based on the proceedings of the workshop, presentations at the Second International Symposium on Nanotechnology and Occupational Health and discussions with NIOSH researchers in preparation for the workshop, key components of the overall federal effort for managing the occupation risks of nanotechnology need to be reconsidered:

- Because of other demands on their expertise and resources, NIOSH and agencies that have a role or interest in managing the occupational hazards of engineered nanomaterials can bring only limited funds and personnel to the table. The limited resources that are available should be directed to critical federal roles, such as establishing toxicology fundamentals and providing near-term assistance to protect workers from currently in-use and emerging nanomaterials.
- Greater interaction and cooperation is needed between the nanotechnology development and user communities and NIOSH and related agencies that are responsible for advancing worker safety and health.
- The federal government's efforts to develop the knowledge base required to manage the occupational risks associated with nanomaterials should be undertaken by way of a unified federal strategy that assures appropriate safety and health research, testing, and assessments for managing the risks of occupational exposures.
- The level of federal resources devoted to the safety and health risks associated with nanotechnology in the workplace needs to be reexamined, including the currently planned level of investments in workplace-risk management.

Acknowledgments

We thank each of the workshop participants, listed in Appendix A, for giving their time and sharing their expertise and insights during the workshop.

Our planning for the workshop benefited greatly from discussions with staff from NIOSH and the U.S. Environmental Protection Agency (EPA). In particular, we thank Mary Lynn Woebkenberg, Frank J. Hearl, George Bockosh, and Vladimir V. Murashov of NIOSH; Carl Mazza of EPA; and Andrew Maynard, during his service with NIOSH and later as a member of the Woodrow Wilson International Center for Scholars. Drs. Woebkenberg and Hearl also served as the NIOSH project managers for this project.

Our RAND colleagues Brian Jackson and Henry Willis helped us develop the workshop agenda and conduct the workshop. Roshon Gibson helped coordinate the workshop. A special thanks to Mary Debold, who ably handled all the administrative needs of the workshop, from extending invitations and arranging travel to organizing facility and audiovisual support.

Acronyms

ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
EPA	Environmental Protection Agency
FY	fiscal year
GMO	genetically modified organism
ISO	International Organization for Standardization
NEHI	Interagency Working Group on Nanotechnology Environmental and Health Implications
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NNI	National Nanotechnology Initiative
NSET	Nanoscale Science, Engineering, and Technology Subcommittee
NVPP	Nanoscale Materials Voluntary Pilot Program
OSHA	Occupational Safety and Health Administration
OEL	occupational exposure limit
PPE	personal protective equipment
R&D	research and development

CHAPTER ONE

Introduction

Nanotechnology is the study and application of engineered materials having structural features with one or more dimensions between 1 and 100 nanometers,[1] where unique physical and chemical properties enable novel applications. Nanotechnology is broadly viewed as a set of critical, ubiquitous technologies that will generate a host of new products and applications to the general benefit of consumers and the environment. Worldwide investment in nanoscience and nanotechnology development is in the billions of dollars, with public spending worldwide estimated at more than $3 billion in 2003 (Roco, 2003).

Annual sales revenue from products manufactured using nanotechnology has already passed $10 billion and is anticipated to exceed $100 billion by 2010 (Hett, 2004). Current applications generally involve using nanotechnology to improve the performance of existing products and services. On the horizon are totally new products that offer major advances in, among other areas, computation, communications, energy production and conservation, pharmaceuticals and health care, worker safety, and environmental protection. A consequence of this progress, however, is that workers are at risk of being exposed to new materials, some of which could present serious health hazards. These at-risk workers include researchers involved in nanotechnology development, industrial workers producing nanomaterials, and industrial and commercial workers using nanomaterials.

Over the past few years, attention has focused on the need for better understanding of the human health and environmental consequences of nanomaterials (Service, 2005; National Institute for Occupational Safety and Health [NIOSH], 2005b; Marlowe, 2005; Marrapese and Wall, 2005; Nanoscale Science, Engineering, and Technology Subcommittee [NSET], 2004; The Royal Academy of Engineering and The Royal Society, 2004; National Science Foundation and the Meridian Institute, 2004; Hett, 2004). Nearly all reports on the human health risks of nanotechnology mention the importance of managing the health risks of occupational exposures to nanomaterials, because workers generating or handling nanomaterials are viewed as especially susceptible to receiving high doses (The Royal Academy of Engineering and The Royal Society, 2004; Hett, 2004). Aware of these issues, both NIOSH and the U.S. Environmental Protection Agency (EPA) are developing plans for understanding how to

[1] A nanometer is one-billionth of a meter.

manage the health risks posed by nanomaterials in the workplace (NIOSH, 2005c; NIOSH, undated(b); Nanotechnology Working Group, 2005). In addition, several collaborations are in place for developing best practices for workplace safety and standards.[2]

What Is the Concern?

The chemical and physical properties of engineered nanomaterials are often poorly predicted by the properties of the bulk forms of the same materials.[3] They are new substances that require research, analysis, and testing to determine whether they pose risks and, if so, how those risks can be managed. Nanomaterials are already in commercially available products, and many hundreds more are likely to be introduced in the coming years, posing a significant challenge to government agencies charged with preventing work-related illnesses.[4]

The challenge is not just the result of the large number and diversity of these new substances but also their nature as nanomaterials, especially when handled as discrete particles in the form of a dry powder or in solution. Specifically, there are significant uncertainties regarding exposure measurement (Günter Oberdörster et al., 2005); exposure routes into and within the human body;[5] acute and chronic toxicology (Denison, 2005; Maynard and Kumpel, 2005);[6] risk assessment (Günter Oberdörster et al., 2005; Hett, 2004; Maynard and Kumpel, 2005);

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[2] Efforts to address concerns regarding nanotechnology and nanomaterials in industry include the following:

- ASTM International has established Committee E56 on Nanotechnology to coordinate and collect input from industry and other stakeholders for standards development (ASTM International, undated).
- The Chemical Industry Vision2020 Technology Partnership, an industry-led partnership among private and public stakeholders in the chemical and allied industries, has identified nanotechnology as one of its "thrust" areas (Chemical Industry Vision2020 Technology Partnership, undated).
- The International Organization for Standardization (ISO) has also established a new technical committee, ISO/TC 229—Nanotechnologies, to establish international standards for nanotechnologies (ISO, 2005).

[3] Quantum dots, nanometer-size semiconductor particles, are among the most well-publicized examples of nanomaterials that are in widespread use within the biological sciences today. Macroscopic semiconductor materials are at the core of virtually every commercially available electronic device. However, changes in the semiconductor electronic band structure that occur as a result of shrinking the particle diameter to nanometer scale result in optical fluorescence in the visible spectrum (Michalet et al., 2001). An example currently in commercial use is that of carbon nanotubes, cylindrical sheets of carbon atoms with nanometer diameters capable of growing up to centimeters in length (Huang et al., 2004). Carbon nanotubes have been shown to have electronic and physical properties that differ from those of other bulk forms of carbon.

[4] As an example of the challenge of screening new chemicals, of the approximately 80,000 chemicals that have been registered for commercial use, only 530 have undergone long-term and 70 have undergone short-term testing by the National Toxicology Program (Nel et al., 2006).

[5] Once inhaled, nanoparticles penetrate deeply into the lungs, reaching regions where oxygen exchange occurs and where the nanoparticles may enter the bloodstream. Other exposure routes of concern include nasal passages and other mucous membranes, the skin, and the alimentary canal (The Royal Academy of Engineering and The Royal Society, 2004; Günter Oberdörster et al., 2005). Once in the body, there is also uncertainty regarding how nanomaterials are transported, absorbed, and eliminated. Recent studies show that some nanomaterials can pass the blood-brain barrier (Eva Oberdörster, 2004; Kim et al., 2006).

[6] Scientists have demonstrated surface treatments that are capable of reducing the toxicity of some nanoscale materials. However, the durability and response of those surface treatments under environmental conditions are still unknown (Goldman and Coussens, 2005).

and performance of control methods, including engineering controls and personal protective equipment (Mark, 2004; Maynard and Kumpel, 2005). There are also uncertainties regarding dose-response relationships (Mark, 2004). For bulk substances, response is generally a function of dose mass. For engineered nanomaterials, however, there is growing consensus that surface area provides a more accurate dose metric for inhalation exposures (NIOSH, 2005c; The Royal Academy of Engineering and The Royal Society, 2004). There is still uncertainty regarding the appropriate metric for other exposure routes.

In formulating plans to learn how to address the health risks of nanotechnology in the workplace, NIOSH researchers have developed a systematic approach that covers the inherent complexities and uncertainties of understanding and managing the risks associated with workers' exposure to nanomaterials. At the time of the RAND workshop, these plans included intensive study of a very limited number of nanomaterials, such as titanium dioxide and simple carbon-based nanomaterials, namely carbon nanotubes and fullerenes.[7] In discussing these plans with NIOSH researchers and research managers, we found unanimous agreement that NIOSH's planned level of effort will cover only a very small number of the potentially toxic nanomaterials to which workers will likely be exposed over the next few years. This raises a serious dilemma for NIOSH, for occupational health and safety professionals, and for industries involved in manufacturing or handling nanomaterials.

About the RAND Workshop

The RAND Corporation hosted a workshop on nanotechnology and occupational safety and health on October 17, 2005, at RAND's Arlington, Virginia, office. The purpose of the workshop was to collect information required to understand the options available to NIOSH in formulating and implementing its strategic objectives to protect the safety and health of workers exposed to nanoscale materials. Policy and planning issues, as opposed to scientific issues,[8] were the intended focus of the workshop. Workshop participants, who are listed in Appendix A, included representatives of industrial firms engaged in developing or using nanomaterials, organized labor, the insurance sector, the occupational health and safety community, industry associations, universities and research institutions, and government agencies. In particular, Dr. John Howard, NIOSH's director, attended all of the workshop sessions. Other government agencies represented at the workshop were the Occupational Safety and Health Administration (OSHA) of the Department of Labor; the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health within the Department of Health and Human Services; and EPA.

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7 *Fullerenes* are any cage-like, hollow molecules composed of hexagonal and pentagonal groups of atoms, especially those formed from carbon (U.S. Patent and Trademark Office, 2006).

8 The workshop was held shortly after the Second International Symposium on Nanotechnology and Occupational Health, which provided researchers with the opportunity to confer and share their scientific findings (see *Proceedings and Final Program, Second International Symposium on Nanotechnology and Occupational Health,* 2005).

To promote frank and open discussion during the workshop, participation was limited to 40 persons, and the meeting was conducted on a not-for-attribution basis.

The workshop consisted of a series of four discussion sessions (see Appendix B for the agenda that was distributed to participants). Each session included a brief introduction or discussion of the topic by a moderator from RAND. One session was devoted to each of the following four questions:

- What are the near-term issues that government and industry should address regarding dose, exposure, toxicology, and surveillance?
- How are "best practices" for worker protection being established and communicated to employers and workers?
- What are the key management issues associated with effectively moving forward?
- What are the long-term strategic options for managing risks to workers involved in nanotechnology or using nanomaterials?

Participants were also encouraged to identify additional issues that they believed were relevant to the workshop's overall objectives.

About This Report of the Proceedings

This report of the workshop proceedings is a summary of the main discussions that took place during the workshop. The emphasis is on recording insights and information that, in the judgment of the authors, are most relevant to clarifying the options available to NIOSH for allocating resources and implementing its plans to address the health and safety risks of nanotechnology in the workplace.

Especially insightful or lucid observations by participants are quoted directly in this report. The discussions summarized here represent the judgment and views of the participants at the time of the workshop and may not reflect current efforts to address these issues within government or industry.

This report is organized as follows. Chapter Two discusses the strategic requirements needed to address nanotechnology and occupational safety and health. Chapter Three describes the current resources that are being applied to address related concerns that have been raised. Chapter Four discusses options and suggestions for NIOSH and other federal agencies offered by the workshop participants to address concerns regarding nanotechnology and occupational safety and health.

CHAPTER TWO

Strategic Challenges

While the workshop discussions covered a broad range of topics, four problem areas were repeatedly raised during the course of the meeting:

1. Knowledge gaps related to health risks and worker protections are raising liability issues that may stymie the development and introduction of new nanomaterials.
2. Efforts to address the occupational risks associated with specific nanomaterials are being impeded by shortfalls in fundamental scientific knowledge common to broad classes of nanomaterials.
3. Public- and private-sector resources and funds being allocated to understanding the occupational and, more broadly, the health and environmental risks of emerging nanomaterials are not commensurate with the pace of development of new nanomaterials.
4. Cooperation among federal agencies and between the public and private sectors is essential for progress.

Uncertain Risks and Liability

Each of the participants appeared to be concerned with the possibility that some nanomaterials that are or will be entering the workplace will result in serious harm to the health of exposed workers. Representatives of large manufacturing companies and insurance companies also raised the issue of corporate liability. They referred to asbestos and Vioxx as examples of products brought to market when the potential health risks were not fully understood, with considerable legal as well as health consequences.

Large manufacturers and their insurers are deeply aware of the liability risks associated with introducing new products. To address this problem and to protect their workers and reputations, these companies generally employ specialists in the health and safety testing and evaluation of products, including occupational exposure testing. They also employ or have access to specialists in occupational safety and health. Participants commented that larger companies are generally taking a highly cautious approach in developing or using new nanomaterials. The result, according to participants, is that product development is more costly and product introduction is slowed, especially when compared to new bulk (i.e., not nanoscale) materials, because of the fundamental scientific uncertainties underlying the occupational (and in some cases the public health or environmental) risks of new nanomaterials, as discussed in the next section of this chapter.

Larger manufacturers appeared to be less concerned with their own products and more concerned about nanomaterials being developed by others, especially university research laboratories and small companies that do not have the occupational health and safety and product safety resources of larger firms. They and others at the workshop meeting worried that any nanomaterial causing adverse health effects to workers could dampen public acceptance of all products based on nanotechnology and could lead to an overly zealous regulatory response. Workshop participants broadly voiced this concern regarding small companies and university-based developers of nanomaterials. The point was made that many small-company and university-based nanomaterial developers are highly specialized scientists who have limited understanding of the research required to establish toxicological properties, especially those properties associated with chronic (multi-year) exposures.[1]

Impediments to Establishing and Managing Occupational Risks

Fundamental scientific uncertainties regarding exposure and dose monitoring, toxicological testing and evaluation, and risk management and control are the principal impediments to progress in establishing and managing the occupational risks of nanomaterials.

Nanomaterials' Toxicity

Inside the human body, nanomaterials may exhibit unique properties that are not associated with "ordinary" materials. Workshop participants discussed how the generally accepted toxicity testing and evaluation protocols may not be applicable to many nanomaterials. Even if a firm developing a new nanomaterial invests in a typical toxicological screening of the nanomaterial, there is likely to be residual uncertainty that major toxic effects were not examined.

The discussion of this problem led the workshop participants to identify, as an overarching need for progress, the development of tools and protocols for testing and evaluating the toxicity of nanoscale materials. Emphasizing the large number of different nanomaterials that are currently being developed, the workshop participants generally agreed that the overall goal should be to roughly predict or classify the potential toxicity of nanomaterials based on their material properties. Toward this end, the workshop addressed the need to study

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[1] While not mentioned during the workshop, we note here that the difference between how small firms and large firms address product and workplace safety leads to an uneven playing field, putting larger firms at a competitive disadvantage in developing nanoscale materials. On the other hand, over the longer term, larger firms may benefit from their investments in managing risks.

systematically classes of related nanomaterials so that the determinants of toxicity can be better understood.[2]

> We are starting in a systematic way to look at the toxicity of some of the naturally occurring and engineered nanomaterials—but it is certainly only a start.
> —*Government representative*

Current studies on the possible health risks of nanomaterials are focusing primarily on acute toxicity. A few of the participants emphasized the importance of research directed at evaluating possible chronic toxic effects. This was recognized as long lead-time research; the development of a model that would be useful for identifying chronic hazards was estimated to require about ten years of work.[3]

Several participants discussed the need for protocols and surveillance strategies for observing worker health in the near term in order to be able to assess the possible long-term chronic toxic effects. Historically, the creation of monitoring and surveillance strategies in the workplace was done in response to a known, well-defined risk. Adapting this after-the-fact approach to surveillance was deemed inappropriate for protecting worker safety and for addressing the liability of manufacturers and users and their insurers.

Participants pointed out that most companies dealing with nanomaterials do not know how to capture surveillance data in such a way that the data can be used for cross-referencing with other types of data. In addition, there is a basic lack of information needed to connect medical surveillance with exposure metrics for assessing workers' health risks associated with nanomaterials. In some cases, the ability to capture surveillance data is limited by federal regulations that are intended to protect individual privacy.

> [W]hen you talk about medical surveillance, you have to ask, what type of health effects will you monitor, and when will they occur? You may be talking about a 10 to 40 year horizon.
> —*Government representative*

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2 Normally, toxicological screening of a nanomaterial focuses on a sample of specific size, composition, and structural characteristics. If toxic effects are found, the underlying cause or causes remain uncertain until related nanomaterials are examined to determine how changes in size, composition, and structure affect toxicity. This information is essential to developing an ability to screen new nanomaterials and to determine whether a new nanomaterial requires a full round of toxicological testing or, going to the other extreme, whether that material is likely to show toxicological properties of materials that have already been examined. For these reasons, workshop participants described the need to establish a systematic approach that would connect classes of properties with possible health or environmental effects.

3 Long-term studies of possible chronic toxic effects are generally more expensive than studies of acute toxic effects, suggesting that fewer nanomaterials can reasonably be tested. This further emphasizes the need to develop a systematic approach for predicting which nanomaterials might cause chronic health effects.

> Most companies don't know how to do the surveillance. They also don't know how to capture the data in a way that they can actually be used. Most are captured in files and therefore can't be cross-analyzed effectively.
>
> —*Professional association representative*

Exposure and Dose

Participants agreed that there was uncertainty regarding whether cumulative mass, surface area, number of particles, or some other metric should be used for measuring exposure or dose. While the effects of nanomaterials in the human body are not understood, a growing number of studies have provided initial findings that indicate toxic effects on biological systems from exposure to nanomaterials (see Kim et al., 2006; Ding et al., 2005; Braydich-Stolle et al., 2005; and Eva Oberdörster, 2004). However, the proper procedures and metrics for monitoring exposure or dose in a workplace or industrial setting are yet to be established. Once a dose metric (mass, volume, surface area, particle count, etc.) is determined, it would need to be translated into a metric that could be utilized by safety engineers for evaluating exposure and safety in the workplace environment. This would also require evaluating the effectiveness of administrative and engineering strategies for controlling occupational exposure.

Currently, there are no standard guidelines or practices for sampling or monitoring nanoscale material exposure. Industries are beginning to develop their own processes for sampling and monitoring. However, the effectiveness of these protocols for measuring nanomaterials is still untested.

Controlling Exposures

Some of the workshop participants expressed skepticism about the feasibility of adapting the current framework for controlling occupational exposure to toxic materials in the workplace to the problem of exposure to nanoscale materials. The current framework centers on establishing occupational exposure limits (OELs) for each material and keeping worker exposures within OELs through a combination of administrative controls, engineering controls, and the use of personal protective equipment (PPE). In this area, the principal concern was that the formal process of establishing OELs would overwhelm NIOSH and OSHA capabilities, considering the current knowledge base in nanomaterials toxicity and exposure/dose monitoring and in anticipation of many hundreds of new nanomaterials entering the workplace over the next few years.

Participants mentioned using an alternative framework centered on the concept of control banding.[4] They also briefly discussed the possibility of applying the ALARA (as low as reason-

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[4] Control banding is "a process in which a single control technology (such as general ventilation or containment) is applied to one range or band of exposures to a chemical (such as 1–10 mg/m3) that falls within a given hazard group (such as skin and eye irritants or severely irritating and corrosive). . . . The most developed model for control banding has been established by the Health and Safety Executive of the United Kingdom" (see NIOSH, undated[a]).

ably achievable) method, which is used for the handling of radiological materials.[5] However, workshop participants expressed concern that requiring industries and academic institutions to handle nanomaterials, even those that have not undergone screening for toxicity, in the way they would handle radiological materials would hamper necessary research and dissuade industries from pursuing nanotechnologies.

> We can bring in a Ph.D. with a cart of equipment to assess measures [for controlling exposures to nanomaterials]. But if we had to do that every day, we would go broke. We need small, cheap, accurate ways to validate our engineering controls and the effectiveness of personal protective equipment.
>
> —*Industry representative*

Participants also discussed the lack of information regarding the effectiveness of PPE in controlling exposures to nanomaterials. While considerable progress was recently reported in the area of air filtration (*Proceedings and Final Program, Second International Symposium on Nanotechnology and Occupational Health*, 2005), there was general agreement that much additional research needs to be directed at assessing the effectiveness of engineering and PPE controls.

Dissemination and Education

Participants commented on the need to disseminate information and educate workers about the potential risks and mitigation strategies for handling nanomaterials. A concern is the development of accurate Material Safety Data Sheets. Examples were identified in which Material Safety Data Sheets for various nanomaterials were either incomplete or referred to controls proposed for other nanoscale or bulk materials of the same chemical composition.

Participants stressed the importance of leveraging the training infrastructure already available through NIOSH and OSHA for educating workers about occupational risks. The interim guidance and information provided by NIOSH immediately after Hurricane Katrina for workers in New Orleans, and following the 2001 anthrax attacks in the United States, were viewed as possible models for disseminating preliminary information to workers about nanotechnology. Another recommendation proposed that NIOSH produce a series of short fact sheets that would explain in lay terms the current risks and best practices concerning specific nanomaterials.

Standards Development

Participants suggested that preliminary standards for nanomaterials be developed and promulgated based on current information. The proposed preliminary standards would be updated

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5 The ALARA method assumes that every radiation dose, regardless of magnitude, can produce some type of detrimental effect (e.g., genetic mutation, cancer) in living systems (University of California Lawrence Livermore National Laboratory, 2005).

as new data become available. Both public- and private-sector stakeholders are participating in standards bodies and organizations such as ASTM International, the American National Standards Institute (ANSI), and the International Organization for Standardization (ISO). Important challenges involve coordinating the various efforts that are currently under way, identifying a single organization or agency to be responsible, and helping to provide public and private organizations with near-term guidance.

> The problem is that [standards development] isn't a straight line—you don't start out with exposure, then health effects, then standards. It's a circle. You have to do all at the same time and iterate among them.
>
> *—Government representative*

It was agreed that more international harmonization of standards and occupational health and safety practices is needed. A few participants raised concerns that the absence of consistency among international players could result in a significant percentage of nanomaterials manufacturing moving to countries with fewer occupational health and safety policies. This would potentially increase the United States' dependence on foreign countries for manufactured nanomaterials and nano-enabled products. Alternatively, if the United States is able to establish effective international collaborations with other countries currently pursuing nanotechnology, it may have the opportunity to set the global standard for nanotechnology occupational safety and health.

CHAPTER THREE

Resources

Resources and Funding

During the workshop, nongovernment participants[1] repeatedly expressed their concern that adequate resources and funding were not being directed at understanding the occupational risks of emerging nanomaterials. This concern was expressed not only by participants representing labor, public health, and environmental protection communities, but also by participants associated with organizations engaged in nanotechnology development and the insurance industry.

Prior to the workshop, NIOSH made available a peer-reviewed draft of its Strategic Plan for Nanotechnology Research (NIOSH, 2005a). While workshop participants who were familiar with this draft plan characterized it as technically sound, they also expressed their concern that the draft plan could not be implemented unless NIOSH was committed to a large increase in the amount of its funds and personnel time devoted to nanotechnology.

Fairly strong criticism was directed at public-funding levels. The argument was made that funding from the federal government is the principal driving force for advances in nanoscience and nanotechnology in the United States. This federal funding is responsible for the magnitude of the number of new nanomaterials that are anticipated to enter the marketplace, and the workplace, over the next few years. The federal government sees benefits associated with the timely commercial introduction of new nanomaterials. Therefore, just as a private firm would do, the federal government should devote increased funding and attention to the occupational and, more broadly, health and environmental risks from those new nanomaterials that are likely to enter into commerce.

The alternative to public funding is private-sector funding of needed research in health and safety.[2] For large firms, these investments are being made; but for smaller organizations, occupational health and safety issues do not appear to be adequately addressed, as discussed

[1] Recognizing the sensitivity of funding issues, the government participants declined to comment on the adequacy of their agency budgets.

[2] For example, provisions for new chemicals under the Toxic Substances Control Act require industry to submit to EPA only existing health and safety data at the time of notification to EPA. Upon review, EPA can then require industry to conduct additional tests to generate health- and safety-related data. For products covered by the Federal Insecticide, Fungicide, and Rodenticide Act, industry is required to conduct health and safety research prior to the introduction of each new chemical into commerce.

in the previous chapter.[3] The government has the option of employing its regulatory powers to ensure that no firm allows products to enter the marketplace or workplace until health and safety issues are fully addressed. However, directing these regulatory powers at the emerging field of nanotechnology could significantly impede the commercial introduction of new nanomaterials, including those that might offer benefits for worker health, public health, and environmental protection. In particular, neither government nor industry has developed the fundamental knowledge base required to regulate nanomaterials.

Federal Funding Levels

The National Nanotechnology Initiative (NNI) is "a multi-agency U.S. government program aimed at accelerating the discovery, development, and deployment of nanoscale science, engineering, and technology" (NSET, 2005). For fiscal year (FY) 2005, the NNI reports that the federal government directed an estimated $1.08 billion toward these objectives, and the President's FY 2006 budget request is $1.05 billion (NSET, 2005). Table 3.1 lists NNI's estimate of the NNI FY 2006 funding for environmental, health, and safety research and development (R&D), by funding source. The $38.5 million total represents less than 4 percent of the total NNI budget request for FY 2006. During the workshop, participants estimated that considerably less than $10 million per year—less than 1 percent of the anticipated federal outlay for nanotechnology development—is being allocated to research directed at or

Table 3.1
Estimate of NNI FY 2006 Funding for Environmental, Health, and Safety R&D (in millions of dollars)

National Science Foundation	24.0
Department of Defense	1.0
Department of Energy	0.5
National Institutes of Health	3.0
National Institute for Standards and Technology	0.9
Department of Agriculture	0.5
Environmental Protection Agency	4.0
National Institute for Occupational Safety and Health	3.1
Department of Justice	1.5
Total	38.5

SOURCE: NSET (2005).

[3] There might also be problems with public acceptance of the findings of health and safety research conducted under industry funding, as evidenced by concerns raised regarding industry-funded studies of tobacco, soft drinks, and infant formulas (Proctor et al., 1998), to name a few topic areas.

relevant to managing and understanding the risks associated with occupational exposures to nanomaterials.[4] These estimates would include most of the NIOSH budget request, a sizeable portion of the EPA budget request, and funds supporting National Toxicology Program efforts under the auspices of NIEHS, which are included in the $3 million allocated to the National Institutes of Health.

The Federal Funding Dilemma

Annual funding for NIOSH is approximately $286 million (Department of Health and Human Services, 2005). These funds are directed at areas where workers are being harmed or where their lives are threatened. To date, there are no known worker fatalities, injuries, or diseases related to occupational exposures to engineered nanomaterials. For this reason, NIOSH has been reluctant to shift additional resources from the current known threats to worker safety and health to the future threats potentially posed by the emergence of new nanomaterials in the workplace.[5] NIOSH's legislative mandate is worker health and safety, not the promotion of new materials and technology, except as those materials and technology have a role in promoting worker health and safety.[6]

With a few nanomaterials of concern already in commerce and hundreds more on the way, NIOSH faces a resource constraint. If NIOSH takes its traditional approach of establishing occupational exposure limits (OELs) through in-house research supplemented by knowledge developed through NIOSH-supported research grants, it is likely to require annual budgets in the tens of millions of dollars and a large, dedicated staff. Workshop participants, especially those from government agencies, recognized that obtaining such a large budget and personnel increase is highly unlikely. Discussions with NIOSH staff subsequent to the workshop indicated that alternative approaches might be possible. These alternatives are addressed in Chapter Four of this report.

> We are not going to see more money appropriated to NIOSH or OSHA, for at least the next year. . . . Money won't come from Congress at this point unless there is a push on the labor side and industry in this area. If we want OSHA and NIOSH to do more work, then lobbyists need to push Congress to appropriate more money.
>
> —*Labor union representative*

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4 See also Maynard, undated.

5 We note that NIOSH, like many other federal agencies, does not have full control of its budget, since its budget is part of that of the Centers for Disease Control and Prevention, the Department of Health and Human Services, and the President's budget request.

6 For this reason, in addition to research on the potential occupational risks of some nanomaterials, the NIOSH budget shown in Table 3.1 also covers R&D investments in nanotechnology research that offers to improve the performance of personal protective equipment.

Cooperation

The workshop participants emphasized cooperation and collaboration in two areas: among government agencies with a role or interest in occupational safety and between government and the private sector.

Interagency Cooperation and Collaboration

Because federal resources are limited, the participants emphasized the need for federal agencies to not merely coordinate their activities but also to move toward cooperative and collaborative efforts. The prime targets of this recommendation were NIOSH and EPA. In particular, both EPA and NIOSH have prepared, for public comment, plans for their agencies' programs on nanotechnology and workplace exposures. The participants suggested that separate agency planning, albeit coordinated, is not responsive to funding and personnel constraints. As an alternative, they raised the concept of a unified federal plan, collaboratively prepared and implemented. Additionally, concerns were raised that interagency cooperation is needed to avoid redundant interfaces between these two government agencies and the private sector.

Government-Industry Cooperation

While acknowledging efforts on the part of EPA, NIOSH, and others, it was suggested that federal departments and agencies need to do a better job of engaging the private sector and nongovernmental organizations. Specifically, improved government-industry cooperation was cited as essential for establishing federal plans for near-term R&D, receiving information needed for federal research programs, and assuring early and efficient dissemination of information on best practices for worker protection.

With hundreds of novel nanomaterials under development, both NIOSH and the occupational side of the EPA program need to focus their near-term R&D efforts on those materials that pose the greatest risks to worker safety and health. This requires advance knowledge of when new nanomaterials will be entering the workplace, the number of workers at risk of exposure, and preliminary judgments regarding the adverse consequences of exposure. Obtaining this information requires establishing arrangements under which industry will share with the government sensitive proprietary information associated with product development.

Early production activities by industry also offer opportunities for surveillance and workplace monitoring programs, and the test and evaluation of best practices for controlling worker exposures. At the workshop, NIOSH reported that it already had a few cooperative efforts under way, especially with smaller companies that welcomed the occupational safety and health expertise that NIOSH was able to bring to the table.

EPA has proposed a Nanoscale Materials Voluntary Pilot Program (NVPP) for the purpose of increasing coordination with firms developing new nanomaterials (Interim Ad Hoc Working Group on Nanoscale Materials, 2005). This program was mentioned during the workshop as a possible approach that the government could take to reach out to a broad base of industrial firms. While the establishment of the NVPP has been coordinated with other government agencies, including NIOSH and NIEHS, it is not a collaborative effort, but rather one designed to meet EPA's needs. Workshop participants suggested that integrating an NVPP into a unified federal strategy for worker protection may be productive, especially to avoid redundant information requests. At the time of the workshop, an NVPP was still a development concept and had not yet been implemented.

Information Sharing

Participants stressed the importance of providing information, both positive and negative, to the public in order to gain public confidence and to enable an informed dialogue on the possible benefits and risks of nanotechnology. They also commented on general public fears about nanotechnology and made comparisons with genetically modified organisms (GMOs). Without public acceptance, many of the benefits from federal and private investments in emerging nanotechnologies will go unrealized. Participants expressed concern that some information on nanotechnology risks is not based on sound science.

> In the absence of a reasonable approach to risk management, we will have public-perception problems.
>
> *—Nongovernmental organization representative*

Suggestions for improving public outreach included increasing federal government and industry collaborations with domestic and foreign universities, educating workers about the risks of nanotechnologies, actively seeking information from the public on ways to communicate the risks of nanomaterials, and learning from past experiences with GMOs and asbestos.

CHAPTER FOUR

Toward Nanotechnology Workplace Safety

Throughout the workshop, a number of important policy issues emerged. Some of these issues were explicitly addressed in the meeting and are summarized in Chapters Two and Three; others are implicit consequences of the workshop discussions. In this concluding chapter, the authors draw out several of these key policy issues for further reflection.

Based on the proceedings of the workshop, the presentations made at the Second International Symposium on Nanotechnology and Occupational Health (*Proceedings and Final Program, Second International Symposium on Nanotechnology and Occupational Health*, 2005), and discussions with NIOSH researchers in preparation for and following the workshop, key components of the overall federal effort for managing the occupational risks of nanotechnology need to be reconsidered.

First, because of other demands on their expertise and resources, NIOSH and agencies that have a role or interest managing the occupational hazards of engineered nanomaterials can bring only limited funds and personnel to the table. Consequently, the limited federal occupational safety and health expertise and resources that are available in these agencies ought to be directed to where they are most needed, i.e., where they cannot be replaced by private-sector efforts.

Second, greater interaction and cooperation are needed between the nanotechnology-development and user communities and NIOSH and related agencies that are responsible for advancing worker safety and health.

Third, the federal government's efforts to develop the knowledge base required to manage the occupational risks of nanomaterials should be undertaken under a unified federal strategy. This strategy should require that a government agency supporting the development of a new nanomaterial is also responsible for assuring the performance of appropriate safety and health research, testing, and assessments that are essential for managing the risks of occupational exposures.

And finally, federal resources—funding, personnel, and facilities—devoted to the safety and health risks of nanotechnology in the workplace need to be reexamined. If the intent of the Administration and Congress is to have NIOSH and related agencies address efficiently and effectively the workplace risks of nanotechnology, additional funding will be required. In particular, the NIOSH, EPA, and NIEHS FY 2006 budget requests, as presented by the NNI (NSET, 2005), for nanotechnology workplace-risk management do not appear adequate to support a unified strategy that focuses these agencies on critical federal roles.

Critical Federal Roles

Chapter Two summarized fundamental uncertainties—in toxicology, exposure and dose monitoring, and exposure controls—that are viewed as the principal impediments to managing the risks of nanomaterials in workplaces. Because these uncertainties pertain to fundamental nanomaterial properties, their resolution can be expected to apply to broad classes of nanomaterials that may be beyond the commercial interests of any single firm. Further, the range of expertise required to plan and implement a research program to resolve these fundamental questions is generally beyond the capabilities of most firms, if not all firms, engaged in nanotechnology development. For these reasons, it is difficult to imagine how these important fundamental questions will be resolved unless federal agencies with occupational safety and health expertise take a leading role.

Resolving uncertainties in the toxicology of emerging engineered nanomaterials is also important for protecting public health and the environment, objectives that pertain to the core missions of EPA and NIEHS. For this reason, it may be appropriate for the government to consider an approach in which EPA and NIEHS take leading roles in systematically investigating nanomaterials' toxicology, with the explicit goal of developing a capability to predict potential toxicology based on material properties. This approach would have NIOSH toxicologists focus on dose levels and nanomaterials relevant to workplace (as opposed to public health) exposures, and allow remaining NIOSH personnel and resources to focus on uncertainties associated with occupational exposures, doses, and exposure controls. Under this concept, NIOSH would use information developed by EPA and NIEHS to provide guidance to developers regarding appropriate toxicological testing and assessment protocols.

The second critical role for NIOSH is to help protect workers from the potential adverse effects of nanomaterials that are now or will soon be in workplaces. There are three basic reasons for this role in addressing near-term issues:

1. If the fundamental problems discussed above are to be properly resolved, NIOSH researchers need to understand real-world issues associated with nanomaterials in the workplace.
2. There is a legitimate and growing need for objective information that can be used immediately.
3. There is an opportunity to be collecting real-time information in current industrial applications.

During the workshop, participants observed that small- and medium-sized businesses have an especially hard time getting access to environmental, health, and safety experts. The nanotechnology development community, especially managers and workers in universities and small businesses, ought to be able to receive from NIOSH objective information on protective practices, how to document processes, monitor exposure, and conduct surveillance. Because so much nanotechnology development is taking place in small businesses and universities, the workshop participants suggested that NIOSH expand its work with university researchers and small- and medium-sized businesses to develop optimized measurement strategies and a database of best practices. Small business in particular lack forums for sharing best practices about nanomaterials. A few participants mentioned that NIOSH could play a productive role in catalyzing the creation of a network of industries and organizations to help provide information for those in need. Overall, the suggestions made by the workshop participants appear consistent with the information-exchange mechanism proposed by NIOSH shortly before the workshop.[1]

> Lots of nanoparticles and materials are produced in small companies and university labs—I have a company calling me saying they are producing silver nanoparticles and don't know how to monitor to see if their workers are safe.
>
> —*Academic representative*

In implementing these two critical missions—fundamentals and near-term assistance—NIOSH may face constraints in the number of available NIOSH personnel. For this reason, NIOSH might consider an alternative business model in which work normally done in-house is contracted out. This would involve transitioning from an operating mode in which NIOSH researchers are primarily involved in hands-on research to one in which they are responsible for a blend of hands-on research and contract management.

Working with the Nanotechnology Development Community

The workshop participants frequently stressed the importance of stronger interactions between federal agencies responsible for advancing occupational health and safety and firms and organizations developing or using engineered nanomaterials. Large firms have important insights to share regarding potential toxicity, exposure routes, and best practices. Small firms need assistance and advice. All employers and workers require information on possible threats and best practices. To meet these needs as they pertain to the diversity of emerging nanomaterials, participants suggested that NIOSH significantly broaden its interactions with the nanotechnology development and user communities.[2]

In addition, the workshop addressed the need for NIOSH and related agencies to prioritize their research efforts by anticipating the emergence of nanomaterials that might present adverse exposures to workers. This requires that these federal agencies convincingly demon-

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1 On October 1, 2005, NIOSH requested an information exchange among occupational safety and health practitioners, researchers, product innovators and manufacturers, employers, workers, interest group members, and the general public (NIOSH, 2005b).

2 Shortly after the workshop (December 2005), NIOSH announced that it would form an interdisciplinary field team of NIOSH researchers in the area of nanotechnology. The team will partner with employers and others in conducting field studies to observe and assess occupational health and safety practices in facilities in which nanotechnology processes and applications are used.

strate to industry the value of cooperation as well as their commitment and capability to hold confidential proprietary information.

The NVPP being developed by EPA's Office of Pollution Prevention and Toxics offers an approach for establishing stronger coordination with organizations developing or using engineered nanomaterials (Interim Ad Hoc Working Group on Nanoscale Materials, 2005). If a decision is made to implement NVPP, consideration should be given to providing NIOSH with a stronger role (i.e., collaboration as opposed coordination) in planning and implementing all portions of the NVPP that deal with occupational exposures and controls. Otherwise, the nanotechnology development community may face duplicative information requests and receive conflicting advice regarding near-term measures.

Unified Federal Strategy

The continued development and successful introduction of new nanomaterials require that critical knowledge gaps in occupational risk management are expeditiously addressed. Given the limited numbers of trained federal personnel and budget constraints, workshop participants suggested that NIOSH, EPA, NIEHS, and other relevant agencies collaborate to develop and implement a unified federal strategy for addressing knowledge gaps in the management of occupational risks. Under this concept, each collaborating agency will be responsible for assuring that the unified strategy covers all critical federal roles in filling knowledge gaps and providing near-term support to protect workplaces. Implementation responsibilities would be based on agency charters and capabilities, with the understanding that they must meet milestones for providing intermediate products needed by collaborating agencies.

> Everyone wants to take the lead on this. . . . The problem is there are several groups coming together and determining who is going to successfully take the lead. . . . Everyone is trying to take the lead.
>
> —*Academic representative*

The workshop participants also suggested that federal agencies, such as the Department of Energy, the Department of Defense, the National Institutes of Health, and the National Science Foundation,[3] that are developing specific advanced nanomaterials as part of their core missions be required to ensure that appropriate health and safety research, testing, and risk assessments are being accomplished before those materials are introduced into workplaces. While NIOSH may need to lend resources to assist these agencies in planning and imple-

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[3] Each of these four agencies is slated to invest at least $100 million in nanoscience and technology development in 2006.

menting such work, a number of federal agencies, such as the Departments of Defense and Energy, have notable capabilities in the area of occupational health and safety.[4]

Within the NNI, the Interagency Working Group on Nanotechnology Environmental and Health Implications (NEHI)[5] has been established to coordinate agency activities directed at identifying and prioritizing research associated with the environmental, health, and safety implications of nanotechnology. The NEHI working group provides a forum for achieving the level of collaboration called for in the workshop. On the other hand, the responsibilities of the NEHI working group go well beyond occupational safety and health. In addition, workshop participants familiar with the NNI raised the point that developing a unified strategy goes beyond the current NNI business model, which is directed at coordination, identifying research opportunities and gaps, and public outreach.

Closing Comments and Funding

The workshop on nanotechnology and occupational health and safety covered a broad range of topics. At the conclusion of the workshop, John Howard, Director of NIOSH, provided an overview of a dozen key points raised during the meeting. In this summary of the workshop proceedings, we have focused on what we consider to be the key messages of the participants.[6] The workshop participants also raised and discussed technical topics relevant to program implementation. Notes on these topics were taken by workshop observers from NIOSH and other federal agencies.

Deliberations during the workshop imply that the promotional efforts and multi-billion-dollar investments made under the National Nanotechnology Initiative are at risk due to continuing uncertainties and liabilities associated with managing and controlling the occupational health, public health, and environmental risks posed by emerging nanomaterials. Moreover, with current funding allocations to NIOSH and related efforts, these uncertainties will not be resolved, but rather will grow as new nanomaterials are introduced.

We have summarized recommendations and suggestions raised by workshop participants regarding the implementation of future efforts by NIOSH, EPA, and related agencies to address occupational risks. By calling for greater collaboration and partnership within government and between government and the nanotechnology development community, the workshop participants have provided NIOSH and EPA with an approach that may be implemented within

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[4] A member of the Department of Energy served as a workshop participant. An Army physician specializing in occupational health attended as an observer.

[5] NEHI is a subgroup of the Nanoscale Science, Engineering, and Technology Subcommittee, Committee on Technology of the National Science and Technology Council. The NEHI agency membership includes NIOSH, EPA, NIEHS, the U.S. Food and Drug Administration, the Department of Defense, the Department of Energy, and the National Science Foundation.

[6] Important areas addressed by the workshop and included in Dr. Howard's summary, but not reported here, are (1) the importance of efforts directed at "prevention by design"; (2) the opportunities offered by NIOSH's Education Research Centers; and (3) the importance of collaboration with foreign-based partners, especially Asian firms and governments, that are heavily investing in nanotechnology.

stricter budget and personnel allocations than what would otherwise be required. This potential for lower estimated expenditures in budget and personnel centers on limiting federal health and safety agency involvement to essential roles, operating collaboratively under a unified strategic plan, and requiring that in cases in which federal agencies are promoting the emergence of new nanomaterials, they are responsible, in the same manner as any large corporation would be, for ensuring that adequate information is available for managing occupational risks.

APPENDIX A

Workshop Participants

James Alwood
U.S. Environmental Protection Agency

Kevin Ausman
Center for Biological and Environmental Nanotechnology
Rice University

John M. Balbus
Environmental Defense

Clinton Ballinger
Evident Technologies

Janice Bradley
International Safety Equipment Association

Steven W. Brown
Intel Corporation

Soma Chengalur
Eastman Kodak Company

Stephen Cook
AIG Consultants

Roy Doumani
California Nanosystems Institute

John M. Fajen
AIG Consultants

Judy Graham
American Chemistry Council

Frank J. Hearl
National Institute for Occupational Safety and Health

David Heidorn
American Society of Safety Engineers

Monique C. Hesseling
ACE Group

John Howard
National Institute for Occupational Safety and Health

Bruce B. Johnson
DuPont Company

David S. King
Altairnano Corporation

Bill Kojola
AFL-CIO

Doris L. Konicki
American College of Occupational and Environmental Medicine

Mary Ann Latko
American Industrial Hygiene Association

Andrew Maynard
Woodrow Wilson Center

Sean Murdock
NanoBusiness Alliance

Nhan Nguyen
U.S. Environmental Protection Agency

David Ortlieb
United Steel Workers

William Perry
Occupational Safety and Health Administration

David Y. H. Pui
Particle Technology Lab
University of Minnesota

Margaret Quinn
School of Health and Environment
University of Massachusetts, Lowell

Paul Schulte
National Institute for Occupational Safety and Health

Michael Seymour
Occupational Safety and Health Administration

Glenn Spacht
NanoDynamics, Inc.

Michael Sprinker
International Chemical Workers Union

Patricia B. Strasser
American Association of Occupational Health Nurses

James Votaw
Hyperion Catalysis/Wilmer Cutler Pickering Hale and Dorr LLP

Nigel J. Walker
National Institute of Environmental Health Sciences

Paul Wambach
U.S. Department of Energy

Ronald H. White
John Hopkins Bloomberg School of Public Health

Dee Woodhull
ORC Worldwide

APPENDIX B

Agenda for Policy and Planning Workshop on Nanotechnology and Occupational Safety and Health

Introduction:

- Debra Knopman, Vice President, RAND Corporation
- John Howard, Director, National Institute for Occupational Safety and Health
- James Bartis, Senior Policy Researcher, RAND Corporation
  - Workshop procedures, attribution rules, and RAND report

Morning Session:
Moderator: James Bartis, RAND Corporation

Presentation: Workshop Kickoff—Recent Developments and Key Issues

Discussion: What are the near-term issues that government and industry should address regarding dose, exposure, toxicology, and surveillance?

- What nanomaterials should the government be focusing on?
  - How might the government forecast what materials will be entering the workplace and identify those that may pose a risk to worker health and safety?
  - How should the government prioritize which materials to investigate?
- How can the community enable a predictive capability to classify new materials with regard to potential toxicity?
- How can the community establish nanomaterials testing and evaluation standards (e.g., toxicology testing standards)?
- What is needed to enable surveillance of workers exposed to nanotechnology or nanomaterials?
  - Should surveillance include reporting of exposures and illnesses?
  - How should NIOSH interface with ongoing and planned efforts?
- What are the roles of NIOSH and related agencies in addressing potential risks to workers over the next 5 to 10 years?

Mid-Morning Session:
Moderator: Henry Willis, RAND Corporation

Discussion: How are "best practices" for worker protection being established and communicated to employers and workers?

- For monitoring environments and possible exposures:
  - Is the knowledge base adequate for setting monitoring standards?
  - Is monitoring equipment ready for workplace use?
- What options are available for developing near-term guidelines for environmental, administrative, and personal protective controls?
  - What types of decisionmaking tools are available?
  - What is the proper mechanism for communicating risk to employees (Material Safety Data Sheets, etc.)?
- Where is the greatest need for federal efforts?

Working-Lunch Session:
Moderator: James Bartis, RAND Corporation

Discussion: What are the key management issues associated with effectively moving forward?

- NIOSH resource limitations: personnel and budget
- Federal agency roles: key needs and opportunities for collaboration
- Industry-government collaboration: motivation and barriers
- Role of the insurance industry
- Total community outreach and involvement

Afternoon Session: Long-term strategy for Government and Industry
Moderator: Henry Willis, RAND Corporation

Discussion: What are the long-term strategic options for managing risks to workers involved in nanotechnology or using nanomaterials?

- What are the long-term issues associated with using occupational exposure limits (OELs) to establish exposure limits?
  - Is control banding an appropriate approach?
  - What other approaches might be appropriate?
- What are possible consequences of deferring a decision on a strategic approach for risk management?
  - What research and analysis is needed to support decisionmaking?
- Harmonization
  - Between the efforts of NIOSH/OSHA and EPA?
  - Among major U.S. trading partners?

- How might NIOSH more effectively interact with stakeholders as it develops and implements its programs to address nanotechnology in the workplace?

Wrap-up Session: Summary of major issues discussed and closing remarks

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