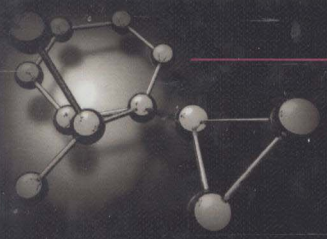

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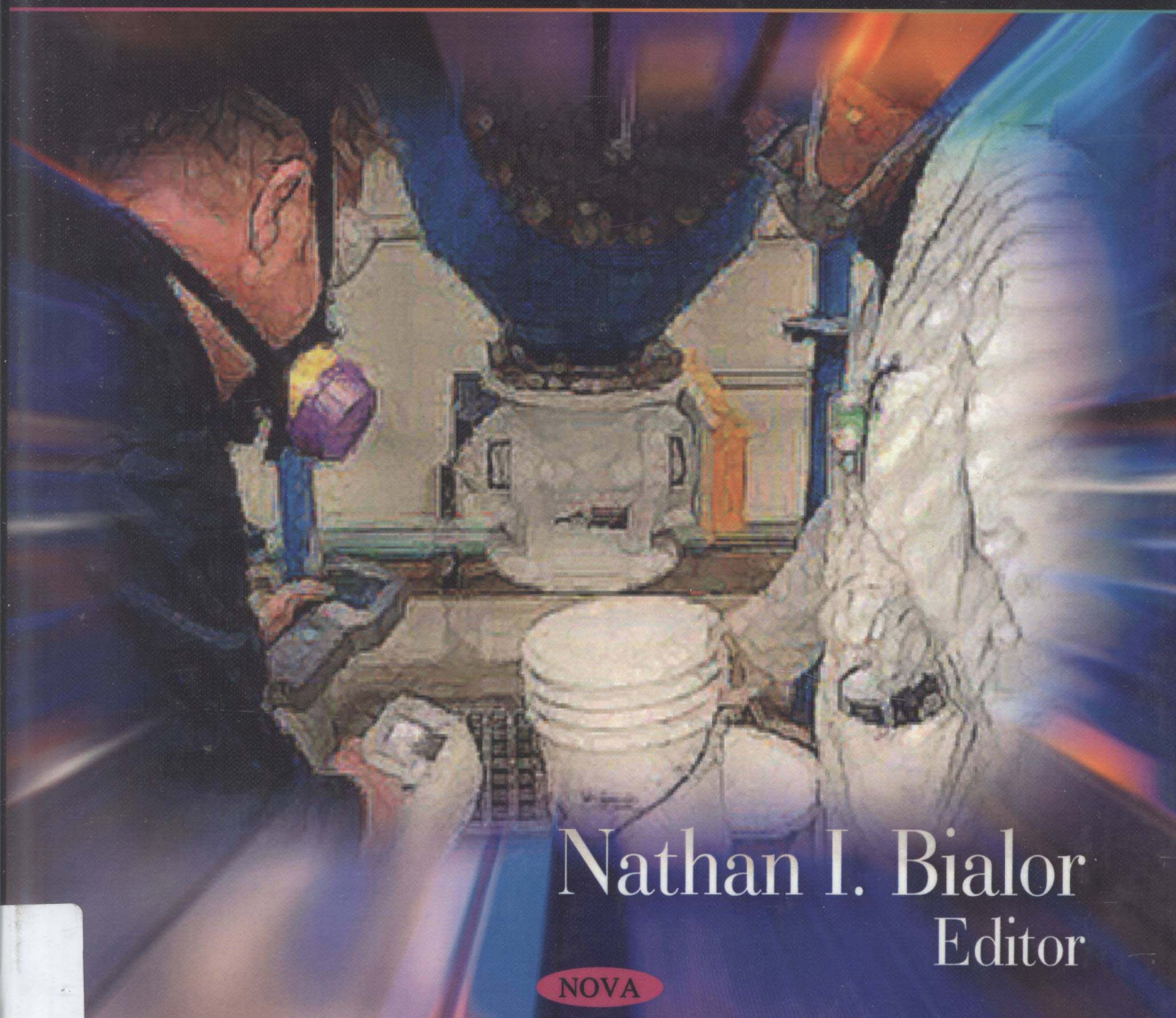

Nathan I. Bialor
Editor

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PREFACE

The National Institute for Occupational Safety and Health (NIOSH) is the Federal agency responsible for conducting research and making recommendations to prevent work-related injury, illness, and death. As such, NIOSH is active in (1) identifying critical issues related to possible health hazards of nanomaterials, (2) protecting the safety and health of workers involved in this emerging technology, and (3) implementing a strategic plan to develop and disseminate methods for safely advancing the technology through workplace controls and safe handling procedures, and (4) investigating the possible applications of nanotechnology to solve workplace safety and health issues. Because of their small size and large surface area, engineered nanoparticles may have chemical, physical, and biological properties distinctly different from larger particles of similar chemical composition. Those properties may include the ability to reach the gas exchange regions of the lung, travel from the lung throughout the body, penetrate dermal barriers, cross cell membranes, and interact at the molecular level. NIOSH is investigating all of these properties, as it would with any new technology or material in the workplace, to provide the necessary guidance to ensure a safe and healthy workplace.

This is an edited, excerpted and augmented edition of a Department of Health and Human Services Centers for Disease Control and Prevention National Instilute for Oocopational Safety and Health.

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FOREWORD

As with any new technology, the earliest and most extensive exposures to engineered nanoparticles are most likely to occur in the workplace. Workers are currently producing and using nanoparticles. Society requires assessment of whether these exposures present any threat to workers. The National Institute for Occupational Safety and Health (NIOSH) is mandated by law to conduct research and develop guidance on worker safety and health. NIOSH, in collaboration with partners in other government agencies, countries, academia, industry, labor, and nongovernmental organizations, has been conducting research and developing guidance to address the occupational safety and health of workers exposed to nanomaterials. This document is a report of the progress of the NIOSH Nanotechnology Research Center (NTRC) since its inception

in 2004 through 2006. Using only internally redirected resources, the NTRC has begun to make contributions to all the steps in the continuum from hazard identification to risk management.

Understanding the occupational safety and health issues of nanotechnology is a complex endeavor. The types of nanomaterials and the opportunities for workplace exposure are growing rapidly. The challenge is to effectively address the safety and health issues of nanotechnology while helping society realize the far- reaching potential benefits. NIOSH will continue to respond to this challenge.

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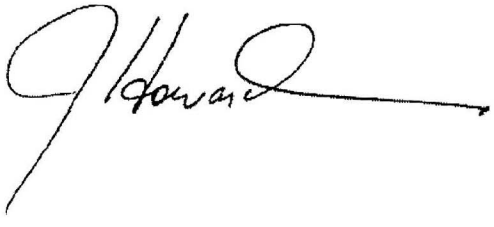

EXECUTIVE SUMMARY

The National Institute for Occupational Safety and Health (NIOSH) is the Federal agency responsible for conducting research and making recommendations to prevent work-related injury, illness, and death. As such, NIOSH is active in (1) identifying critical issues related to possible health hazards of nanomaterials, (2) protecting the safety and health of workers involved in this emerging technology, and (3) implementing a strategic plan to develop and disseminate methods for safely advancing the technology through workplace controls and safe handling procedures, and (4) investigating the possible applications of nanotechnology to solve workplace safety and health issues. Because of their small size and large surface area, engineered nanoparticles may have chemical, physical, and biological properties distinctly different from larger particles of similar chemical composition. Those properties may include the ability to reach the gas exchange regions of the lung, travel from the lung throughout the body, penetrate dermal barriers, cross cell membranes, and interact at the molecular level. NIOSH is investigating all of these properties, as it would with any new technology or material in the workplace, to provide the necessary guidance to ensure a safe and healthy workplace.

NIOSH is mandated by the Occupational Safety and Health Act to determine whether materials in a workplace constitute any harm and to provide recommendations for preventing injury and illness. NIOSH is taking the first steps in assessing hazards posed by various types of nanoparticles by attempting to understand the mechanisms of action of nanoparticles in living systems and assessing risks to workers. The research being conducted by the NIOSH Nanotechnology Research Center (NTRC) was funded by redirecting existing NIOSH programmatic funds: $3.0 million in FY 2005, $3.7 million in FY 2006, and $4.6 million in FY 2007. This budgetary constraint has made a more comprehensive research program specific to nanomaterials difficult to implement. Even with the budgetary constraints, NIOSH investigators have laid the foundation for an evidence-based strategy for providing safe nanotechnology in the workplace. This effort is consistent with the following guidance from the U.S. Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB): to ensure that nanotechnology research leads to the responsible development of beneficial applications, high priority should be given to research on societal implications, human health, and environmental issues related to nanotechnology and to develop, where applicable, cross-agency approaches to the funding and execution of this research [July 8, 2005 memorandum for the Heads of Executive Departments and Agencies]. Because of its mission and the active program of research it has started, NIOSH has been identified as a lead

agency in several high priority areas by the Nanotechnology Environmental and Health Implications (NEHI) Working Group within the National Nanotechnology Initiative (NNI).

NANOTECHNOLOGY RESEARCH CENTER

NTRC was established in 2004 to coordinate and facilitate research in nano- technology and develop guidance on the safe handling of nanomaterials in the workplace. It is a 'virtual center' in which NIOSH scientists and engineers at geographically dispersed locations are linked by shared computer networks and other technologies. This approach surmounts the logistical complications that traditionally arise when scientists and engineers collaborating on common research are not physically in the same locations. This approach has also allowed NIOSH to jump-start research and facilitate ongoing studies. The goals for NTRC are as follows:

1 Determine whether nanoparticles and nanomaterials pose risks of injuries and illnesses for workers.
2 Conduct research on applying nanotechnology to the prevention of work-related injuries and illnesses.
3 Promote healthy workplaces through interventions, recommendations, and capacity building.
4 Enhance global workplace safety and health through national and international collaborations on nanotechnology research and guidance.

As evidenced by the full report, progress has been made toward each of these goals. The following paragraphs present highlights of each goal.

1. DETERMINE WHETHER NANOPARTICLES AND NANOMATERIALS POSE RISKS OF INJURIES AND ILLNESSES FOR WORKERS

Since 2004, the NTRC has conducted toxicology research on the properties and characteristics of nanoparticles that are relevant for predicting whether these particles pose a risk of adverse health effects in workers (see Appendix A for the status of ongoing research and published results). These research projects have involved characterizing occupationally relevant nanoparticles— particularly the toxicity of carbon nanoparticles. Preliminary work by NTRC investigators demonstrated that exposures to specific nanotubes had harmful pulmonary effects (such as a fibrotic response) in mice soon after exposure to relatively low doses. NTRC investigators have evaluated the potential for nanoparticles to enter the bloodstream and move to systemic tissues after being deposited in the lungs. NTRC is also assessing the impact of dermal exposure to nanoparticles. In addition, NTRC established a nanoparticle aerosol generation system and began conducting animal inhalation studies during the summer of 2006. These studies will help scientists determine whether some engineered nanomaterials pose risks to human health in the work setting. They will also help determine the mechanisms by which they operate. Although the results of these studies are preliminary

and limited, more research is needed to predict whether they signal a health risk to humans. The data support the need to address that question and provide promising leads for strategic, ongoing studies.

NTRC investigators have evaluated exposure-response information and developed quantitative risk assessment methods for nanoscale titanium dioxide; these efforts may serve as a model for assessing the risk of other nanoparticles. To gain further knowledge about exposure and control practices, the NTRC has established a field team (see Appendix B) to conduct assessments of workplaces where exposure to engineered nanoparticles may occur. To date, this team has partnered with various companies that produce or use engineered nanoparticles to obtain useful information about potential worker exposures, control technologies, and risk management practices.

2. Conduct Research on Applying Nanotechnology to the Prevention of Work-Related Injuries and Illnesses

NTRC has identified various possibilities for applying nanotechnology to occupational safety and health, including the application of this technology in fabricating more efficient filters, sensors, and protective clothing. NTRC has also conducted numerous discussions with academia and the private sector on other potential projects. Efforts are underway between NTRC, other CDC personnel, and the Georgia Institute of Technology to identify collaborative projects involving nanotechnology applications to occupational and public health problems.

Promote Healthy Workplaces Through Interventions, Recommendations, and Capacity Building

NTRC has provided seminal guidance for workers and employers in nanotechnology through the document entitled Approaches to Safe Nanotechnology: An Information Exchange with NIOSH. This document was posted on the NIOSH Web site in 2005 and updated in August 2006 (see Appendix H for a summary). The document concludes the following:

- Given the limited amount of information for determining with confidence whether adverse human health effects may be associated with production and use of engineered nanoparticles, interim precautionary measures should be taken to minimize worker exposures.
- For most processes and job tasks, the control of airborne exposure to nanoaerosols can be accomplished using a wide variety of engineering control techniques (e.g., exhaust ventilation, process enclosure) similar to those used in reducing exposure to other types of aerosolized particulates.
- Implementing a risk management program in workplaces where workers are exposed to nanomaterials can help to minimize the potential for exposure to nanoaerosols. Elements of such a program should include engineering control techniques and good

work practices. Engineering controls such as source enclosure (i.e., isolating the generation source from the worker) and local exhaust ventilation systems should be effective for capturing airborne nanoparticles. Current knowledge indicates that a well-designed exhaust ventilation system with a high-efficiency particulate air (HEPA) filter should effectively remove nanoparticles. The use of good work practices (e.g., handling and transfer practices, using wet methods, cleaning of contaminated surfaces), the education and training of workers, and the use of personal protective equipment (PPE) when needed should help reduce the potential for exposure.

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. Currently, there are no specific exposure limits for airborne exposures to engineered nanoparticles, although occupational exposure limits exist for larger particles of similar chemical composition. Preliminary evidence shows that for respirator filtration media, particulates as small as 2.5 nm in diameter are efficiently captured, in keeping with single fiber filtration theory. Although this evidence needs confirmation, it suggests that it is likely that NIOSH-certified respirators will be useful for protecting workers from nanoparticle inhalation when properly selected and fit tested as part of a complete respiratory protection program.

Other information products on the NIOSH Web site include the Nanotechnology topic page (with an extensive section on Frequently Asked Questions) and the Nanoparticle Information Library (NIL), which is a resource on particle information, including physical and chemical characteristics. In addition, NTRC has convened a cross-Federal group to develop a framework document for health surveillance of workers exposed to nanomaterials. This document will also involve the business community to identify the range of issues involved in occupational health surveillance.

Nationally and internationally, NTRC has delivered a wide range of presentations on occupational safety and health issues associated with nano- technology. These have included presentations at scientific conferences, trade associations, and professional associations; meetings of government agencies and nongovernmental organizations (NGOs); and special panels convened by government agencies, NGOs, and professional associations (see Appendix A for a listing of NTRC presentations and other activities). NIOSH has cosponsored the three major international meetings on occupational safety and health involving nanomaterials. These research summits furthered the exchange of the latest information among leading scientists and promoted the application of research findings to actual workplace practice for minimizing occupational exposures. The third meeting will be held in Taiwan in 2007, and two NTRC scientists serve on the planning committee. NIOSH also cosponsored a major occupational safety and health research-to-practice (r2p) conference in Cincinnati, Ohio during December 2006, which drew more than 450 participants from 11 countries. In addition, NTRC is collaborating with the U.S. Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and other government agencies to obtain and evaluate exposure and good work practice information.

4. Enhance Global Workplace Safety and Health Through National and International Collaborations on Nanotechnology Research and Guidance

NTRC has established several national and international collaborations to advance understanding of occupational safety and health for nanotechnology workers. NTRC participates in the NNI and has contributed to the nanotechnology strategic plan for the Nation through the working group of NEHI. Occupational Safety and Health has been a major priority of the NEHI effort, and the NIOSH strategic research plan and activities are addressing most of the major issues in the NEHI plan.

The NTRC has collaborated with the Organization for Economic Cooperation and Development (OECD) to build cooperation, coordination, and communication between the United States and 30 OECD member countries (including the European Union), and with more than 180 nonmember economies as well.

NTRC is part of the U.S. leadership on the International Organization for Standardization (ISO) TC 229 Nanotechnology Working Group on Health, Safety, and the Environment. NTRC also works with the World Health Organization (WHO) Collaborating Centers on global projects of information dissemination and communication.

Together, the research and guidance efforts of the NTRC are expected to enhance the safe use of nanotechnology in the workplace and safe work-related handling of nanomaterials. However, until more information becomes available, it is appropriate to take precautions and apply recognized occupational exposure control measures where nanoparticle exposure may occur.

Steps to Addressing Occupational Safety and Health Implications

The NTRC research and guidance effort has been initiated to fill the knowledge gaps in prevention and control of workplace exposures to engineered nanoparticles. To accomplish this, the NTRC has focused its research program on hazard identification and characterization, exposure assessment, risk assessment, and risk management. While research continues, NIOSH partners and stakeholders have urged NIOSH to provide interim guidance for risk management until scientists understand those properties, characteristics, and behaviors of nanomaterials that may pose occupational safety and health risks. NTRC has provided such interim guidance and will continue to do so as research is being conducted.

The NTRC research program has identified 10 critical topic areas important for understanding the potential health risks and developing and disseminating recommendations. The report describes each of these critical topic areas and the research being conducted. These 10 topic areas are the core of the NTRC research program and represent the areas that are most critical to addressing occupational safety and health issues. They include toxcity and internal dose, risk assessment, epidemiology and surveillance, engineering controls and PPE, measurement methods, exposure assessment, fire and explosion safety, recommendation and guidance, communication and education, and applications.

By working in these 10 critical areas, NIOSH has comprehensively begun to address the information and knowledge gaps necessary to protect workers and responsibly move nanotechnology forward so that its far-reaching benefits may be realized.

NIOSH Resource Limitations

Since its inception in 2004, the NTRC has published more than 70 papers in the peer-reviewed scientific literature (see specific research projects in the appendices) and provided a broad range of information and guidance. Publications in the area of hazard identification and characterization, exposure assessment, risk assessment, and risk management have provided a framework for beginning to address the potential hazards and risks from engineered nanoparticles. While these accomplishments have contributed significantly to our understanding of the potential health risks to nanoparticles, NIOSH research and subsequent development and dissemination of interim guidance efforts are limited by

the amount of funding available. To the best of its ability in allocating limited resources to competing priorities, NIOSH has redirected funds internally over the past 3 years to build modest increases in nanotechnology research program support. New infusions of funding beyond the current NIOSH budget, specifically directed toward the program, would be needed for significant expansion of research to address the following research gaps:

1 Although NIOSH toxicology studies have provided better understanding of the ways in which some types of nanoparticles may enter the body and interact with the body's organ systems, the breadth and depth of such research efforts have been limited to a few nanoparticle types. More types of nanoparticles need to be assessed for characteristics and properties relevant for predicting potential health risk.
2 NIOSH field investigators have assessed exposure to engineered nanoparticles in some workplaces, but few data exist on the extent and magnitude of exposure to other types of nanoparticles in workplaces that manufacture or use nanomaterials, nanostructures, and nanodevices.
3 NIOSH guidance is a first step toward controlling nanoparticles in the workplace; however, more research is needed on the efficacy and specificity of engineering and work practice control measures. NIOSH needs support to conduct more field investigations.
4 An increasing number of workers are involved with the research, development, production, and use of nanomaterials, but there is a lack of specific guidance for occupational health surveillance. NIOSH needs support to conduct research on the short- and long-term potential health risks in nanotechnology workers. This may involve the conduct of large-scale prospective epidemiologic studies and the establishment of exposure registries.
5 The utility of nanotechnology to support the development of new technologies (such as sensors, more efficient filters, and better protective materials) that can enhance the protection of workers requires further research and development and can be advanced by additional resources.

In summary, the NTRC has advanced the scientific knowledge in understanding the possible health risks of engineered nanoparticles. Continuing research will help to expand this knowledge and provide opportunities for advancing the safe use of nanotechnology.