Protecting the Nanotechnology Workforce

NIOSH Nanotechnology Research and Guidance Strategic Plan, 2013–2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Foreword

The National Institute for Occupational Safety and Health (NIOSH) is pleased to present *Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan, 2013–2016*. This plan updates the November 2009 strategic plan with knowledge gained from results of ongoing research, as described in the 2012 report *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace: A Progress Report from the NIOSH Nanotechnology Research Center, 2004–2011*. The NIOSH Nanotechnology Research Program follows a comprehensive plan that is managed as a matrix structure across NIOSH and supports multiple sectors in the National Occupational Research Agenda (NORA).

Nanotechnology provides many opportunities for advancing the economic value and impact of new U.S. technologies and products as it expands into every industrial sector. Today, nanomaterials are found in hundreds of products, ranging from cosmetics, to clothing, to industrial and biomedical applications. The potential benefits of nanotechnology are huge, and these benefits should be realized by society. However, there is ongoing concern that the full potential of the societal benefits may not be realized if research efforts are not undertaken to determine how to best manage and control the potential occupational safety and health hazards associated with the handling of these nanomaterials.

The research conducted over the past 8 years has proven that NIOSH is a global leader in promoting the responsible development of nanotechnology. NIOSH has built business partnerships, established itself as a key player in nanotoxicology, published precautionary guidance (*Approaches to Safe Nanotechnology: Managing the Safety and Health Concerns Associated with Engineered Nanomaterials*), and issued recommended exposure limits for nanoscale titanium dioxide and for carbon nanotubes and nanofibers.

This *NIOSH Nanotechnology Research and Guidance Strategic Plan* is the roadmap being used to advance basic understanding of the toxicology and workplace exposures involved so that appropriate risk management practices can be implemented during discovery, development, and commercialization of engineered nanomaterials. NIOSH will strive to remain at the forefront of developing guidance that supports and promotes the safe and responsible development of such a promising technology.

John Howard, M.D.
Director, National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

Executive Summary

Nanotechnology—the manipulation of matter on a near-atomic scale to produce new materials and devices—has the ability to transform many industries, from medicine to manufacturing, and the products they produce. By 2020, the National Science Foundation estimates, nanotechnology will have a $3 trillion impact on the global economy and employ 6 million workers in the manufacture of nanomaterial-based products, of which 2 million may be manufactured in the United States [NSF 2011]. Nanomaterials may present new challenges to understanding, predicting, and managing potential health risks to workers.

Many knowledge gaps still remain on how to work safely with all of these materials. Through strategic planning, research, partnering with stakeholders, and making information widely available, the National Institute for Occupational Safety and Health (NIOSH) is working to continue to provide national and world leadership in providing solutions that will prevent work-related illness and injury.

Nanotechnology and NIOSH Research

Nanotechnology and the commercialization of products and devices containing engineered nanomaterials could help address critical global problems concerning energy, transportation, pollution, health, and food. The potential benefits of nanotechnology are huge, and these benefits should be realized. Nonetheless, there is concern that the full potential of the societal benefits may not be realized if cautions about the adverse human health effects are not heeded and concerns are not honored. Timely, targeted research is needed to define hazards, exposures, and risks and to provide guidance for safe handling of nanomaterials. A concerted effort by industry, academia, labor, the professions, and government is needed to identify and address the knowledge gaps in a transparent and credible process that coincides with development of this new technology. NIOSH is playing an active part in this process by supporting the development of a broad spectrum of research and prevention strategies for health and safety hazards related to nanotechnology. In a series of reports [NIOSH 2007, 2009a, 2012a], NIOSH has summarized its progress in conducting nanotechnology research and recommending risk management strategies (see *http://www.cdc.gov/niosh/topics/nanotech/*). NIOSH investigators have identified adverse health effects in animals exposed to various engineered nanomaterials; assessed exposure of workers; initiated epidemiologic research; and provided guidance on control technologies and medical surveillance. There are many questions still to be answered. A vast number of potential new nanomaterials are possible and could result in a seemingly limitless combination of physicochemical factors. There is need for an expeditious approach to controlling exposure to the large number of nanomaterials in science and commerce now and in the future. Moreover, the advanced nanomaterials under development are likely to have additional potentially hazardous characteristics that will need to be addressed [Murashov et al. 2012].

NIOSH Nanotechnology Research Center (NTRC)

The NIOSH Nanotechnology Research Center (NTRC) was established in 2004 to coordinate nanotechnology research across the institute. Ten critical areas of research were identified, each having at least one key scientist serving as a coordinator. The NTRC and its steering committee of critical area coordinators are responsible for developing and guiding NIOSH scientific and organizational plans in nanotechnology health and safety research.

Strategic Plan

The development of nanotechnology has reached a point where it is being widely applied, and numerous nanomaterials and nano-enabled products are in commerce. Nanotechnology has the potential to provide great benefit to society, but it must be developed responsibly. This responsibility involves addressing any adverse human and environmental impacts of the technology associated with engineered nanomaterials (ENMs). Workers are among the first people in any society to be exposed to the potential health hazards caused by the products of new technology, and their exposure to any new material is often greater than for the general population. Therefore, worker safety and health can be seen as the core of responsible development (Figure 1).

Through its strategic plan for fiscal years (FY) 2013–2016, NIOSH will marshal its resources and partner with others efficiently and effectively to advance efforts to protect the nanotechnology workforce. With the input of a broad range of stakeholders in government, academia, and the private sector, NIOSH will continue to operate under a strategic plan for nanotechnology research and guidance. The most recent previous version was published in November 2009 and included research plans through FY 2012 (see *http://www.cdc.gov/niosh/docs/2010-105/*).

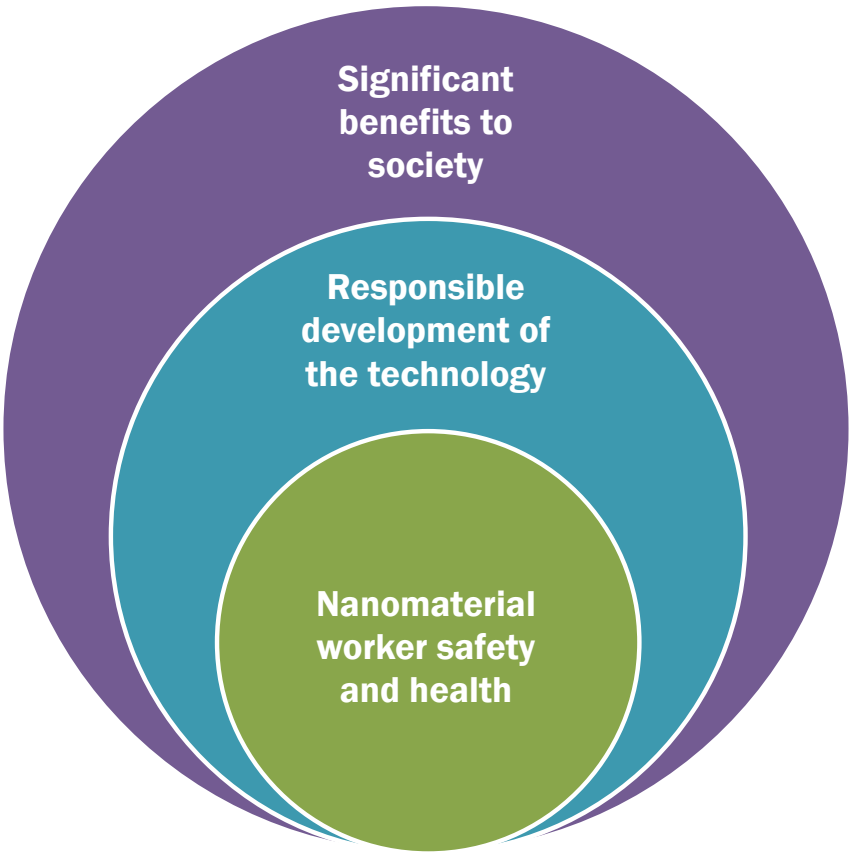

Figure 1. The core of responsible development of nanotechnology.

This document presents the NTRC Strategic Plan for FY2013–FY2016. The strategic plan also highlights how the critical research and guidance efforts of NIOSH align with and support the comprehensive Environmental, Health, and Safety Research Strategy needs of the National Nanotechnology Initiative. For the period FY2013–FY2016, NIOSH will continue to fill information and knowledge gaps that address the five NIOSH NTRC strategic goals:

1. Increase understanding of new hazards and related health risks to nanomaterial workers.
2. Expand understanding of the initial hazard findings of engineered nanomaterials.
3. Support the creation of guidance materials to inform nanomaterial workers, employers, health professionals, regulatory agencies, and decision-makers about hazards, risks, and risk management approaches.
4. Support epidemiologic studies for nanomaterial workers, including medical, cross-sectional, prospective cohort, and exposure studies.
5. Assess and promote national and international adherence with risk management guidance.

To address these strategic goals and promote the responsible development of engineered nanomaterials, the strategic plan will expand research activities in 10 NTRC critical areas: toxicity and internal dose; measurement methods; exposure assessment; epidemiology and surveillance; risk assessment; engineering controls and personal protective equipment (PPE); fire and explosion safety; recommendations and guidance; global collaborations; and applications.

Contents

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Carol Rice, Ph.D., CIH
University of Cincinnati
Cincinnati, OH

Michael Kosnett, M.D.
University of Colorado
Denver, CO

James Bonner, Ph.D.
North Carolina State University
Raleigh, NC

Lindsey Darrow, Ph.D.
Rollins School of Public Health
Atlanta, GA

Ellen Eisen, Ph.D.
University of California, Berkeley
Berkeley, CA

Michael Ellenbecker, Ph.D.
University of Massachusetts, Lowell
Lowell, MA

Lawrence Gibbs, M.Ed., M.P.H., CIH
Stanford University
Stanford, CA

Steven Gordon, Ph.D.
3M
St. Paul, MN

Bruce Lippy, Ph.D., CIH, CSP
CPWR, The Center for Construction
Research and Training
Baltimore, MD

Günter Oberdörster, D.V.M., Ph.D.
University of Rochester Medical Center
Rochester, NY

Michele Ostraat, Ph.D.
RTI International
Research Triangle Park, NC

Gurumurthy Ramachandran, Ph.D.
University of Minnesota
Minneapolis, MN

Darius Sivin, Ph.D.
United Auto Workers
Washington, D.C.

Keith A. Swain, B.S.
Dupont
Wilmington, DE

David Warheit, Ph.D.
Dupont
Newark, DE

John Weaver, B.S.
Purdue University
West Lafayette, IN

Abbreviations

AFL-CIO	American Federation of Labor and Congress of Industrial Organizations
AIHA	American Industrial Hygiene Association
ANSES	The French Agency for Food, Environmental and Occupational Health and Safety
ANSI	American National Standards Institute
ASSE	American Society of Safety Engineers
ASTM	American Society for Testing and Materials (currently ASTM International)
CNT	carbon nanotube
CPSC	Consumer Product Safety Commission
DHHS	Department of Health and Human Services
DOT	Department of Transportation
EHS	environment, health and safety
ENM	engineered nanomaterial
EPA	U.S. Environmental Protection Agency
EU	European Union
FMSH	Federal Mine Safety and Health
FY	fiscal year
ICOH	International Commission on Occupational Health
ICON	International Council on Nanotechnology
IEC	International Electrotechnical Commission
ILO	International Labour Organization
ISEA	International Safety Equipment Association
ISO	International Organization for Standardization
MSHA	Mine Safety and Health Administration
NanoBCA	Nanobusiness Commercialization Association
NCER	National Center for Environmental Research
NEHI	Nanotechnology Environmental and Health Implications
NFPA	National Fire Protection Association
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NNI	National Nanotechnology Initiative
NORA	National Occupational Research Agenda

NSC	National Safety Council
NSF	National Science Foundation
NTRC	Nanotechnology Research Center
OECD	Organization for Economic Cooperation and Development
OEP	Office of Extramural Programs
OSH	occupational safety and health
OSHA	Occupational Safety and Health Administration
PPE	personal protective equipment
PtD	Prevention through Design
r2p	Research to Practice
TNO	The Netherlands Organization for Applied Scientific Research
UN	United Nations
WHO	World Health Organization

1 INTRODUCTION

1.1 Background

Nanotechnology is a system of innovative methods to control and manipulate matter at near-atomic scale to produce new materials, structures, and devices. Nano-objects are nanomaterials that have at least one dimension less than 100 nanometers [ISO 2008]. Nanoparticles are a specific class or subset of these nano-objects, having three dimensions that are less than 100 nanometers. Nanoparticles exhibit unique properties because of their nanoscale dimensions. Nanotechnology offers the potential for tremendous improvement and advances in the development of commercial products that may benefit society, such as integrated sensors, semiconductors, medical imaging, drug delivery systems, structural materials, sunscreens, cosmetics, and coatings. Nanotechnology is one of the most enabling technologies across the world. By 2020, the global market for nanotechnology-related products is predicted to reach $3 trillion and employ 2 million workers in the United States alone [NSF 2011]. A review of the 2013 version of the Nanowerk nanomaterials database (*http://www.nanowerk.com/phpscripts/n_dbsearch.php*) revealed more than 3,000 commercially available nanomaterials.

However, the properties of engineered nanoparticles (e.g., size, surface area, reactivity) that yield many improvements in commercial products may also pose health risks. Increasing numbers of workers are potentially exposed to nanomaterials in research laboratories, start-up companies, production facilities, and operations where nanomaterials are processed, used, disposed, or recycled. The challenge is to determine whether the nature of intentionally produced (engineered) nanostructured materials and devices presents new occupational safety and health risks. At the same time, there is a need to address how the benefits of nanotechnology can be realized while the risks are proactively minimized.

Efforts across multiple federal agencies and the private and academic sectors are fostering the development and use of nanotechnology. In 2001, the President's Council of Advisors on Science and Technology collaborated with the interagency National Science and Technology Council to create the National Nanotechnology Initiative (NNI) [NNI 2001]. This initiative supports basic and applied research in nanotechnology to create new nanomaterials and to disseminate new technical capabilities to industry. The purpose of the NNI is to facilitate scientific breakthroughs and maintain U.S. competitiveness in nanoscience. A stated goal of this interagency program is to ensure that nanotechnology research leads to the responsible development of beneficial applications by giving high priority to research on human health, environmental issues, and societal implications related to nanotechnology.

1.2 Mission of NIOSH

In the Occupational Safety and Health Act of 1970 (OSH Act, Public Law 91-596) and the Federal Mine Safety and Health Act of 1977 (FMSH Act, Public Law 95-164), Congress declared that the intent of these acts was to ensure, insofar as possible, safe and healthful working conditions for every working man and woman, to preserve our human resources. In these acts, NIOSH is given the responsibility for recommending occupational safety and health standards and defining exposure levels that are safe for various periods of employment. These include (but are not limited to) the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result

of his or her work experience. By means of criteria documents and other publications, NIOSH communicates these recommended standards to the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and others in the occupational safety and health community.

Under the OSH Act, NIOSH is charged with conducting "research, experiments, and demonstrations relating to occupational safety and health" and with developing "innovative methods, techniques, and approaches for dealing with [those] problems." The act specifies target areas of research that include identifying criteria for setting worker exposure standards and exploring problems created by new technology in the workplace. In an amendment to the act, NIOSH was given responsibility for conducting training and education "to provide an adequate supply of qualified personnel to carry out the purposes of the Act" and for assisting employers and workers with applying methods to prevent occupational injuries and illness (Section 21 of the OSH Act).

NIOSH has over 40 years of experience in conducting research and formulating recommendations for occupational safety and health. During this period, NIOSH has developed considerable expertise in measuring, characterizing, and evaluating new processes and new materials by conducting quantitative exposure assessments and evaluating health effects. NIOSH also has expertise in developing exposure control systems and prevention strategies as well as experience in conducting risk assessments and recommending effective risk management practices.

In 2003, NIOSH became a member of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council. As a member, NIOSH participates in (1) identifying critical issues related to possible hazards of nanomaterials, (2) protecting worker safety and health in this emerging technology, and (3) developing a strategic plan to address such issues and recommend prevention strategies for the safe handling and use of nanomaterials.

In 2004, NIOSH created the Nanotechnology Research Center (NTRC) to identify critical issues, create a strategic plan for investigating these issues, coordinate the NIOSH research effort, develop research partnerships, and disseminate information gained. The NTRC comprises nanotechnology-related activities and projects supported by approximately 50 scientists in various NIOSH divisions and laboratories. Through the NTRC, NIOSH has identified 10 critical research areas for nanotechnology research and communication. These 10 critical research areas, updated for FY2013–FY2016, are toxicity and internal dose; measurement methods; exposure assessment; epidemiology and surveillance; risk assessment; engineering controls and personal protective equipment (PPE); fire and explosion safety; recommendations and guidance; global collaborations; and applications. By conducting a complete plan of research in these critical areas in a coordinated, concurrent manner, NIOSH is comprehensively addressing the information and knowledge gaps necessary to protect workers and responsibly move nanotechnology forward so that its far-reaching benefits may be realized.

The NIOSH NTRC is working strategically to fill nanomaterial occupational safety and health knowledge gaps through active intramural and extramural research programs and collaborations. Extramural research is carried out through the NIOSH Office of Extramural Programs (OEP), in which nanotechnology research (through R01, K01, R03, R21, and R43/44 grant mechanisms) is funded to increase the knowledge of nanotechnology and engineered nanomaterials (ENMs) as they relate to occupational safety and health. Research areas supported by the NIOSH OEP include emission and exposure assessment methods for nanoparticles in the workplace, toxicology of ENMs, and use of nanotechnology for the development of sensors. NIOSH is committed

to conducting and supporting studies that will improve scientists' abilities to identify potential occupational health effects of nanomaterials. NIOSH will facilitate the translation of those findings into effective workplace practices.

NIOSH reported on the progress of the NTRC in *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace* (Figure 2). This report presents the program accomplishments of the NTRC from its inception in 2004 through 2011.

The NIOSH NTRC continues to be part of the U.S. leadership on the International Organization for Standardization (ISO) TC 229 Nanotechnology Working Group on Health, Safety, and the Environment and continues to work with the World Health Organization (WHO) collaborating centers on global projects of information dissemination and communication. Through these collaborations, the NIOSH NTRC assists in developing risk communications on the safe handling of nanomaterials.

1.3 NIOSH Logic Model

NIOSH receives input on identifying and addressing occupational safety and health problems through a logic model (i.e., a process) in which the seriousness of the problem or hazard is evaluated, the type and level of research needed are determined, and a plan and process for communicating the research outcomes are formulated. The overall NIOSH logic model (Figure 3) has a conventional horseshoe shape, with the operational upper branch proceeding from inputs to mission relevant outcomes and the strategic lower branch supporting those operations through a process of measurable goals and management objectives. The two branches are correlated and are subject to external factors.

The NIOSH operational model (Figure 4) for conducting research adheres to the logic model in the acquisition and analysis of inputs from customers/stakeholders (*production inputs*) and internal/external research capabilities (*planning inputs*) to determine and prioritize research.

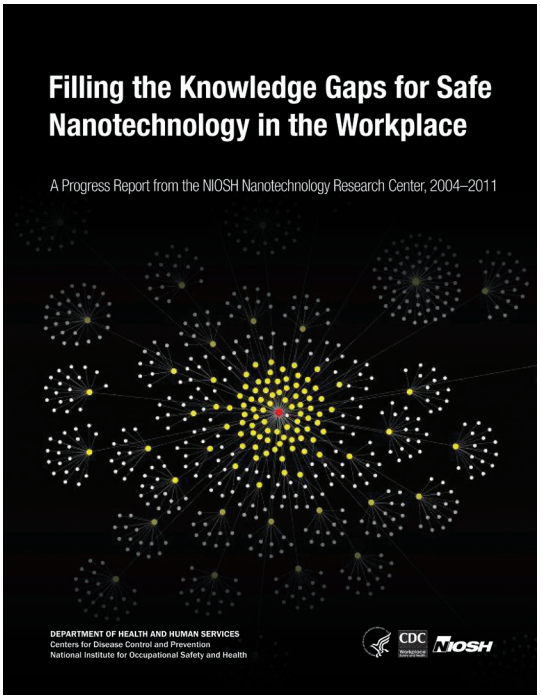

Figure 2. The cover of DHHS (NIOSH) Publication No. 2013–101, the progress report of the NTRC.