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
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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/*).

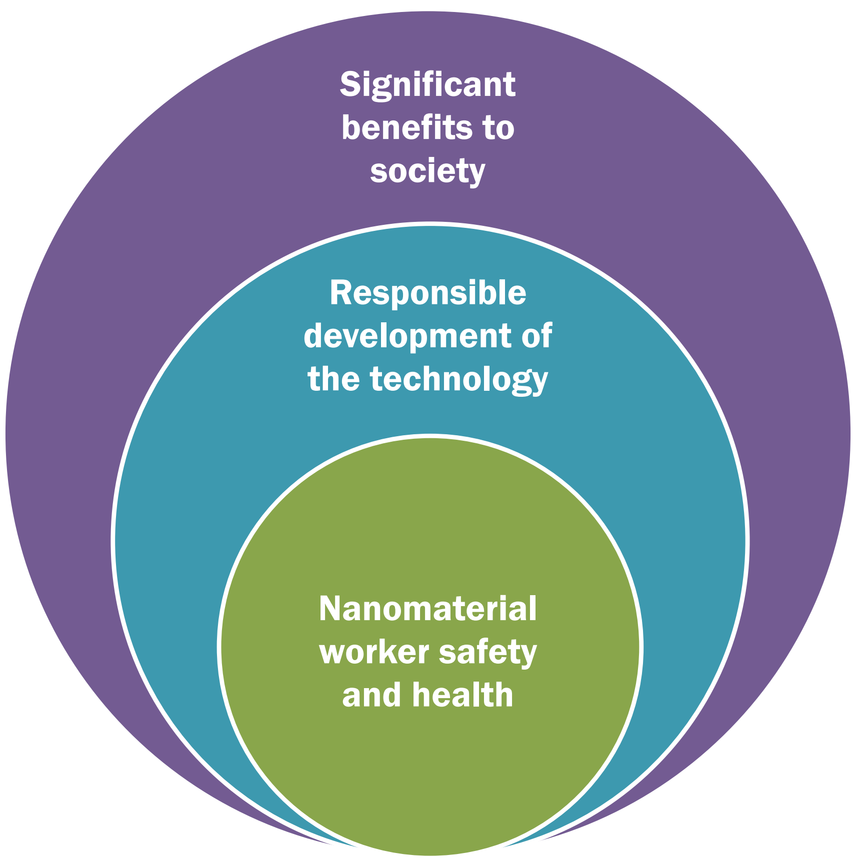

Figure 1. The core of responsible development of nanotechnology.

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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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.

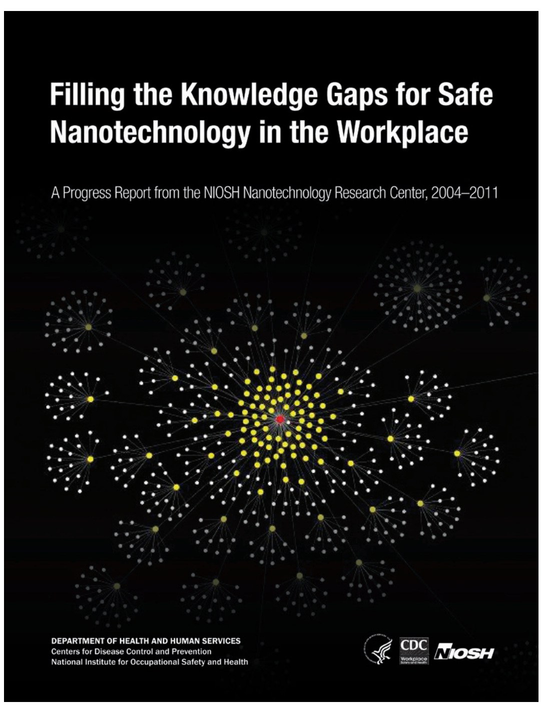

Figure 2. The cover of DHHS (NIOSH) Publication No. 2013–101, the progress report of the NTRC.

Intramural and extramural researchers present their project proposals, which receive appropriate internal and external review and are funded on the basis of merit. The conduct of research (*activities)* produces "outputs" such as guidance documents and reports that address effective risk management practices, worker and employer education, and new technologies for assessing and controlling workplace hazards. NIOSH outputs are transferred directly to the final customers and stakeholders (who implement improvements in workplace safety and health) or to intermediate customers (who utilize NIOSH outputs to produce *intermediate outcomes*). These intermediate outcomes, such as training programs, regulations, and occupational standards, are used to advance workplace safety and health. Since NIOSH is not a regulatory agency, it relies heavily on efforts by intermediate and final customers to achieve ultimate outcomes in the form of workplace safety and health improvements. The effectiveness in achieving these outcomes is influenced at all stages of the program operation by both external factors (such as economic and social conditions) and the regulatory environment. Results of NIOSH-funded research and customer feedback (*intermediate and final outcomes*) contribute to the subsequent rounds of program planning.

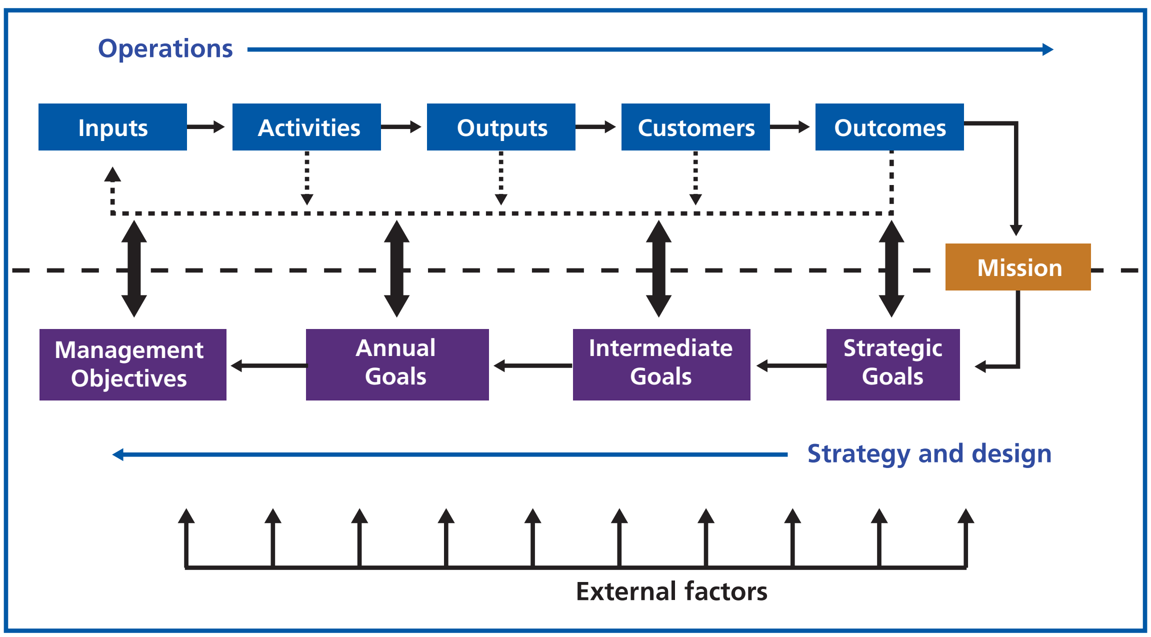

Figure 3. Schematic of the overall NIOSH logic model.

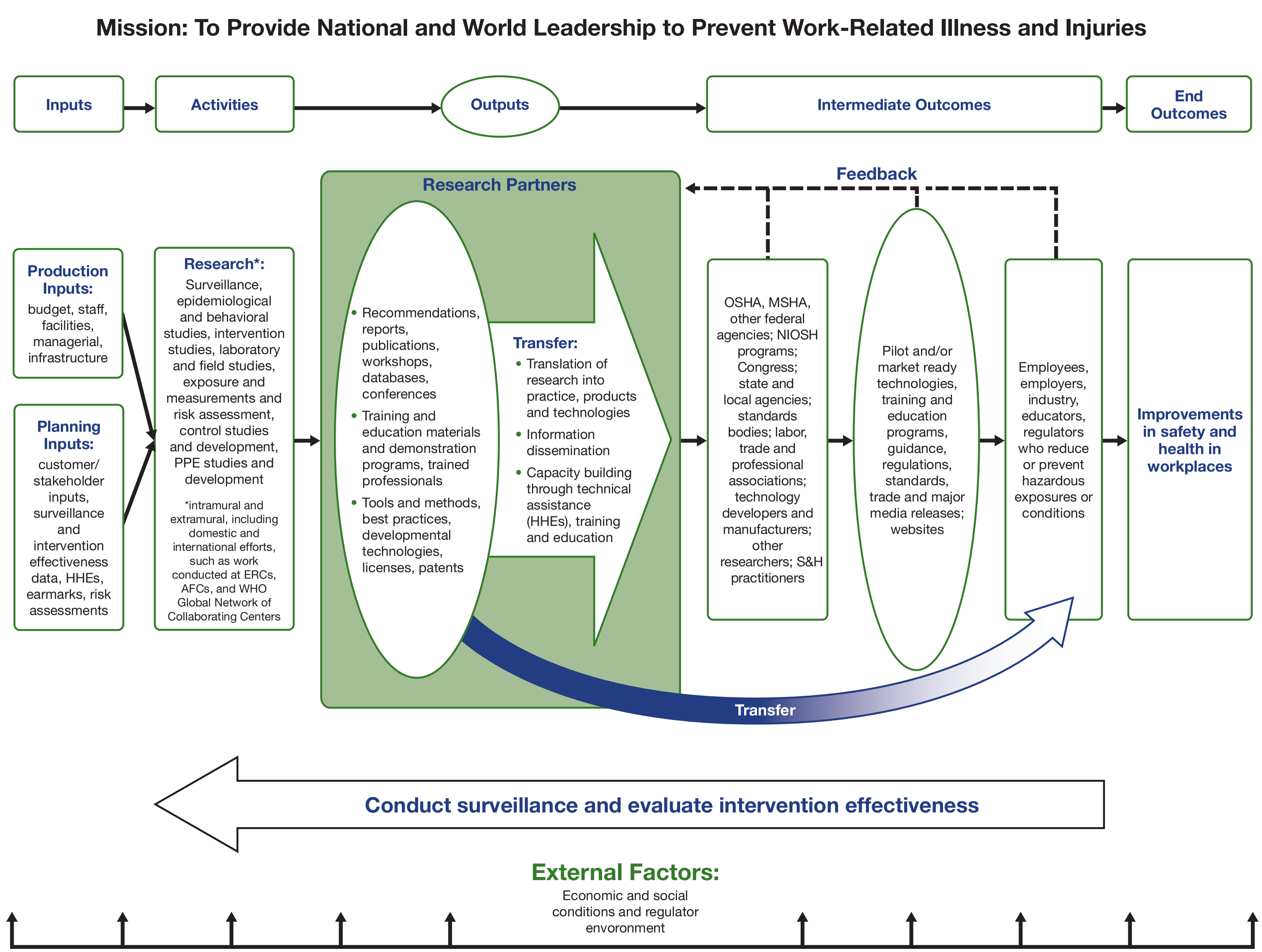

Figure 4. Schematic of the NIOSH operational model.

2 INPUTS

2.1 Nature of Nanomaterials

The universe of nanomaterials is potentially large because of the array of possible combinations of physicochemical parameters, impurities, and manufacturing and production conditions (Figure 5). NIOSH recognizes the extensive diversity and number of nanomaterials and the even larger number of applications for those materials. Consequently, it continues to use approaches that allow for a holistic view of nanomaterials and development of priorities that will be beneficial to many workers.

2.2 Nature of the Nanomaterial Workplace

Worker exposure to nanomaterials may occur along the life cycle of the nanomaterial, from research through scale-up, manufacturing, product development, use, and end of life (Figure 6). Each of the functional areas represents workplaces with different potential exposure scenarios and risks. NIOSH continues to focus on the wide array of workplaces where exposure to nanomaterials may occur.

2.3 Customer and Stakeholder Input

To direct its research and fulfill its responsibilities under the OSH Act and the FMSH Act, NIOSH has relied on input from OSHA and MSHA, workers, employers, trade associations, unions, occupational safety and health practitioners and researchers, and the general public. NIOSH also seeks input through formal committees, such as the NIOSH Board of Scientific Counselors, the National Advisory Committee on Occupational Safety and Health, and the Mine Safety and Health Research Advisory Committee. It also receives

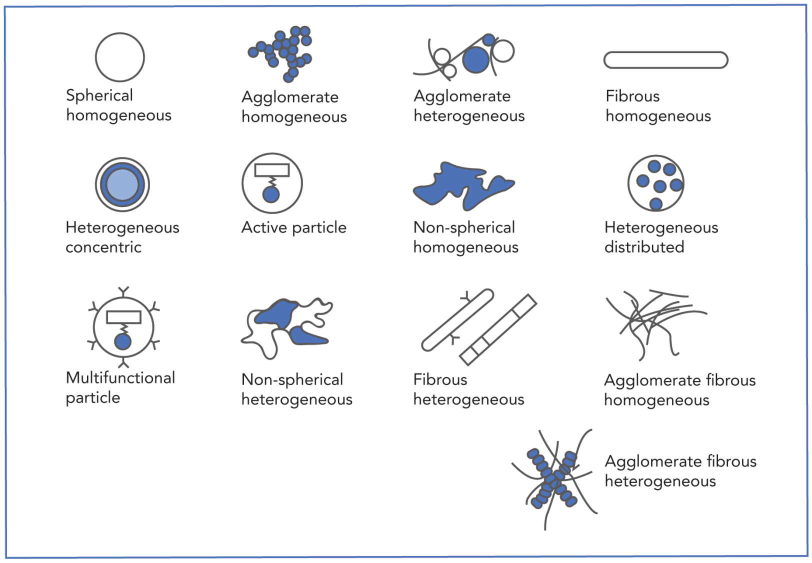

Figure 5. The wide variety of physicochemical parameters of engineered nanomaterials [Schulte et al. 2009].

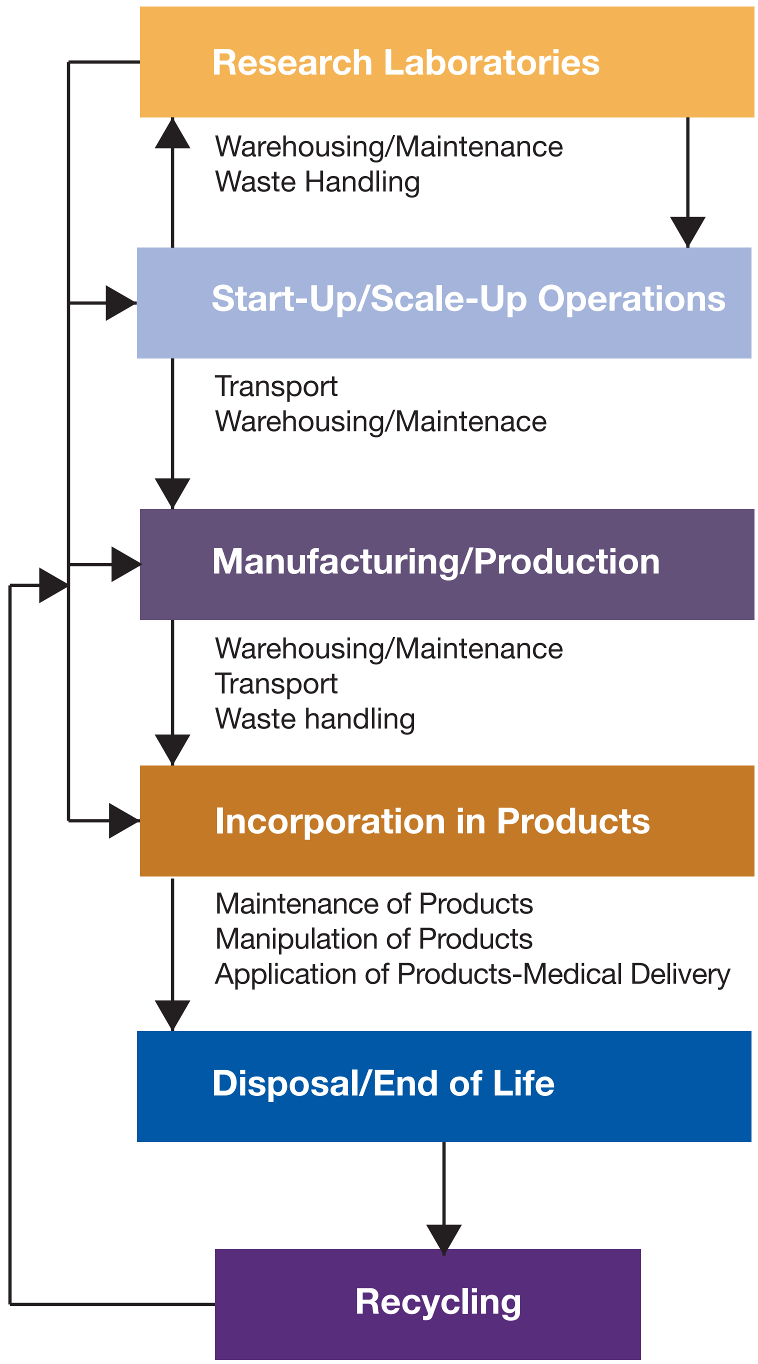

Figure 6. The life cycle of nanomaterials [Schulte et al. 2008a].

input through ad hoc mechanisms such as the NIOSH Web site (*www.cdc.gov/niosh)*, a toll-free telephone line (1-800-CDC-INFO), personal contacts with occupational safety and health professionals, and participation in professional conferences and interagency committees. In addition, NIOSH provides stewardship of the National Occupational Research Agenda (NORA) (*http://www.cdc.gov/niosh/nora),* which is a framework to guide occupational safety and health research into the new millennium—not only for NIOSH but for the entire occupational safety and health community.

NIOSH continues to be a participating and partnering agency in the National Nanotechnology Initiative (NNI) and provides occupational health and safety expertise in support of the U.S. Government's Strategic Plan for Nanotechnology Environmental, Health, and Safety Research [NNI 2011]. NIOSH is co-leader of the NNI Nanotechnology Environmental and Health Implications Working Group (NEHI) and contributed to the development of the 2011 NEHI Environmental, Health, and Safety (EHS) Research Strategy. The 2011 NEHI EHS research strategy identified five core nanotechnology EHS research categories: (1) nanomaterial measurement infrastructure, (2) human exposure assessment, (3) human health, (4) environment, and (5) risk assessment and management methods (Appendix A) [NNI 2011]. NIOSH provided significant input for the strategy and was the lead agency for developing recommendations on human exposure assessment. The NNI EHS research strategy focuses on the use of science-based risk analysis and risk management to protect public health and the environment while fostering the technological advancements that benefit society. NIOSH has strived to keep the overarching research activities of the NTRC nanotechnology strategic plan (Section 4.3) consistent with the NNI EHS research strategy.

The NIOSH NTRC also fosters stakeholder input with trade associations, professional associations, labor, nongovernmental organizations, and a number of private nanomaterial companies. These collaborations have provided expertise and resources critical for reviewing research activities and for developing and disseminating health and safety information on engineered nanoparticles. Some of the ongoing NTRC stakeholders are the American Industrial Hygiene Association (AIHA), American Society of Safety Engineers (ASSE), International Safety Equipment Association (ISEA), National Safety Council (NSC), American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), and NanoBusiness Commercialization Association (NanoBCA).

2.4 NIOSH Research Capabilities

Within its divisions, NIOSH has world-renowned researchers who are trained and experienced in the full spectrum of scientific skills needed to evaluate and characterize workplace hazards and devise intervention strategies for protecting workers. In addition to this expertise, NIOSH has significant laboratory capabilities in particle measurement, aerosol collection and characterization, particle surface analysis, measurement of particle surface radicals and activity, and in vitro and in vivo analysis of toxicity and pathogenesis. Laboratories conducting nanomaterial research are located in Cincinnati, Ohio; Pittsburgh, Pennsylvania; and Morgantown, West Virginia. NIOSH researchers work closely with a broad range of scientists from industry, academia, and other government agencies. The involvement of NIOSH in national and international initiatives and programs is an important component of its capacity to address critical occupational safety and health issues in nanotechnology.

2.5 NIOSH Partnerships

NIOSH recognizes both the practical need and the leadership obligation to extend its internal capabilities by leveraging activities and expertise found in other research institutions, industries, federal agencies, and nongovernmental organizations. These partnerships serve to deliver on multiple objectives; most important, they add to the body of knowledge on workplace health and safety issues associated with nanotechnology. Partnerships have taken several forms, ranging from formal letters or memoranda of understanding to informal working agreements on a specific topic. NIOSH will continue to pursue partnerships as a means of achieving the goals of this strategic research plan and as effective vehicles to develop and disseminate research results.

The NIOSH NTRC has successfully used partnerships with industry to gain a better understanding of actual industrial nanomaterial processes, workplace exposures, work practices, and exposure control techniques. The field research conducted by the NTRC to assess exposures to engineered nanoparticles represents ongoing partnerships with numerous companies. The NTRC will continue to develop these partnerships to

- better understand how engineered nanoparticles are being produced and used
- develop recommendations for the safe handling of nanomaterials
- develop sampling and analytical methods
- evaluate exposure controls that are or could be used in nanomaterial processes
- evaluate the need for and determine the effectiveness of PPE, including respiratory protection
- develop communication and information materials that will assist industry in communicating with workers and the public.

Several of the industrial partnerships have provided opportunities for the NTRC to identify areas in which additional research is needed.

The continued collaboration with other national and international research institutes, academia, and government agencies provides the NTRC the opportunity to combine its expertise in workplace health and safety with the capabilities of other organizations to investigate specific areas of concern. Working relationships with other research institutes provide the NTRC with the information needed to guide its own research, focus its limited resources effectively, and expand its research capabilities through scientific collaboration. The NTRC has developed partnerships in the areas of toxicology, risk assessment modeling, exposure measurement methods, epidemiology, industrial hygiene, control technologies, filtration of nanoparticles, and communication of research results and safe work practices.

The NTRC has broadened its activities with collaborators and stakeholders by participating in a number of national and international committees and working groups. This participation provides NTRC scientists the opportunity to provide and receive input on the key research that is needed to address priority areas.

3 ACTIVITIES

3.1 NIOSH Nanotechnology Research Center (NTRC)

Vision of the NTRC

The vision of the NTRC is as follows:

Safe nanotechnology by delivering on the Nation's promise—safety and health at work for all people through research and prevention.

Mission of the NTRC

The mission of the NTRC is to provide national and world leadership for research and guidance on the implications of nanoparticles and nanomaterials for work-related injury and illness, and the application of nanoparticles and nanomaterials in occupational safety and health.

3.2 NTRC Steering Committee

The NTRC Steering Committee is chaired by the NTRC Coordinator. The committee is made up of the program manager, program coordinator, program assistant coordinator, and critical area coordinators for each of the 10 research areas (some areas have multiple research coordinators). The steering committee is responsible for guiding NIOSH scientific and organizational plans in nanotechnology research (including coordination for science and budget) and for developing strategic goals and objectives and performance measures for the NTRC. Regular updates and progress reports on internal research activities are managed through biweekly teleconferences among members of the NTRC Steering Committee. In addition, to ensure the responsiveness, relevance, and impact of the NIOSH nanotechnology program, members of the NTRC and appropriate stakeholders meet in person every 2 years at a scientific exchange meeting.

3.3 Current NIOSH NTRC Intramural Nanotechnology Research Activities

Current NIOSH NTRC research activities in nanotechnology are focused on occupational safety and health implications and applications of ENMs. Data gathered from ongoing research studies with engineered nanoparticles are used to better understand workplace nanoparticle exposures, the hazards posed by nanomaterials, and the potential risk of adverse health effects from occupational exposures. Studies are also providing data on the characteristics of nanomaterials produced and used in the workplace, routes of exposure, and the effectiveness of work practices and engineering controls in preventing worker exposure. Findings from these intramural studies are providing scientific data to support the development of occupational safety and health recommendations. NIOSH progress and accomplishments in nanotechnology research can be found in the report *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace* [NIOSH 2012a].

3.3.1 Evaluation of the nanotechnology research program

NIOSH evaluates its research progress in nanotechnology through a series of internal and external reviews. Past reviews of its nanotechnology research program have been conducted by the National Academies and by a workgroup of scientists chaired by two members of the NIOSH Board of Scientific Counselors. Based on these reviews, a revised strategic plan was published in November 2009 that proposed focused research and guidance on (1) identifying categories of nanomaterials that can be distinguished by their physical and chemical properties; (2) recommending specific exposure limits for various nanomaterials; (3) assessing hazards, risks, and exposures; and (4) developing intervention strategies [NIOSH 2009b]. In addition to external reviews, NIOSH continues to conduct annual program reviews and regular project reviews, and it publishes periodic progress reports describing ongoing research and accomplishments.

This *NIOSH Nanotechnology Research and Guidance Strategic Plan* was reviewed by a workgroup of scientists chaired by two members of the NIOSH Board of Scientific Counselors, and public comment was solicited through an announcement in the Federal Register.

3.4 Current NIOSH Extramural Nanotechnology Research Activities

The NIOSH Office of Extramural Programs (OEP) manages the competitive process for awarding occupational safety and health grants and cooperative agreements to the research community outside the Institute. This process involves peer review, program relevance, and priorities of the National Occupational Research Agenda (NORA), the NIOSH Research to Practice (r2p) initiative, congressional mandates, and sector, cross-sector, or coordinated emphasis areas of the NIOSH Program Portfolio (*http://www.cdc.gov/niosh/programs*).

Since 2001, the NIOSH OEP has funded nanotechnology research through Occupational Safety and Health Research Program Announcements (R01), Mentored Scientist Grants (K01), Small Research Grants (R03), Developmental Grants (R21), and Small Business Innovation Research Grants (R43/44). During the period 2001 to 2012, the NIOSH OEP has committed approximately $12 million to extramural nanotechnology research.* Summaries of the projects funded by the NIOSH OEP are included in the document *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace* [NIOSH 2012a]. Through continued collaboration with the Environmental Protection Agency/National Center for Environmental Research (EPA/NCER), National Science Foundation (NSF), National Institutes of Health/National Institute of Environmental Health Sciences (NIH/NIEHS), and international agencies, the NIOSH OEP continues to support nanotechnology research that focuses on occupational safety and health issues. In addition, the NIOSH OEP routinely confers with the NIOSH NTRC regarding research needs.

*This includes all extramural projects that involve any aspect of nanotechnology.

4 GOALS

4.1 Address Each Element in the Risk Management Continuum

Ultimately, the goal of the NTRC is to develop information, knowledge, and guidance to protect the nanotechnology workforce. It is relatively early in the emergence of nanotechnology and there are many gaps in knowledge, yet nano-enabled products are in commerce and workers are being exposed to nanomaterials. Consequently, there is a need to address all elements in the risk management continuum concurrently.

The process for managing potential workplace exposures to engineered nanoparticles during their synthesis, manufacture, and incorporation into new materials and devices consists of the following steps to ascertain the appropriate risk management strategy:

1. identifying and characterizing the health and safety hazard;
2. conducting dose-response risk assessment;
3. assessing the extent of exposure;
4. characterizing the risk on the basis of exposure; and
5. developing control and management procedures [Schulte et al. 2008b].

As exposure assessment data for nanomaterials become available, the existence of any occupational risk—and the conditions under which exposure to the hazard would be harmful to workers—can be determined. A goal of the risk characterization is to determine whether exposure to a type of material (in this case, nanomaterials) used in a given technology is likely to result in adverse health effects. Exposure assessment data provide a means to determine whether workers might be exposed and what type of control strategy might be effective in preventing exposure. Epidemiologic research is needed to provide etiologic evidence for new hazards and quantitative exposure–response information for recommended exposure limits. Decisions about which nanomaterials to study epidemiologically require collecting information on workforce size, exposure levels, and expected hazard (from toxicological or other information). The NIOSH NTRC is involved in conducting research and answering questions posed in each element of the risk management process to address knowledge gaps in the protection of workers (Figure 7).

A challenge of the NIOSH NTRC program is to determine how to conduct timely research that addresses the elements of hazard identification through risk management, as introduction of nanomaterials to the workplace continues and the workforce exposed to them becomes more diversified. The approach taken by the NTRC has been to conduct concurrent, focused research to address knowledge gaps in each step of the risk management process to provide occupational safety and health guidance.

4.2 Identification of NTRC Data Needs for Knowledge Gaps

In preparing this strategic plan, the NTRC steering committee met in spring 2012 to identify data needs and research gaps. Information was gleaned from various sources:

- research studies conducted by the NIOSH NTRC and others
- comments received during public review from open meetings or submitted to the NIOSH Docket on *Interim Guidance for*

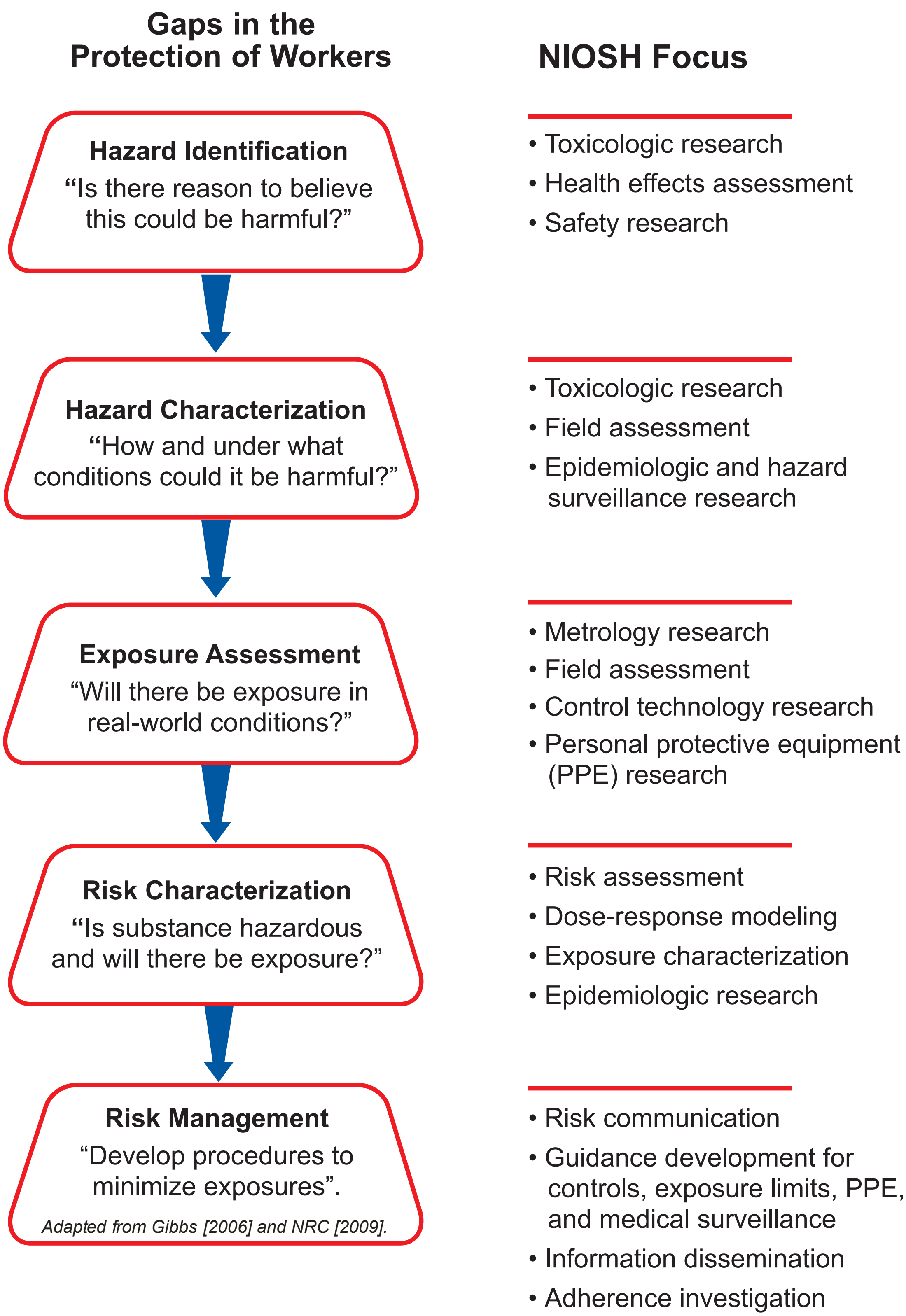

Figure 7. Addressing knowledge gaps in protecting nanomaterial workers.

Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles

- comments received during public review from open meetings or submitted to the NIOSH Docket on *Current Intelligence Bulletin for Occupational Exposure to Carbon Nanotubes and Nanofibers*
- comments received in the NIOSH Docket on the draft strategic goals [76 Fed. Reg.* 123612]
- the 2011 NEHI Environmental, Health, and Safety (EHS) Research Strategy
- various scientific meetings and collaborations, including tripartite attendance (labor, industry, and government) and stakeholder input workshops.

On the basis of this information, the following data needs and research gaps have been identified.

Increase understanding of new hazards and related health risks to nanomaterial workers

- Identify emerging commercial ENMs through market forecasting and research, technology surveillance, and partner and stakeholder input.
- Determine how workers might be exposed to nanoparticles during manufacturing, handling, and use of nanomaterials.
  - — Expand research from primary manufacturer to second-, third-, and fourth-generation use of ENMs.
  - — Continue field investigations to better understand worker exposures throughout the life cycle, including processing of nano-enabled products.
  - — Determine how ENMs interact with the body's systems.
  - — Determine relationships between specific physicochemical properties of ENMs and adverse biological effects.

*Federal Register.

Expand understanding of the initial hazard findings of engineered nanomaterials

- Determine carcinogenicity of carbon nanotubes (CNTs).
- Determine whether the cardiovascular system is more sensitive than the lungs to effects from ENM exposures.
- Determine whether ENMs cause immune dysfunction.
- Explore the usefulness of biomarkers for identifying and determining the extent of worker exposure and the potential for adverse health effects.
- Conduct research on measurement methods for nanomaterials.
  - — Align laboratory and field exposure metrics and measurement techniques.
  - — Expand and refine workplace measurement techniques for assessing exposure (tiered approach).
  - — Develop a microscopy method for CNTs and other ENMs.
  - — Identify the critical reference materials needed for measurement.
- Continue to evaluate additional ENMs for dustiness, explosibility, flammability, and electromagnetic hazard potential.
  - — Correlate dustiness, explosion, fire, and electromagnetic data with existing hazard indexes.

Support the creation of guidance materials to inform nanomaterial workers, employers, health professionals, regulatory agencies, and decision-makers about the hazards, risk, and risk management approaches.

- Develop categorical and specific occupational exposure limits.
  - — Conduct research to recommend specific exposure limits for various ENMs (e.g., nanosilver, graphene, carbon black, nano silica, nanoceramics, nano clays, nano catalysts), and

evaluate the adequacy of existing exposure limits.

- Identify categories of nanomaterials that can be distinguished by physicochemical parameters.
- Conduct risk assessments.
  - — Nanoparticle lung dosimetry modeling
  - — Categorization and comparative potency methods
- Link risk assessment, toxicology, exposure measurement, and control strategies.
- Demonstrate effective risk management practices.
- Develop guidance materials.
  - — Update guidance for medical surveillance (include sensitivity and specificity of medical tests).
  - — Evaluate and provide guidance on control technology.
  - — Integrate Prevention through Design (PtD) into ENM risk management guidelines.
  - — Use categorical approaches for ENMs to develop guidance on controlling exposures (hazard and control banding).
  - — Evaluate and provide guidance on PPE for use with ENMs.
- Partner with businesses to promote safe and responsible handling of ENMs.
- Determine whether there are potential applications of nanomaterials for safety and health (e.g., improved sensors or PPE).

Support epidemiologic studies for nanomaterial workers, including medical, cross-sectional, prospective cohort and exposure studies.

- Conduct epidemiologic research on the health of nanomaterial workers by employing both cross-sectional and prospective designs.
- Partner with other U.S. agencies and groups that have begun epidemiologic and other surveillance studies.
- Determine appropriate tools for medical screening and mechanisms of medical surveillance among workers exposed to specific EMNs.
- Create an exposure database that harmonizes with global exposure databases.

Assess and promote national and international adherence with risk management guidance

- Conduct a national assessment to determine the extent of use of nanomaterial exposure controls and any barriers to their use.
- Provide intervention strategies for industry sectors where adherence to good risk-management practices is low.
- Partner with other businesses, U.S. agencies, and the international community to promote safe, responsible development of nanomaterials.

4.3 Coalescing Priorities for NIOSH NTRC Research and Guidance for FY2013–FY2016

The NIOSH NTRC has proposed specific research activities (see Section 4.5) for FY2013–FY2016 that address the previously identified research needs and gaps (Section 4.2). Figure 8 provides a schema for how NIOSH will focus its research activities in accordance with the goals of the NTRC Strategic Plan:

- Increase understanding of new hazards and related health risks to nanomaterial workers.
- Expand understanding of the initial hazard findings of engineered nanomaterials.
- Support the creation of standards and guidance materials to inform nanomaterial workers, employers, health professionals, regulatory agencies, and decision-makers

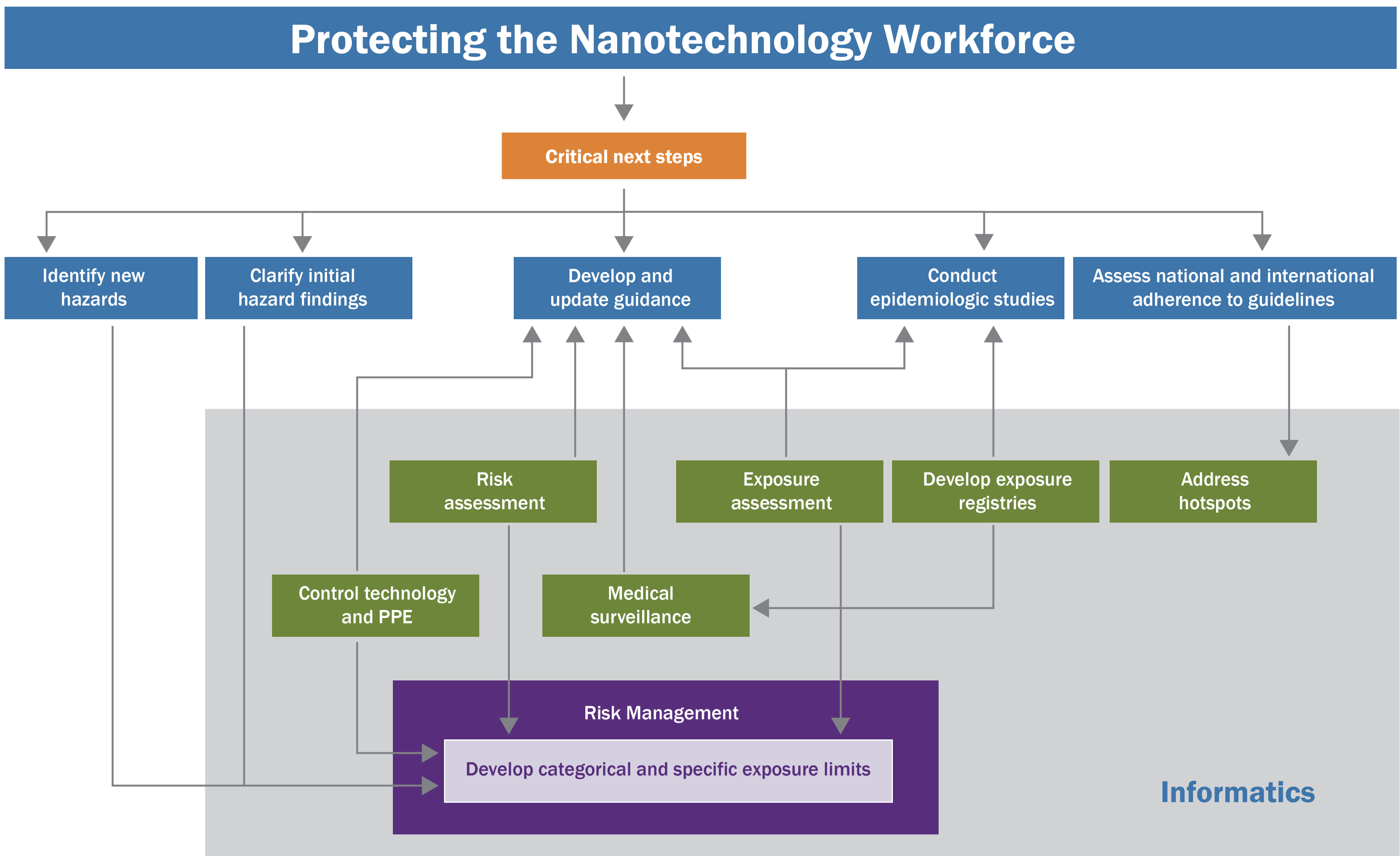

Figure 8. Focus of NIOSH nanomaterial research, 2013–2016.

about hazards, risks, and risk management approaches.

- Support epidemiologic studies for nanomaterial workers, including medical, cross-sectional, prospective cohort, and exposure studies.
- Assess and promote national and international adherence with risk management guidance.

The overall focus of the strategic plan will be to continue to generate data, information, and knowledge to protect the nanotechnology workforce, by using effective risk management techniques and particularly keeping exposure below occupational limits. Research is proposed to develop and update good risk-management practices, including categorical and specific exposure limits. Research data and information will be cataloged and shared via informatics (resources, devices, and methods required to optimize the acquisition, storage, retrieval, and use of information).

4.4 Coordination with the National Nanotechnology Initiative

NIOSH research priorities address many of the strategic goals proposed by the NNI Strategy for Nanotechnology Environmental, Health, and Safety Research. Table 1 shows the alignment of the NIOSH NTRC strategic goals and 10 NTRC critical research areas with the NNI EHS priority research needs (Appendix A).

4.5 Proposed NIOSH NTRC Research

The following proposed research for FY2013–FY2016 has been coalesced to focus on specific research needs to fill data gaps (see Section 4.2) and the EHS priority research needs of the NNI (see Section 4.4). As knowledge gaps are filled and as resources become available, these research priorities could change.

Strategic Goal 1 (PPNANSG1): Increase understanding of new hazards and related health risks to nanomaterial workers.

Intermediate Goal 1.1 (PPNANIG1.1): Conduct market forecasting and review available surveillance data to determine emerging commercial ENMs and next-generation uses of existing ENMs.

Activity/Output Goal 1.1.1 (PPNANAOG1.1.1): Prioritize high-volume emerging ENMs to identify the next candidates for toxicological testing and field evaluation of workplace exposures.

Performance Measure 1.1.1: In FY2013, complete an initial market research and forecasting report for internal use. Update the report within 3 years.

Activity/Output Goal 1.1.2 (PPNANAOG1.1.2): Complete a secondary market analysis on high volume nanomaterials.

Performance Measure 1.1.2: By FY2014, complete a market landscape analysis of formulators and users of nano titanium dioxide, silver, graphene and cellulose. Identify key industries using these materials in current products and those to be commercialized in the near term.

Intermediate Goal 1.2 (PPNANIG1.2): Conduct research to contribute to the understanding of the toxicology and internal dose of emerging ENMs.

Activity/Output Goal 1.2.1 (PPNANAOG1.2.1): Evaluate acute and chronic effects in the lungs and in other organ systems and tissues. Determine dose-response and time-course relationships. Determine rates of clearance of these nanoparticles after pulmonary exposure and translocation to systemic organs; characterize systemic effects.

Performance Measure 1.2.1: Complete toxicologic studies on ENMs such as nanosilver, graphene, and nanocellulose; present the data via the Society of Toxicology and publish in the peer-reviewed literature by FY2016.

Table 1. Alignment of Critical Research Areas with the Five Strategic Goals of the NIOSH NTRC and the NNI EHS Priority Research Needs (RNs)

NIOSH NTRC Strategic Goal/ Critical Research Area	Increase understanding of new hazards and related health risks to nanomaterial workers	Expand understanding of the initial hazard findings of engineered nanomaterials	Support the creation of guidance materials to inform nanomaterial workers and employers about hazards, risks, and risk management approaches	Support epidemiologic studies for nanomaterial workers, including medical, cross–sectional, prospective cohort, and exposure studies	Assess and promote national and international adherence with risk management guidance
Toxicity and internal dose	✓*	✓	✓		
	3-RN1†	3-RN1†			
	3-RN2	3-RN2			
	3-RN3	3-RN3			
	3-RN4	3-RN4			
	3-RN5	3-RN5			
	4-RN1				
Measurement methods	✓	✓	✓		
	1-RN1	1-RN1			
	1-RN2	1-RN2			
	1-RN3	1-RN3			
	2-RN1	2-RN1			
	3-RN2	3-RN2			

(continued)

Table 1 (Continued). Alignment of Critical Research Areas with the Five Strategic Goals of the NIOSH NTRC and the NNI EHS Priority Research Needs (RNs)

NIOSH NTRC Strategic Goal/ Critical Research Area	Increase understanding of new hazards and related health risks to nanomaterial workers	Expand understanding of the initial hazard findings of engineered nanomaterials	Support the creation of guidance materials to inform nanomaterial workers and employers about hazards, risks, and risk management approaches	Support epidemiologic studies for nanomaterial workers, including medical, cross–sectional, prospective cohort, and exposure studies	Assess and promote national and international adherence with risk management guidance
Exposure assessment	✓ 2-RN1 2-RN3 3-RN2 4-RN1 5-RN2	✓ 2-RN1 2-RN3 3-RN2 4-RN1 5-RN2	✓		
Epidemiology and surveillance	✓	✓	✓	✓ 2-RN1 2-RN3 2-RN4 3-RN6 5-RN2	✓ 5-RN2
Risk assessment	✓ 5-RN1 5-RN2 5-RN5	✓ 5-RN1 5-RN2 5-RN5	✓ 5-RN3 5-RN4		

(continued)

Table 1 (Continued). Alignment of Critical Research Areas with the Five Strategic Goals of the NIOSH NTRC and the NNI EHS Priority Research Needs (RNs)

NIOSH NTRC Strategic Goal/ Critical Research Area	Increase understanding of new hazards and related health risks to nanomaterial workers	Expand understanding of the initial hazard findings of engineered nanomaterials	Support the creation of guidance materials to inform nanomaterial workers and employers about hazards, risks, and risk management approaches	Support epidemiologic studies for nanomaterial workers, including medical, cross–sectional, prospective cohort, and exposure studies	Assess and promote national and international adherence with risk management guidance
Engineering controls and PPE	✓ 2-RN1 5-RN1 5-RN2	✓ 2-RN1 5-RN1 5-RN2	✓		✓ 5-RN2
Fire and explosion safety	✓ 1-RN5	✓ 1-RN5	✓		
Recommendations and guidance			✓ 5-RN‡ 5-RN§ 5-RN¶		✓ 5-RN2
Global collaborations‡	✓	✓	✓	✓	✓§
Applications¶			✓		

*A check mark (✓) indicates that a goal is currently being addressed by projects within the NIOSH critical research area.

†Alphanumeric identifications indicate specific NNI priority research needs (see Appendix A) being met by the NIOSH projects in each critical research area.

‡International engagement is a priority of the NNI and a critical component of the 2011 NNI EHS Research Strategy. However, it is not identified as a research need in the NNI Strategy.

§NIOSH will work with other governments to determine global adherence.

¶The NNI EHS plan does not address applications of nanomaterials for EHS use. However, the NNI strategic plan includes applications as a driving force behind several Federal nanotechnology programs, and it has the potential to improve safety and health, such as through the development of advanced sensors or PPE.

Performance Measure 1.2.2: Identify probable combinations of nanomaterial uses and if frequent combinations are identified, conduct preliminary toxicologic evaluations to determine if synergistic effects occur by FY2016.

Intermediate Goal 1.3 (PPNANIG1.3): Determine whether nanomaterial toxicity can be categorized on the basis of physicochemical properties and mode of action.

Activity/Output Goal 1.3.1 (PPNANAOG1.3.1): Systematically investigate the physical and chemical properties of particles that influence their toxicity (e.g., size, shape, surface area, solubility, chemical properties, and trace components).

Activity/Output Goal 1.3.2 (PPNANAOG1.3.2.): Determine the biological mechanisms for toxic effects (e.g., oxidant stress, dissolution, fibrogenicity, and hydrophobicity) and how the key chemical and physical factors may influence these mechanisms.

Activity/Output Goal 1.3.3 (PPNANAOG1.3.3): Integrate mechanistic models (including animal models and in vitro screening tests) for assessing the potential toxicity of new nanomaterials, and provide a basis for developing predictive algorithms for structure/function relationships and comparative toxicity analyses for risk assessment. Determine whether toxicologic data from new studies can be linked to existing toxicologic data.

Performance Measure 1.3.1: By FY2016, determine whether ENMs can be categorized (hazard banded) on the basis of physicochemical properties and/or the toxicologic mode of action.

Intermediate Goal 1.4 (PPNANIG1.4): Conduct nanomaterial workplace exposure assessments at sites developing, producing, or using emerging ENMs.

Activity/Output Goal 1.4.1 (PPNANAOG1.4.1): Collaborate with nanomaterial businesses to identify processes that may release nanomaterials during manufacturing or use of ENMs. Evaluate potential exposures and document risk mitigation processes.

Performance Measure 1.4.1.1: Complete a minimum of four field evaluations per year at facilities producing or using emerging ENMs. By FY2014, publish summary findings in a peer-reviewed journal.

Performance Measure 1.4.1.2: Evaluate ENM use and risk management practices at user facilities across the life cycle, including secondary and tertiary facilities. By FY2015, publish summary findings in a peer-reviewed journal.

Strategic Goal 2 (PPNANSG2): Expand understanding of the initial hazard findings of engineered nanomaterials.

Intermediate Goal 2.1 (PPNANIG2.1): Conduct research to evaluate the adverse chronic effects of single-walled carbon nanotubes, multi-walled carbon nanotubes, and carbon nanofibers.

Activity/Output Goal 2.1.1 (PPNANAOG2.1.1): Conduct toxicologic testing to determine the potential of single-walled carbon nanotubes, multi-walled carbon nanotubes, and carbon nanofibers to have long-term pulmonary effects (fibrosis, lung cancer, mesothelioma).

Performance Measure 2.1.1: By FY2016, publish a report on the carcinogenicity of carbonaceous nanomaterials, based on completed carcinogenicity-toxicology studies.

Intermediate Goal 2.2 (PPNANIG2.2): Determine whether human biomarkers of nanomaterial exposure and/or response can be identified.

Activity/Output Goal 2.2.1 (PPNANAOG2.2.1): Conduct research to determine whether blood, urine, or nasal lavage markers can accurately predict initiation and progression of adverse responses to ENMs.

Performance Measure 2.2.1: By FY2017, publish results of human biomarker studies.

Activity/Output Goal 2.2.2 (PPNANAOG2.2.2): Conduct research to determine whether cardiovascular or immune responses are sensitive indicators of pulmonary exposure to ENMs.

Performance Measure 2.2.2: By FY2016, publish findings on cardiovascular and immune responses to pulmonary exposure to ENMs.

Intermediate Goal 2.3 (PPNANIG2.3): Determine the relevance of in vitro and in vivo screening tests to worker response to inhalation of ENMs.

Activity/Output Goal 2.3.1 (PPNANAOG 2.3.1): Evaluate the relationship of deposition patterns and biological responses to pulmonary bolus exposure (intratracheal instillation or pharyngeal aspiration) vs. exposure extended over time (inhalation) of ENMs in rodent models.

Performance Measure 2.3.1: By FY2016, publish findings on the relationship of deposition patterns and biological responses to pulmonary bolus exposure vs. exposure extended over time.

Activity/Output Goal 2.3.2 (PPNANAOG 2.3.2): Evaluate predictive in vitro screening tests for fibrogenicity, genotoxicity, and/or cell transformation.

Performance Measure 2.3.2: Publish results from predictive in vitro screening tests for fibrogenicity, genotoxicity, and/or cell transformation, over the next 2 to 4 years (FY2014–FY2016).

Intermediate Goal 2.4 (PPNANIG2.4): Conduct research on measurement methods for nanomaterials.

Activity/Output Goal 2.4.1 (PPNANAOG2.4.1): Continue interactions with national metrology institutes and qualify cellulose and single-walled CNT nanoscale reference materials (RMs) and/or benchmark materials for evaluating measurement tools, instruments, and methods for exposure assessment and toxicology.

Performance Measure 2.4.1.1: By FY2014, complete a round-robin evaluation of a transmission electron microscopy (TEM) sample-preparation procedure using National Institute of Standards and Technology (NIST) gold nanoparticle RMs 8011, 8012, and 8013.

Performance Measure 2.4.1.2: By FY2014, translate this TEM sample-preparation procedure into a consensus standard practice or guide through ASTM International Committee E56: Nanotechnology.

Performance Measure 2.4.1.3: Within 4 years (FY2016), utilize NIST gold nanoparticle RMs 8011, 8012, and 8013 to evaluate filter- and grid-based sample-collection techniques and TEM analysis for spherical ENMs.

Performance Measure 2.4.1.4: By FY2016, develop measurement protocols for dynamic light scattering (hydrodynamic diameter), laser Doppler electrophoresis (zeta potential), and gas adsorption (surface area) measurements that utilize RMs (as appropriate) for particle characterization for internal use to promote reproducibility of testing.

Performance Measure 2.4.1.5: By FY2016, develop instrument sampling cards that provide a succinct summary on the operation and utility of condensation particle counters, scanning mobility particle sizers, and diffusion chargers for internal use to promote measurement quality.

Activity/Output Goal 2.4.2 (PPNANAOG2.4.2): Understand relationships between laboratory instrumentation used to characterize aerosols for toxicology studies and field-measurement instrumentation used to characterize workplace atmospheres.

Performance Measure 2.4.2: By FY2016, complete a series of studies to evaluate test atmospheres with real-time and integrated laboratory and field-measurement instruments for a range of metrics, including particle number, size, and surface area.

Activity/Output Goal 2.4.3 (PPNANAOG2.4.3): Conduct further research on the dustiness testing of powders and to benchmark the Venturi (University of North Carolina) dustiness testing device against a more traditional dustiness test (e.g., a standard method prescribed in EN 15051).

Performance Measure 2.4.3: By FY2015, compare the Venturi dustiness testing device against at least one other method for a range of fine and nanoscale materials.

Activity/Output Goal 2.4.4 (PPNANAOG2.4.4): Conduct further research on determining the advantages and limitations of direct reading instruments in assessing nanoparticle work-place emissions and exposures.

Performance Measure 2.4.4: By FY2015, publish at least one further study on the performance of direct reading instruments for assessing nanoparticle emissions or exposures in the workplace.

Activity/Output Goal 2.4.5 (PPNANAOG2.4.5): Develop and improve methods and approaches (including direct reading and time-integrated sampling) for assessing workplace exposures to ENMs.

Performance Measure 2.4.5.1: By FY2015, publish updated strategies for assessing workplace exposures.

Performance Measure 2.4.5.2: By FY2015, validate method 5040 for a series of CNT including. NIST Standard Reference Material 248: Single-Wall Carbon Nanotubes (Raw Soot).

Activity/Output Goal 2.4.6 (PPNANAOG2.4.6): Evaluate scanning electron microscopy, transmission electron microscopy, and dark-field microscopy as analytical tools for measurement of carbon nanotubes using NIST Standard Reference Material 248: Single-Wall Carbon Nanotubes (Raw Soot).

Performance Measure 2.4.6: By FY2015, publish a microscopy method (or methods) for sample preparation, identification, and/or possible semi-quantification that is applicable to some ENMs.

Activity/Output Goal 2.4.7 (PPNANAOG2.4.7): Conduct research to advance the use of nanomaterials in the development of sensors (e.g., detection of harmful chemicals) and other health and safety–related applications that can be used in the workplace to ensure effective control of exposure.

Performance Measure 2.4.7.1: By FY2016, develop an effective sensor employing nanomaterials for the real-time measurement of a workplace agent, and publish the results.

Performance Measure 2.4.7.2: By FY2016, compile and publish a compendium on applications of nanotechnology to improve workplace safety and health.

Intermediate Goal 2.5 (PPNANIG2.5): Conduct research to better define the potential fire and explosion safety hazards of ENMs.

Activity/Output Goal 2.5.1 (PPNANAOG2.5.1): Identify physical and chemical properties that contribute to dustiness, combustibility, flammability, explosibility, and electromagnetic hazards of ENMs.

Performance Measure 2.5.1: By FY2014, publish preliminary findings from explosibility testing of some ENMs.

Performance Measure 2.5.2: By FY2016, publish findings that may influence the National Fire Protection Association (NFPA) or Department of Transportation (DOT) flammability placard information and the DOT Emergency Response Guidebook.

Intermediate Goal 2.6 (PPNANIG2.6): Develop and use informatics to process and communicate information.

Activity/Output Goal 2.6.1 (PPNANAOG2.6.1): Create a harmonized database to share exposure measurement, control, and epidemiologic data.

Performance Measure 2.6.1: By FY2015, have a populated dataset containing NIOSH results on measurement, control, and epidemiologic data.

Activity/Output Goal 2.6.2 (PPNANAOG2.6.2): Lead the nanoinformatics community to develop an open literature monograph on nanoinformatics principles and practice.

Performance Measure 2.6.2: Complete and publish the nanoinformatics monograph by FY2015.

Strategic Goal 3 (PPNANSG3): 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.

Intermediate Goal 3.1 (PPNANIG3.1): Develop categorical and specific exposure limits.

Activity/Output Goal 3.1.1(PPNANAOG3.1.1): Conduct a risk assessment for high-volume ENMs.

Performance Measure 3.1.1: By FY2015, complete a quantitative risk assessment (QRA) on ultrafine and fine materials from existing studies. Evaluate QRA methods for nanomaterials. Start QRA for nanoparticles, with use of new NIOSH data. Use NIOSH nanoparticle data to calibrate and validate dosimetry models for nanoparticles.

Activity/Output Goal 3.1.2 (PPNANAOG3.1.2): Develop a risk-assessment framework for evaluating the hazard and predicting the risk of exposure to ENMs.

Performance Measure 3.1.2: By 2017, develop a risk-assessment framework to rank hazard and estimate risk from exposure to selected ENMs in the workplace.

Activity/Output Goal 3.1.3 (PPNANAOG3.1.3): Use a nanomaterial hazard banding classification scheme to group ENMs.

Performance Measure 3.1.3: By FY2016, develop a hazard banding classification scheme for ENMs on the basis of toxicological, chemical, and physical properties.

Intermediate Goal 3.2 (PPNANIG3.2): Conduct research to better understand engineering controls and PPE for use with ENMs.

Activity/Output Goal 3.2.1 (PPNANAOG3.2.1): Evaluate the effectiveness of engineering control techniques for ENMs and develop new approaches as needed.

Performance Measure 3.2.1: Conduct field investigations of workplaces where ENMs are manufactured and used to evaluate existing engineering controls and make recommendations on improving exposure control. By FY2015, publish case studies and workplace survey reports, and by FY 2016, publish updated engineering control solutions.

Activity/Output Goal 3.2.2 (PPNANAOG3.2.2): Conduct laboratory evaluations of commercially available engineering controls for a variety of common ENM production, handling, and downstream processes.

Performance Measure 3.2.2: By FY2016, publish in-depth reports and journal articles on the effectiveness of the commercially available engineering control devices.

Activity/Output Goal 3.2.3 (PPNANAOG3.2.3): Evaluate the effectiveness of PPE (respirators, and protective clothing including gloves) for reducing worker exposures to ENMs.

Performance Measure 3.2.3: By FY2016, publish updated guidance on the effectiveness of PPE for reducing worker exposures to ENMs.

Intermediate Goal 3.3 (PPNANIG3.3): Incorporate Prevention through Design (PtD) into nanomaterial health and safety programs.

Activity/Output Goal 3.3.1 (PPNANAOG3.3.1): Promote PtD principles for nanomaterials, including safer nanomaterials that have the same functionality; process containment and control; and management system approaches to include occupational safety and health into the nanoparticle synthetic process, product development, and product manufacture.

Performance Measure 3.3.1: By FY2015, publish a document specific to PtD for nanomaterials.

Intermediate Goal 3.4 (PPNANIG3.4): Foster the collection, management, and dissemination of relevant information to protect nanomaterial workers.

Activity/Output Goal 3.4.1 (PPNANAOG3.4.1): Develop and disseminate effective information, education, and training materials to various target audiences such as nanotechnology workers and employers, occupational safety and health professionals, policy-makers, decision-makers, and/or the scientific community.

Performance Measure 3.4.1.1: By FY2015, create nanomaterial guidance documents for workers, including small business and construction workers.

Performance Measures 3.4.1.2: By FY2015, update *Approaches to Safe Nanotechnology: Managing the Safety and Health Concerns Associated with Engineered Nanomaterials*.

Performance Measures 3.4.1.3: By FY2016, update the *Progress Report on the NIOSH Nanotechnology Research and Communication Effort*.

Performance Measure 3.4.1.4: Create new guidance documents on use of engineering controls, PPE, and PtD, as per Performance Measures 3.2.1, 3.2.2, 3.2.3, and 3.3.1.

Performance Measure 3.4.1.5: By FY2016, support a conference on risk management of ENMs, with a focus on engineering controls.

Performance Measure 3.4.1.6: By FY2016, evaluate Nanomaterial Safety Data Sheets for adherence with the updated OSHA HazCom rule (including the use of Global Harmonization System), and issue guidance documents based on the updated findings.

Intermediate Goal 3.5 (PPNANIG3.5): Enhance global workplace safety and health through international activities.

Activity/Output Goal 3.5.1 (PPNANAOG3.5.1): Establish and maintain national and international partnerships so that knowledge gaps, research needs and priorities, approaches, and databases could be shared.

Performance Measure 3.5.1.1: Strengthen coordination of research through government-level organizations such as the Organization for Economic Cooperation and Development (OECD) and United Nations (UN).

Performance Measure 3.5.1.2: By FY2015, expand collaborations to developing nations.

Activity/Output Goal 3.5.2 (PPNANAOG3.5.2): Improve sharing critical data globally.

Performance Measure 3.5.2.1: By FY016, develop a global portal for information on ENMs relevant to occupational safety and health.

Performance Measure 3.5.2.2: If feasible, by FY2016 initiate the development of a global exposure registry database.

Performance Measure 3.5.2.3: In FY2015, participate in OECD Nanomaterial Safety Testing Program by sponsoring nanomaterial testing and by data exchange.

Activity/Output Goal 3.5.3 (PPNANAOG 3.5.3): Lead the development of global standards on occupational safety and health for nanotechnology.

Performance Measure 3.5.3.1: Over the next 3 years (FY2014–FY2016), lead the development of at least one standard in the International Organization for Standardization.

Performance Measure 3.5.3.2: Over the next 3 years (FY2014–FY2016), lead the development of at least one guidance document for the UN.

Performance Measure 3.5.3.3: Over the next 3 years (FY2014–FY2016), lead the development of at least one guidance document for the OECD.

Strategic Goal 4 (PPNANSG4): Support epidemiologic studies for nanomaterial workers, including medical, cross-sectional, prospective cohort, and exposure studies.

Intermediate Goal 4.1 (PPNANIG4.1): Conduct epidemiologic research and evaluate feasibility of conducting surveillance of nanomaterial workers.

Activity/Output Goal 4.1.1 (PPNANAOG4.1.1): Complete the epidemiological health studies of U.S. workers exposed to CNTs and carbon nanofibers.

Performance Measure 4.1.1: By FY2016, complete data collection for industry-wide exposure and epidemiological studies of workers exposed to carbonaceous nanomaterials.

Activity/Output Goal 4.1.2 (PPNANAOG4.1.2): Evaluate the need for and feasibility of initiating worker exposure registries for workers exposed to existing nanomaterials (e.g., titanium dioxide, CNTs) or producing and using new nanomaterials.

Performance Measure 4.1.2: By FY2016, develop a template and begin population of worker exposure registries.

Activity/Output Goal 4.1.3 (PPNANAOG4.1.3): Integrate nanotechnology safety and health guidance into existing hazard surveillance systems. Determine whether these systems are adequate by conducting evaluations.

Performance Measure 4.1.3: By FY2016, update *NIOSH Current Intelligence Bulletin 60: Interim Guidance for the Medical Screening and Hazard Surveillance of Workers Potentially Exposed to Engineered Nanoparticles* [NIOSH 2009d].

Strategic Goal 5 (PPNANSG5): Assess and promote national and international adherence with risk management guidance.

Intermediate Goal 5.1 (PPNANIG5.1): Determine the extent to which control measures are being adopted by industry. Identify any barriers to use of controls and partner with business to address barriers.

Activity/Output Goal 5.1.1 (PPNANAOG 5.1.1): Determine whether NIOSH or other precautionary guidance recommendations are being adopted by businesses.

Performance Measure 5.1.1: Within the next 3 years, conduct formal and informal assessments of the controls used in ENM-producing or -handling facilities. By FY2016, publish findings.

Activity/Output Goal 5.1.2 (PPNANAOG 5.1.2): Develop a plan for industrial sectors where adherence to good risk-management practice is low.

Performance Measure 5.1.2: By 2016, publish a plan for intervening in industry sectors with low adherence to risk management guidance.

Activity/Output Goal 5.1.3 (PPNANAOG 5.1.3): Develop a follow-back program for the field investigation activities.

Performance Measure 5.1.3: By 2014, have a follow-back program in place to determine if facilities are implementing suggestions from the field investigations.

Activity/Output Goal 5.1.4 (PPNANAOG 5.1.4): Support the International Commission on Occupational Health (ICOH) and other organizations in assessing whether precautionary guidance recommendations are being adopted worldwide.

Performance Measure 5.1.4: By 2016, support ICOH in developing a plan to address locations where adherence to good risk-management practice is low.

5 OUTPUTS

A summary of NIOSH NTRC research outputs and accomplishments is presented in the report *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace* [NIOSH 2012a].

5.1 NIOSH Publications on Nanotechnology Since 2009

NIOSH NTRC scientists will continue to develop documentation that provides guidance and technical information for workers, employers, health professionals, regulatory agencies, and decision-makers in government, academia, industry, and labor. Examples of such documentation include the following:

- *Current Intelligence Bulletin (CIB) 65, Occupational Exposure to Carbon Nanotubes and Carbon Nanofibers*, DHHS (NIOSH) Publication No. 2013–145 [NIOSH 2013]. This document includes a recommended exposure limit for carbon nanotubes and nanofibers. It is available at *http://www.cdc.gov/niosh/docs/2013-145/*.
- *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace*, DHHS (NIOSH) Publication No. 2013–101 [NIOSH 2012a]. It is available at *http://www.cdc.gov/niosh/docs/2013-101/*.
- *Current Intelligence Bulletin (CIB) 63, Occupational Exposure to Titanium Dioxide*, DHHS (NIOSH) Publication No. 2011–160 [NIOSH 2011]. This document includes a recommended exposure limit for both fine and ultrafine (nano) titanium dioxide (TiO_2). It is available at *http://www.cdc.gov/niosh/docs/2011-160/*.
- *General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories*, DHHS (NIOSH) Publication No. 2012–147 [NIOSH 2012b]. It is available at *http://www.cdc.gov/niosh/docs/2012-147/* .
- NIOSH sponsored a supplement to the Journal of Occupational and Environmental Medicine, entitled Selected Papers from the Nanomaterials and Worker Health, Medical Surveillance, Exposure Registries and Epidemiologic Research Conference, July 21–23, 2010 [JOEM 53(6S):S1–S112].
- *Progress Toward Safe Nanotechnology in the Workplace: A Report from the NIOSH Nanotechnology Research Center*, DHHS (NIOSH) Publication No. 2010–104 [NIOSH 2009a]. This document reports on the status of nanotechnology research conducted by the NIOSH NTRC in 2007–2008. It is available at *http://www.cdc.gov/niosh/docs/2010-104/*.
- *Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials*, DHHS (NIOSH) Publication No. 2009–125 [NIOSH 2009c]. This document served a dual purpose of summarizing NIOSH's current thinking and interim recommendations and fostering the exchange information to ensure that no worker suffers material impairment of safety or health as nanotechnology develops. It is available at *http://www.cdc.gov/niosh/docs/2009-125/*.
- *Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles*, DHHS (NIOSH) Publication No. 2009–116 [NIOSH 2009d]. This document recommended prudent precautionary interim measures for reducing work-related exposures and assessing potential risk. It is available at *http://www.cdc.gov/niosh/docs/2009-116/*.

5.2 NIOSH Peer-Reviewed Publications

NIOSH NTRC scientists will continue to publish results of research as the data become available. More than 500 peer-reviewed articles were published between 2004 and 2012 that addressed scientific and technical issues in the field of nanotechnology. NIOSH will continue to evaluate the utility of its publications and their impact on the scientific, regulatory, and occupational health community.

5.3 Sponsored Conferences

The NIOSH NTRC will continue to partner with others in sponsoring and conducting conferences on nanotechnology. To date, NIOSH has co-sponsored 15 international nanomaterial health and safety meetings. NTRC staff members also have participated on several scientific and technical panels convened by government agencies, nongovernmental agencies, and professional associations.

5.4 Presentations

NTRC staff will continue to deliver presentations nationally and internationally concerning occupational safety and health issues associated with nanotechnology, including presentations at scientific conferences and to trade and professional associations. To date, NTRC staff members have given more than 650 presentations on nanomaterial health and safety topics.

6 RESEARCH TO PRACTICE (r2p)

Research to practice (r2p) involves the translation of research into products, practices, and usable information. The NIOSH NTRC nanotechnology strategic plan reflects the r2p vision to work with partners and stakeholders to translate research findings into NIOSH products (e.g., guidance documents, instrumentation, nanoparticle filtration methods, and exposure controls) that will be used to reduce or prevent worker injury and illness from nanotechnology. R2p also involves moving others to action. NIOSH will continue to work with national and international organizations to translate research to actions that will protect the nanomaterial workforce.

6.1 Capacity Building through Technical Assistance

The NIOSH NTRC is currently collaborating with a number of industries to develop appropriate engineering controls and effective administrative practices for the safe handling of nanomaterials. Specifically, the NTRC will continue to work with industry and labor in evaluating workplace exposures to ENMs and provide recommendations that will minimize worker exposures. NIOSH has several complimentary resources that reside in the Health Hazard Evaluation, Industrywide Study, and Engineering Control Technology Programs that can provide expertise in augmenting ongoing NTRC efforts of evaluating workplace nanoparticle exposures, related health effects, and risk management efforts. The NIOSH NTRC will continue to make recommendations and provide information based on its research and findings reported in the published scientific literature. The recommendations will pertain to all areas of risk management described in Section 4.1.

7 INTERMEDIATE CUSTOMERS AND INTERMEDIATE OUTCOMES

7.1 Federal Government Agencies

NIOSH will conduct and coordinate research with other agencies to foster the responsible development and safe use of nanotechnology, as identified by the NNI. Specifically, NIOSH will continue to collaborate with OSHA, EPA, NIST, NIEHS, and the Consumer Product Safety Commission (CPSC).

7.2 Standards Development Organizations

NIOSH actively participates in the development of national and international standards for promoting the health and safety of workers in the nanotechnology industries. The NIOSH NTRC participates in the American National Standards Institute (ANSI) Nanotechnology Standards Steering Panel, which coordinates the identification and development of critical standards in all areas of nanotechnology.

NIOSH NTRC scientists also participate in the ASTM International E56 Committee on Nanotechnology, which is developing an integrated family of standards. Committee E56.03 is addressing environmental and occupational safety and health.

NIOSH NTRC scientists will continue leading as chair and members of the U.S. Technical Advisory Group to the International Organization for Standardization (ISO) Technical Committee 229 on Nanotechnologies (ISO TC 229). Work on instrumentation-related standards will continue with committees of the International Electrotechnical Commission (IEC).

NIOSH NTRC scientists will also continue collaboration on the development of nanotechnology-related guidance with authoritative bodies including the National Council on Radiation Protection and Measurements.

7.3 Industry, Labor, and Academia

NIOSH is coordinating input from industry, labor, academics, and a wide range of government agencies in creating guidance for occupational health surveillance. Additionally, the NIOSH NTRC plans to coordinate input from those same groups of partners and stakeholders with the goal of developing standardized data systems for epidemiological research in workplaces producing and using nanomaterials. Through collaborations with industry, government, and academia, NIOSH [2009c] has developed a "best practices" document, *Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials* [DHHS (NIOSH) Publication No. 2009–125; *http://www.cdc.gov/niosh/docs/2009-125/*] and will continue to develop other communication materials on the safe handling of ENMs. NIOSH NTRC is continuing to work with industry to characterize occupational exposure to ENMs and implement effective risk-management practices to minimize worker exposure to ENMs.

7.4 Professional Organizations

NIOSH is collaborating with various professional organizations, including the American Industrial Hygiene Association (AIHA) and

National Safety Council (NSC), to identify mutual efforts for developing new worker training programs.

7.5 Research Collaborations

NIOSH has established several national and international collaborations to advance research into the safe use of nanotechnology. The NIOSH NTRC participates in the National Nanotechnology Initiative (NNI) and has contributed to the nanotechnology environmental, health, and safety (EH&S) research strategy for the nation through the working group of Nanotechnology Environmental and Health Implications (NEHI). NIOSH's strategic research plan and activities have been developed to address the occupational safety and health issues in the NSET/NEHI plan [NNI 2011].

7.6 International Activities

NIOSH will continue to engage with a number of international entities at all levels—as principle investigator as well as in national, regional, and global organizations. At the national organization level, the NIOSH NTRC has been communicating and collaborating with the United Kingdom Institute of Occupational Medicine and the Health and Safety Laboratory; the Netherlands Organization for Applied Scientific Research (TNO); the French Agency for Food, Environmental and Occupational Health and Safety (ANSES); the Finnish Institute of Occupational Health; and the Australian Safety and Compensation Council (Safe Work Australia).

NIOSH is collaborating with the OECD to build cooperation, coordination, and communication between the United States and 30 OECD member countries, including the European Union (EU), and more than 180 nonmember economies. NIOSH is also working with the UN World Health Organization (WHO); the UN International Labour Organization (ILO); the International Organization for Standardization (ISO); the International Electrotechnical Commission (IEC), the International Commission on Occupational Health (ICOH); and the International Council on Nanotechnology (ICON) on global projects of information dissemination and communication.

8 OUTCOMES

Nanotechnology is a rapidly developing area of science and technology that promises great benefits. To realize these benefits, it is important to protect workers potentially exposed to ENMs in nanomaterial research, production, and use [Schulte and Salamanca-Buentello 2007; Nasterlack et al. 2008; Howard and Murashov 2009]. The NIOSH NTRC strategic plan is designed to identify and create the information needed for risk management programs that will control and prevent negative impacts on worker health. Outcomes of the NIOSH NTRC research will be translated into products that can be used by the nanotechnology community to develop and implement appropriate risk management practices to minimize worker exposure to ENMs. NIOSH also will evaluate how research results and risk management guidance developed by NIOSH influence others to take action to prevent exposure to hazards related to ENMs.

NIOSH will assess the extent to which its research efforts have addressed each element of the risk management process (illustrated in Figure 6) and determine how the outcomes of research have influenced others to take action to prevent exposure to hazards related to ENMs. NIOSH will publish a report of its research outcomes for the 2013–2016 period. A summary of proposed research for FY2013–2014 and FY2015–2016 is shown in Appendix B

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Appendix A

Comprehensive Chart of the NNI 2011 EHS Research Needs

[National Nanotechnology Initiative: Environmental, Health, and Safety Research Strategy. Washington, DC: United States Executive Office of the President, Office of Science and Technology Policy, Nanotechnology Environmental and Health Implications (NEHI) Working Group, Table D–1.]

Table D–1. The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
1. Nanomaterial Measurement Infrastructure Research Needs Develop measurement tools to detect and identify engineered nanoscale materials in products and relevant matrices and determine their physico-chemical properties throughout all stages of their life cycles. Develop measurement tools for determination of biological response and to enable assessment of hazards and exposure for humans and the environment from engineered nanomaterials and nanotechnology-based products throughout all stages of their life cycles.	
RN#1. Develop measurement tools for determination of physico-chemical properties of ENMs in relevant media and during the life cycles of ENMs and NEPs	• Physical dimensions and morphology: size, size distribution, characteristic dimensions, shape • Internal structure: atomic-molecular, core-shell • Surface and interfacial properties: surface charge, zeta potential, surface structure, elemental composition, surface-bound molecular coatings and conjugates, reactivity • Bulk composition: elemental or molecular composition, crystalline phase(s) • Dispersion properties: degree and state of dispersion • Mobility and other transport properties: diffusivity, transport in biological and environmental matrices
RN#2. Develop measurement tools for detection and monitoring of ENMs in realistic exposure media and conditions during the life cycles of ENMs and NEPs	• Sampling and collection of ENMs • Detecting the presence of ENMs • Quantity of ENMs-concentration based on surface area, mass, and number concentrations • Size and size distribution of ENMs • Spatial distribution of ENMs • Discriminating ENMs from ambient NMs such as combustion products and welding fumes • Discriminating multiple types of ENMs such as metals and metal oxides
RN#3. Develop measurement tools for evaluation of transformations of ENMs in relevant media and during the life cycles of ENMs and NEPs	• Agglomeration and de-agglomeration • Dissolution and solubility • Absorption of natural organic matter and bioconstituents • Oxidation and reduction • Deposition of ENMs on surfaces

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
RN#4. Develop measurement tools for evaluation of biological responses to ENMs and NEPs in relevant media and during the life cycles of ENMs and NEPs	• Adequacy of existing assays • New assays or high-throughput, high content assays • Correlation of biological responses with physico-chemical properties • Surface reactivity at the interfaces between ENMs and biological receptors • Biomarkers of toxicological response
RN#5. Develop measurement tools for evaluation of release mechanisms of ENMs from NEPs in relevant media and during the life cycles of NEPs	• Release by fire, combustion, and incineration • Release by mechanical degradation, such as abrasion, deformation, and impact • Release by dissolution of matrix material • Release by chemical reactions of the matrix material • Release by photo-induced degradation of the matrix material • Release by consumer interactions, such as spraying, mouthing, and swallowing • Release by interactions with biological organisms in the environment
2. Human Exposure Assessment Research Needs Identify potential sources, characterize the exposure scenarios, and quantify actual exposures of workers, the general public and consumers to nanomaterials. Characterize and identify the health outcomes among exposed populations in conjunction with information about the control strategies used and exposures to determine practices that result in safe levels of exposure.	
RN#1. Understand processes and factors that determine exposures to nanomaterials	• Conduct studies to understand processes and factors that determine exposure to engineered nanomaterials • Develop exposure classifications of nanomaterials and processes • Develop internationally harmonized and validated protocols for exposure surveys, sample collection and analysis, and reporting through existing and newly created international frameworks • Develop comprehension predictive models for exposures to a broad range of engineered nanomaterials and processes • Characterize process- and task-specific exposure scenarios in the workplace

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
RN#2. Identify population groups exposed to engineered nanomaterials	• Systematically collect and analyze information about nanomaterial manufacture, processing, and direct use in commercial and consumer products over time to discern geographic areas where engineered nanomaterials may be emitted into the environment, consumed in the form of ingredients of products, and/or disposed of in solid waste, wastewater, etc. • Conduct population-based surveys to obtain information on use patterns for consumer products • Identify potential subpopulations that are more susceptible to exposure to engineered nanomaterials than others • Develop quantitative assessment methods appropriate for target population groups and conduct assessments of those population groups most likely to be exposed to engineered nanomaterials
RN#3. Characterize individual exposures to nanomaterials	• Expand currently available exposure assessment techniques to facilitate more accurate exposure assessment for engineered nanomaterials at benchmark concentration levels using feasible methods • Develop new tools through national and international surveys to support effective exposure characterization of individuals • Characterize and detect nanomaterials in biological matrices and conduct studies to understand transformations of nanomaterials during transport in the environment and in human bodies • Conduct studies to examine emissions and human contact during normal use and after wear and tear have degraded a product, as well as during repeated exposures • Develop engineered nanomaterials exposure assessment models based on identified critical exposure descriptions • Develop databases to contain the collected data and information
RN#4. Conduct health surveillance of exposed populations	• Establish a program for the epidemiological investigations of physician case reports and reports of suspicious pattern of adverse events • Establish exposure registry and medical surveillance programs for workers • Analyze injury and illness reporting in existing programs

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
3. Human Health Research Needs Understand the relationship of physico-chemical properties of engineered nanoscale materials to *in vivo* physico-chemical properties and biological response. Develop high-confidence predictive models of *in vivo* biological responses and casual physico-chemical properties of ENMs.	
RN#1. Identify or develop appropriate, reliable, and reproducible *in vitro* and *in vivo* assays and models to predict *in vivo* human responses to ENMs	• Establish a system to develop and apply reliable and reproducible *in vitro* and *in vivo* test methods • Evaluate the degree to which an *in vitro* response correlates with an *in vivo* response • Evaluate the degree to which *in vitro* and *in vivo* models predict human response • Translate structure-activity relationship and other research data into computational models to predict toxicity *in silico*
RN#2. Quantify and characterize ENMs in exposure matrices and biological matrices	• Determine critical ENM measurands in biological and environmental matrices and ensure the development of tools to measure ENMs in appropriate matrices as needed • Determine matrix and/or weathering effects that may alter the physico-chemical characteristics of the ENM measurands • Identify key factors that may influence the detection of each measurand in a particular matrix (e.g., sample preparation, detection method, storage, temperature, solvents/solutions) • Characterize and quantify exposure for all exposure routes using *in vivo* models to identify the most likely routes of human exposure • Identify biomarkers of exposure and analytical methods for their determination
RN#3. Understand the relationship between the physico-chemical properties of ENMs and their transport, distribution, metabolism, excretion, and body burden in the human body	• Characterize ENM physico-chemical properties and link to mechanisms of transport and distribution in the human body • Understand the relationship of the physico-chemical properties of ENMs to the mechanisms of sequestration in and translocation of ENMs out of the exposure organ and secondary organs, and to routes of excretion from the human body • Determine the metabolism or biological transformation of ENMs in the human body

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
RN#4. Understand the relationship between the physico-chemical properties of ENMs and uptake through the human port-of-entry tissues	• Characterize ENMs at and in port-of-entry tissues, including nontraditional routes of entry such as the ear and eye, and identify mechanisms of ENM uptake into tissues • Determine the relationship of ENM physico-chemical properties to deposition and uptake under acute exposure conditions and under chronic exposure conditions • Translate data on ENM properties and uptake to knowledge that may be used to intentionally redesign ENMs for optimum human and environmental safety and product efficacy
RN#5. Determine the modes of action underlying the human biological response to ENMs at the molecular, cellular, tissue, organ, and whole body levels	• Determine the dose response and time course of biological responses at the primary site of exposure and at distal organs following ENM exposure • Understand the mechanisms and molecular pathway(s) associated with ENM biology within cellular, organ, and whole organism systems • Link mechanisms of response with ENM physico-chemical properties and employ this information in the design and development of future ENMs • Develop translational alternative *in vitro* testing methods for the rapid screening of future ENMs based on mechanism(s) of response that are predictive of *in vivo* biological responses
RN#6. Determine the extent to which life stage and/or susceptibility factors modulate health effects associated with exposure to ENMs and nanotechnology-enabled products and applications	• Determine the effect of life stage and/or gender on biological response to ENMs • Establish the role of genetic and epigenetic susceptibility on the biological response to ENMs in the context of life stage and/or susceptibility factors • Understand mechanistically the influence of preexisting disease on the biological response to ENMs in the context of life stage and other susceptibility factors • Identify exposure conditions that make susceptible individuals more vulnerable to the health effects associated with ENMs and nanotechnology-enabled applications • Establish a database that contains published, peer-reviewed literature, occupational and consumer reports, and toxicological profiles that describe altered responses to ENMs and nanotechnology-enabled applications in susceptible animal models or individuals following exposure

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
4. Environment Research Needs Understand the environmental fate, exposure, and ecological effects of engineered nanomaterials, with priority placed on materials with highest potential for release, exposure, and/or hazard to the environment.	
RN#1. Understand environmental exposures through the identification of principal sources of exposure and exposure routes	• Manufacturing processes and product incorporation • Life cycle of technology and exposures subsequent to product manufacturing • Analytical approaches to measure temporal changes in nanoparticle properties throughout the life cycle • Models to estimate releases • Environmental receptors for exposure assessment
RN#2. Determine factors affecting the environmental transport of nanomaterials	• Determine key physico-chemical properties affecting transport • Determine key transport and fate processes relevant to environmental media • Develop new tools and adaptation of current predictive tools to accommodate unique properties of nanomaterials
RN#3. Understand the transformation of nanomaterials under different environmental conditions	• Identify and evaluate nanomaterial properties and transformation processes that will reduce environmental persistence, toxicity, and production of toxic products • Determine the rate of aggregation and long-term stability of agglomeration/aggregation and the long-term stability of these aggregates and agglomerates • Develop tools to predict the transformations or degradability of nanomaterials
RN#4. Understand the effects of engineered nanomaterials on individuals of a species and the applicability of testing schemes to measure effects	• Test protocols • Dose-response characterization • Uptake/elimination kinetics, tissue/organ distribution • Mode/mechanism of action, predictive tools • Tiered testing schemes/environmental realism
RN#5. Evaluate the effects of engineered nanomaterials at the population, community, and ecosystem levels	• Population • Community • Other ecosystem-level effects • Predictive tools for population-, community-, and ecosystem-level effects

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
5. Risk Assessment and Risk Management Methods Research Needs Increase available information for better decision making in assessing and managing risks from nanomaterials, including using comparative risk assessment and decision analysis; life cycle considerations; and additional perspectives such as ELSI considerations, stakeholders' values, and additional decision makers' considerations.	
RN#1. Incorporate relevant risk characterization information, hazard identification, exposure science, and risk modeling and methods into the safety evaluation of nanomaterials	• Characterization, fate, and release of nanoparticles throughout the life cycles of nanotechnology-enabled products • Development of predictive models on accumulation, migration, and release of nanoparticles throughout the life cycles of nanotechnology-enabled products • Safety of nanoparticles throughout the life cycles of the nanotechnology-enabled products • Comprehensive and predictive models to assess the potential risks of nanoparticles during the manufacturing and life cycle of nanoproducts, with inputs from human and environment exposures and on nanomaterial properties
RN#2. Understand, characterize, and control workplace exposures to nanomaterials	• Dissemination and implementation of effective techniques and protocols to measure exposures in the workplace • Identification and demonstration of effective containment and control technologies including for accidents and spills • Development of an effective industry surveillance system • Design and deployment of a prospective epidemiological framework relevant to exposure science • Systematic approaches for occupational risk modeling
RN#3. Integrate life cycle considerations into risk assessment	• Establishment of nanotechnology-specific taxonomy for life cycle stages • Integration of risk assessment, life cycle analyses, and decision-making approaches into regulatory decision making processes • Application of adaptive management tools based on monitoring/implementation to evaluate life cycle analysis implementation • Development of case studies, e.g., green chemistry, nanomaterials selection, nanomaterials acquisition process, illustrating application of these risk management methods

(continued)

Table D–1 (Continued). The Core EHS Research Categories and their Highest-Priority Research Needs (RNs)

Key Research Needs	Subordinate Research Needs
RN#4. Integrate risk assessment into decision-making frameworks for risk management	• Development of comparative risk assessment and formal decision-analytical methods as opposed to "absolute" risk assessment strategies • Application of formal decision-analytical methods to prioritize risk management alternatives • Use of gap analyses and value of information analysis to identify research needs • Integration of stakeholder values and risk perceptions into risk management processes • Application of integrated decision framework through case studies in risk management decision making
RN#5. Integrate and standardize risk communication within the risk management framework	• Development and use of standardized terminology in risk communications • Early information-sharing on hazards and risk among Federal agencies • Development of appropriate risk communication approaches for agency-specific needs
Informatics and Modeling Research Need	
RN#1. Develop computational models of ENM structure-property-activity relationships to support the design and development of ENM with maximum benefit and minimum risk to humans and the environment	• Validate the predictive capability of *in vitro* and *in vivo* assays and employ that subset of assays in data generation to establish computational models to predict ENM behavior in humans and the environment • Establish a standard set of physical and chemical characterization parameters, dose metrics, and biological response metrics • Design and establish structures and ontologies for methods development, data capture, sharing, and analysis • Evaluate and adapt as necessary existing computational models by beginning with existing models for exposure and dosimetry and using data generated from validated assays • Use ENM exposure and dosimetry models to develop ENM structure-activity models to predict ENM behavior in humans and the environment • Establish training sets and beta test sites to refine and validate ENM structure-activity models • Disseminate ENM structure-activity models through publicly accessible nanotechnology websites

APPENDIX B

Timeline for NIOSH Nanotechnology Research

Summary of Proposed Research Projects, FY2013–FY2014

Critical research area	Projects
Toxicity and Internal Dose	Evaluate long-term fibrogenic and carcinogenic potential of carbon nanotubes and carbon nanofibers. Determine immune and cardiovascular responses to pulmonary exposure to CNT, TiO_2, and nanosilver. Evaluate the pulmonary effects of nanosilver.
Measurement Methods	Develop updated methods and approaches to assess occupational exposures to nanomaterials. Utilize reference materials and technically sound protocols to improve measurement quality. Develop techniques to characterize nanoparticles, using advanced microscopy methods. Study the performance of direct reading instruments for assessing emissions and exposure to nanoparticles in the workplace.
Exposure Assessment	Complete evaluation of workplace exposures to emerging, second-generation, and third-generation ENMs and their potential routes of exposure. Complete evaluation of size, concentration, and morphology of ENMs emitted by various processes.
Epidemiology and Surveillance	Evaluate occupational exposures among carbonaceous nanomaterial workers. Complete field work for a cross-sectional epidemiologic survey among workers exposed to carbonaceous nanomaterials. Collect data on specific biomarkers as markers of exposure or early health endpoints in workers exposed to carbon nanotubes or carbon nanofibers.

(continued)

Summary of Proposed Research Projects, FY2013–FY2014

Critical research area	Projects
Risk Assessment	Develop a strategy and criteria to utilize the best available scientific data to develop hazard- and risk-based occupational exposure limits and other risk management guidance. Identify nanomaterial categories by physicochemical properties and biological mode of action, and perform case study evaluations for nanomaterials within each major category. Analyze toxicity data, including identifying the adverse health endpoint(s) and performing dose-response analyses and/or comparative potency analyses. Contribute to the development and evaluation of dosimetry models and methods to assess internal dose of nanomaterials in workers.
Engineering Controls and PPE	Conduct field studies to assess and improve engineering control strategies in the workplace. Evaluate effectiveness of commercially available engineering controls in the laboratory. Finalize development of a standardized aerosol test method using magnetic passive aerosol samplers for testing of protective clothing material. Expand particulate penetration project to include evaluation of different types of fabrics, use of electrostatic charges, and bellows effects. Evaluate balance between comfort and protection of protective clothing and gloves with ENMs.
Fire and Explosion Safety	Evaluate nano metals and other ENMs for fire and explosion potential. Evaluate a variety of ENMs for electromagnetic hazard potential. Correlate dustiness of ENMs with various physical and chemical safety hazards. Evaluate current DOT and NFPA guidance for adequacy with ENMs. Provide recommendations to first responders about safety issues of ENMs.
Recommendations and Guidance	Continue conducting r2p activities (ongoing), such as developing brochures and fact sheets and updating the topic page. Develop a small business guide for nanomaterial producers and users.

(continued)

Summary of Proposed Research Projects, FY2013–FY2014

Critical research area	Projects
Applications	Further develop and refine end-of-service indicators using nanomaterials.
Global Activities	Strengthen participation with globally recognized organizations ICON, ISO, OECD, and UN (WHO, ILO). Participate in the US/EU nanomaterial working groups hosted by the NNI.

Summary of Proposed Research Projects for FY2015–FY2016

Critical research area	Projects
Toxicity and Internal Dose	Identify biomarkers of response to ENMs. Develop predictive algorithms for relationships between nanoparticle properties and bioactivity. Determine the relevance of in vitro and in vivo screening tests. Evaluate the pulmonary and systemic effects of graphene and nanocellulose.
Measurement Methods	Publish updated exposure measurement methods. Assist with round-robin evaluations of ENM reference materials.
Exposure Assessment	Publish exposure results. Provide guidance on exposure assessment methods and sampling protocols.
Epidemiology and Surveillance	Analyze biomarker samples from cross-sectional epidemiologic study of carbon nanotube and nanofiber workers. Analyze data (medical and biomarker with exposure) from cross-sectional epidemiologic study of carbon nanotube and nanofiber workers. Begin collecting data for exposure registry and prospective epidemiologic study among carbon nanotube–exposed and carbon nanofiber–exposed workers. Assess feasibility of epidemiologic study of health outcomes among workers exposed to nanomaterials other than carbonaceous nanomaterials.
Risk Assessment	Extend evaluations of the hazard and risk of workplace exposure to new nanomaterials. Utilize the latest data from toxicity studies, workplace exposure measurements, and/or biomonitoring data to identify potential hazards in the respiratory tract and/or other organs. Contribute to the refinement and validation of dosimetry models for nanomaterials. Contribute to the evaluation and development or updating of recommended exposure limits and other risk management guidance.

(continued)

Summary of Proposed Research Projects for FY2015–FY2016 (Continued)

Critical research area	Projects
Engineering Controls and PPE	Continue to assess engineering controls in the field and update recommendations for controlling exposure. Continue to evaluate commercially available engineering controls in the lab and publish test results. Evaluate respirator performance with ENMs in laboratory and workplace settings. Develop a passive method for measuring particle penetration through protective clothing materials.
Fire & Explosion Safety	Continue evaluation of various ENMs for fire and explosion potential. Evaluate a variety of ENMs for electromagnetic hazard potential. Correlate dustiness of ENMs with various physical and chemical safety hazards. Publish findings in journals and provide summaries to DOT and NFPA.
Recommendations and Guidance	Update Approaches to Safe Nanotechnology Develop hazard bands and RELs for high-volume commercially available ENMs.
Applications	Evaluate ENM-enabled PPE.
Global Activities	Lead or co-lead committees with globally recognized organizations: ICON, ISO, OECD, and UN (WHO, ILO).

NOTE: DOT, Department of Transportation; ENMs, engineered nanomaterials; ICON, International Council on Nanotechnology; ILO, International Labour Organization; ISO, International Organization for Standardization; NFPA, National Fire Protection Association; NNI, National Nanotechnology Initiative; OECD, Organization for Economic Cooperation and Development; PPE, personal protective equipment; UN, United Nations; WHO, World Health Organization.

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