Continuing to Protect the Nanotechnology Workforce: NIOSH Nanotechnology Research Plan for 2018-2025 (Draft Research Plan)

Original Development Brief – Describes the strategic plan of the Nanotechnology Research Center (NTRC) for fiscal years (FY) 2018-2025, which addresses measures to protect the nanotechnology workforce.

Updated last **June 1, 2018**

WHAT IT DOES

The National Institute for Occupational Safety and Health (NIOSH) released its draft research plan on April 24, 2018 entitled "Continuing to Protect the Nanotechnology Workforce: NIOSH Nanotechnology Research Plan for 2018-2025." This draft research plan (noticed via 83 FR 17824) describes the nanomaterial-related risks associated with workplace exposure. It also outlines the plan established by the NIOSH Nanotechnology Research Center (NTRC) to understand and mitigate these risks with the ultimate goal of protecting the nanotechnology workforce. The research plan highlights the progress of NIOSH NTRC between 2003 and 2017, then describes planned research activities for the next several years and how progress will be measured.

NIOSH seeks to fill knowledge gaps addressing the five key goals of NIOSH NTRC first presented in its 2013 strategic plan, which are to:

- Increase understanding of the hazards and risks nanomaterial workers encounter in the workplace.
- Develop comprehensive understanding of hazards initially found to be associated with engineered nanomaterials.
- Support the creation of materials to inform nanomaterial workers, their employers, health professionals, regulatory agencies, and decision-makers about hazards and risks and how to manage them.
- Support epidemiologic studies for nanomaterial workers.
- Promote adherence with risk management guidance.

The NTRC receives critical input from customers, stakeholders, and national and international partnerships that informs the direction of NTRC research. The NTRC plans to continue developing these partnerships in order to:

- Better understand how engineered nanomaterials (ENMs) are being produced and used.
- Develop recommendations for handling ENMs safely.
- Develop sampling and analytical methods.
- Evaluate exposure controls that are or could be used in ENM processes.
- Evaluate the need for and determine the effectiveness of PPE.
- Develop materials that communicate information and will assist industry in its efforts to communicate with workers and the public.

The ultimate goal of the NTRC is to protect the nanotechnology workforce by gathering information and providing guidance to relevant parties. Recognizing that knowledge gaps still exist regarding nanomaterial health and safety even while worker exposure to nanomaterials is occurring, the NTRC strives to conduct timely research to identify the associated hazards and risks. To do so, the NTRC plans to address knowledge gaps in each of the 5 steps in the risk management process through focused research in:

- Hazard Identification— Determines if there is reason to believe the substance could be harmful.
- Hazard Characterization— Determines how and under what conditions the substance could be harmful.
- Exposure Assessment—Determines whether there will be exposure in real-world conditions.

- Risk Characterization— Asks whether the substance is hazardous and whether there will be exposure.
- Risk Management—Develop procedures to minimize exposures.

To accomplish the goal of protecting the nanotechnology workforce, the NTRC outlines specific research activities for FY2018-2025 that will fill knowledge gaps as well as the environmental, health, and safety (EHS) priority research needs of the National Nanotechnology Initiative (NNI), with which NIOSH is a partnering agency. The corresponding strategic goals (SG) for these research activities are:

- SG 1 – Increase understanding of new hazards and related health risks to nanomaterial workers;
- SG 2 – Expand understanding of the initial hazard findings of engineered nanomaterials;
- SG 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;
- SG 4 – Support epidemiologic studies for nanomaterial workers, including medical, cross-sectional, prospective cohort, and exposure studies;
- SG 5 – Assess and promote national and international adherence with risk management guidance.

The NTRC uses the concepts of burden, need, and impact to guide research priorities. Based on these criteria, NTRC identifies three strategic priorities (SP), based on their perceived impact:

- SP 1 – Increase understanding of new hazards and related health risks to nanomaterial workers;
- SP 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;
- Priority Activity/Output Goal 3.1.3—Use a nanomaterial hazard banding classification scheme to group ENMs.

To monitor progress, NIOSH uses the NIOSH Project Planning & Management system (NPPM), which enables tracking of activities, outputs, and outcomes, such as: presentations, webinars, participation in international committees, publishing of peer-reviewed journal articles, or adoption of a NIOSH recommendation by a governmental agency.

The 5 strategic goals of the NIOSH NTRC draft research plan align with many of the 10 EHS goals of the NNI, including specific priority research needs identified by NNI that are being addressed by NIOSH projects, like exposure assessment and engineering controls.

RELEVANT SCIENCE

While scientists have yet to unanimously decide on a definition for nanomaterial, a chemical substance is classified as a nanomaterial based on its extremely small size, measured in nanometers (nm). A substance is considered a nanomaterial if it has at least one dimension that is between 1 and 100 nm. Examples of naturally-occurring nanomaterials include volcanic ash, sea spray, and smoke. In contrast to naturally occurring nanomaterials, engineered (or man-made) nanomaterials are substances that are intentionally manufactured to have at least one dimension between 1 and 100 nm. And Nanotechnology is technology dealing with nanoscale materials having unique properties due to their size and can be manipulated on the atomic scale.

Nanomaterials have unique and dynamic properties that result in numerous applications. They are used as additives in consumer products, including fabrics, eyeglasses, computer displays, sporting equipment, vehicles, and personal care items. Nanomaterials are also advancing computing and electronics by enabling smaller and faster systems. The rise of nanomedicine is allowing for faster medical diagnoses and targeted drug therapies. And the use of nanotechnology in energy applications is improving alternative energy approaches.

However, working with nanomaterials in research, production processes, or manufacturing (nanomanufacturing) could result in exposure via inhalation, skin contact, or ingestion. The risks for exposure are greater if nanomaterials are in a form that is easily dispersed, such as powders or sprays. There is evidence that exposure to nanomaterials can lead to adverse health effects, which

are likely to vary based on the route of exposure. For example, nanoparticles that are airborne are more likely to be inhaled; and because of their small size, they can easily penetrate the lungs, where they could enter the bloodstream and travel to other organs. Inhalation is the most studied route of exposure, yet there is evidence that suggests skin contact could damage cell structures and processes. Furthermore, ingestion of nanomaterials could cause damage to cells in the liver and intestines.

While a decent amount of study has focused on the hazards of nanomaterials, researchers performed most of this work in cell cultures, which doesn't account for the exposure workers face in the workplace. The extent of nanomaterial exposure will impact the degree to which the nanomaterial could present a hazard to the worker. Information addressing hazard in the context of exposure is currently lacking and is needed to enable a complete risk assessment for workplace exposure to nanomaterials.

WHY IT MATTERS

The field of nanotechnology is growing rapidly, and the number of individuals pursuing education in nanotechnology and entering the nanotechnology workforce is projected to grow along with it. The nanotechnology workforce works with nanomaterials every day, but the hazards and risks associated with them are not yet fully understood.

The availability of research-backed recommendations to those working with nanomaterials is crucial. The development of research plans, like the one described herein, with the purpose of identifying and managing risks in a timely manner is critical for maintaining a safe work environment for the nanotechnology field.

RELEVANT EXPERTS

Mark Wiesner, Ph.D., Professor in the Duke University Pratt School of Engineering, Director of the Center for the Environmental Implications of NanoTechnology (CEINT) Duke University.

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BACKGROUND

Tools for imaging nanoscale materials became available about 30 years ago, marking the beginning of modern nanotechnology. In 2000, the United States established the National Nanotechnology Initiative (NNI), which coordinates the activities of 20 departments and independent agencies to advance nanotechnology in the United States.

Many years earlier, the Occupational Safety and Health Act of 1970 created NIOSH as part of the U.S. Centers for Disease Control and Prevention (CDC) to serve as a research agency for worker safety. NIOSH comprises employees from diverse backgrounds including chemistry, epidemiology, engineering, economics, and medicine.

In 2004, NIOSH established the Nanotechnology Research Center (NTRC), which is tasked with identifying and tackling critical issues in nanotechnology. Specifically, the NIOSH NTRC focuses on 10 critical areas for nanotechnology research and communication: (1) toxicity and internal dose; (2) measurement methods; (3) exposure assessment; (4) epidemiology and surveillance; (5) risk assessment; (6) engineering controls and personal protective equipment (PPE); (7) fire and explosion safety; (8) recommendations and guidance; (9) global collaborations; (10) applications and informatics. NIOSH prioritizes research based on input from stakeholders and communicates their findings in outputs such as reports or guidance documents.

Since its inception, the NIOSH NTRC has conducted site evaluations, developed novel sampling and analytical methods, formed partnerships with industry and others in the U.S. and abroad, and has produced several guidance documents and publications. When

NIOSH published its first Strategic Plan for Nanotechnology Research in 2005, it became the first government agency to do so. However, NIOSH is not a regulatory agency and therefore relies on individual customers to implement its recommendations to achieve desired workplace safety outcomes. Several universities, federal, state, and local governmental agencies, organizations and societies, and foreign governments have their own recommendations for working safely with nanomaterials.

Recently, NIOSH published four new guidance documents for safely working with nanomaterials, including one poster and three workplace design solutions, which emphasize minimizing hazards and risks by adopting Prevention through Design (PtD), a NIOSH-developed initiative.

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