OFFICE OF THE UNDER SECRETARY OF DEFENSE



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ACQUISITION, TECHNOLOGY AND LOGISTICS OCT 2 3 2009

MEMORANDUM FOR DEPUTY ASSISTANT SECRETARY OF THE ARMY (ENVIRONMENT, SAFETY & OCCUPATIONAL HEALTH) DEPUTY ASSISTANT SECRETARY OF THE NAVY (ENVIRONMENT) DEPUTY ASSISTANT SECRETARY OF THE NAVY (SAFETY) DEPUTY ASSISTANT SECRETARY OF THE AIR FORCE (ENERGY, ENVIRONMENT, SAFETY & OCCUPATIONAL HEALTH) DIRECTOR, DEFENSE RESEARCH AND ENGINEERING

SUBJECT: Framework with the National Institute for Occupational Safety and Health (NIOSH) for Nanomaterial Investigation

While health and safety information about nanomaterials evolves, DoD must apply best management practices to minimize exposures. DoD also requires more information on the potential exposure scenarios of nanomaterials to improve risk assessment prior to field testing its products containing these materials. The creation of a DoD interface with NIOSH will hasten the identification of those possible exposure risks. With the goal of improving the handling methods of nanomaterials, this inter-Agency collaboration will provide information for the Components safety and health programs to enhance the protection of DoD researchers.

The attached framework for cooperation between NIOSH and DoD is a strategic leveraging of expertise and abilities, and represents a common sense approach to problems commonly shared. The framework will further DoD's understanding of nanomaterial risks that are unique to the military, and strengthen DoD's decision-making processes. The framework will also free-up valuable resources that would otherwise be wasted on duplicative efforts.

Participation in the framework, which sets-up a sequence of actions for a successful DoD-NIOSH interaction based on lessons learned, is free-of-cost and voluntary. Your involvement is encouraged, if only to share your organization's best management practices. Please disseminate the framework freely to your colleagues, especially to DoD's many laboratories and centers, making them aware of the NIOSH capability and utility. My contact on the matter is Dr. Carole LeBlanc, (703) 604-1934 or <u>Carole.LeBlanc@osd.mil</u>.

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Dorothy Robyn Deputy Under Secretary of Defense (Installation and Environment)

Attachment: As stated

## EXAMINATION OF POTENTIAL OCCUPATIONAL EXPOSURES OF ENGINEERED NANOMATERIAL AT THE DEPARTMENT OF DEFENSE (DoD): A PRELIMINARY FRAMEWORK FOR THE DoD AND THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

1. Background Information. Engineered nanoscale particles (also called nanomaterials) sometimes display different physical and chemical characteristics compared to larger sized particles of the same composition. Research at DoD facilities is leading to unique and exciting applications of engineered nanomaterials for use by warfighters and civilians in DoD agencies. While rapid advances are being made in the creation and use of these nanomaterials, the understanding of nanomaterials' human and environmental health effects is still in its infancy. There is potential for direct and indirect occupational exposures to these nanomaterials. Furthermore, there is very little safety guidance available to work with nanomaterials in the research laboratory.

While many generated nanomaterials may prove highly advantageous for DoD uses, it is possible that there are multiple unforeseen disadvantages with their uses. These unintended consequences include, but are not limited to:

- Injury to warfighters and workforce
- Incompatibility with existing DoD materiel
- Contamination of DoD training and operational environments, and
- Migration of engineered nanomaterials to communities surrounding DoD installations.

As stewards of DoD-funded research, it is in the best interest of all DoD researchers and R&D agencies to be proactive in their approaches to fully understand the characteristics of engineered nanomaterials in all stages of the materials' life cycle. In taking this approach, time, resources, and money are saved by focusing on improved engineered nanomaterial selection and synthesis, reducing occupational exposure, and improved product safety.

2. Assessing Exposure. NIOSH, a part of the Center for Disease Control and Prevention (CDC), has been tasked with studying occupational exposures and protective techniques associated with the creation, handling and use of engineered nanomaterials (http://www.cdc.gov/niosh/topics/nanotech/). The NIOSH Nanotechnology Research Center (NTRC) has a field research team available to visit and assess emissions from processes related to this class of materials. The team will characterize materials, processes, tasks, sources of emissions, potential worker exposures (estimated by personal breathing zone [PBZ] samples), work practices, and exposure control procedures. Information and recommendations are shared with the collaborating facility and the field data (with identifiers removed) are used by NIOSH to update the guidance that appears on the NIOSH Nanotechnology Topic page. That the NIOSH NTRC team does not act in a regulatory capacity is noteworthy. This is strictly a voluntary process and there is no cost to participate. The NTRC field research team has already evaluated more than 25 facilities involved in the production and use of engineered nanomaterials. In fact, the NTRC field team has evaluated emissions and potential exposures at several DoD facilities, such as the environmental toxicology laboratories at the U.S. Army Engineer Research and Development Center (ERDC); multiple laboratories at the Air Force Research Laboratory (AFRL), and a pilot plant facility at U.S. Army Research, Development and Engineering Command (RDECOM)-Armament Research, Development and Engineering Center (ARDEC) that has a reactor for the fabrication of nanoscale particles with the intent of developing

prototype manufacturing processes for transition to industry. These field evaluations have helped discover previously unknown sources of nanomaterial emissions and concomitant potential occupational exposure. The results of these studies have lead to changes in safety practices, implementation/modification of engineering controls, as well as information dissemination (e.g., "Potential for occupational exposure to engineered carbon-based nanomaterials in environmental laboratory studies," *Environmental Health Perspectives*—in press).

**3.** Task Descriptions. DoD seeks to establish an Interagency Agreement with NIOSH to evaluate environment, safety, and occupational health (ESOH) issues related to the creation, handling, and use of engineered nanomaterials at facilities across all DoD agencies. This partnership can be effected across the DoD or on an individual basis (Department of Army, Department of Navy, etc.), dependent upon the degree of interest and need for such ESOH evaluations. Like the NIOSH policy stated above, the NIOSH NTRC field evaluation will be voluntary. However, participation in this program is strongly encouraged to improve ESOH at all stages of engineered nanomaterial life cycles, as per the DoD memorandum on ESOH risk from engineered nanomaterials (May 13, 2008). NIOSH and the DoD industrial hygiene programs are encouraged to establish communications, share information, and collaborate, where feasible.

Specific tasks listed below:

**TASK 1.** Prior to any field visit, the DoD facility should provide critical information on the nanomaterials(s) created/handled/used so that appropriate analytical and sampling strategies can be formulated. Also necessary is information on existing engineering controls, type and use of personal protective equipment (PPE), and the quantity of nanomaterials handled. The NTRC field team will then visit the site and perform a walk-through evaluation of the entire nanomaterial laboratory or production flow process and identify tasks and points of potential nanomaterial emission that can result in worker exposure.

**TASK 2.** Evaluate airborne engineered nanomaterials during routine operations and compare these results to background levels. If necessary, other operating conditions can be created and analyzed (e.g., "extreme case" scenario - no ventilation used when transferring powdered nanomaterials). The NIOSH NTRC field team will use an assortment of instruments and air sampling methods to characterize nanomaterial source emissions and potential worker exposures. Engineered nanomaterial emissions will be evaluated according to NIOSH's <u>Approaches to Safe Nanotechnology – Managing the Health and Safety Concerns Associated with Engineered Nanomaterials</u>. Since engineered nanomaterials emission/exposure assessment techniques are an evolving area of research, it is possible that, with time, the NIOSH NTRC assessment techniques may change or others may be added or deleted as time progresses.

**TASK 3.** Evaluate engineering controls, if present, and their effectiveness in reducing emissions and exposures by measuring the airborne concentration of the material of interest inside/outside the control (or) with/without the control operating. If no engineering controls are present, but sampling data indicate that control(s) are needed, NIOSH NTRC will make recommendations on such controls. Once the controls are installed, the NIOSH NTRC can return to the site and determine whether the

implemented controls are performing effectively.

**TASK 4.** Document work practices used during the production or use of engineered nanomaterials and link these observations to exposure data, when possible.

**TASK 5.** Document the use of Personal Protective Equipment (PPE) in use, if any, including respiratory and dermal protection. If no PPE is used, make recommendations on the need for and type of PPE based on emission/potential exposure data collected during the site visit.

**TASK 6.** The NIOSH NTRC field team will issue a report on the findings to each collaborating facility. The report will include the processes and tasks evaluated, particle number concentrations, mass concentrations, transmission- or scanning-electron micrographic (TEM or SEM) images, an evaluation of the work practices, PPE and engineering controls used, and recommendations for improving engineered nanomaterial ESOH at the facility.

**TASK 7.** NIOSH will use the data generated from these site evaluations to populate its database and evaluation of engineered nanomaterial ESOH in the workplace. Following operational security review by DoD, NIOSH may use cleared data for peer-reviewed publications and incorporation into appropriate databases. Data elements of interest to the DoD can be incorporated into the DoD-wide Defense Occupational & Environmental Health Readiness System (DOEHRS) program, or a related ESOH data warehouse, for data reporting and recordkeeping. Data may be used for ESOH health assessments with engineered nanomaterials at DoD facilities. As a first attempt at assessing emissions/exposures, our goal is to determine whether emissions/exposure can occur.

**4. Further Considerations.** Should there be sufficient numbers of DoD facilities that request NIOSH NTRC field team evaluations or repeat visits, and depending on how many of those sites have multiple nanomaterials in new and multiple processes, DoD and NIOSH may wish to explore the ability to provide funding and a formal process in support of additional efforts. In particular, NIOSH's priority is to evaluate processes beyond research laboratory scale quantities (e.g., a few grams), and/or to explore processes that have not been evaluated and may lead to unexpected releases. Such issues exemplify the need for pre-survey information exchange.

Future reports could also consider incorporating the use of the Control Banding Nanotool developed by S. Paik et al. (referenced below). This will require additional planning as well as input to each site visit; specifically, a team member skilled in conducting control banding evaluations and comparing the outcome of an assessment (the type of control specified) with the controls in place at the time of the site visit.

Samuel Y. Paik, David M. Zalk, and Paul Swuste. Application of a pilot control banding tool for risk level assessment and control of nanoparticle exposures (*Annals of Occupational Hygiene* 52(6):419-428) 2008.

David M. Zalk, Samuel Y. Paik, Paul Swuste. Evaluating the Control Banding Nanotool: a qualitative risk assessment method for controlling nanoparticle exposures (Accepted for publication by *Journal of Nanoparticle Research* on May 30, 2009)