Miller, Diane M. (CDC/NIOSH/EID)

From: Volckens,John [John.Volckens@ColoState.EDU]
Sent: Thursday, May 15, 2008 11:14 AM
To: NIOSH Docket Office (CDC)
Subject: NIOSH-134

Attachments: JV NIOSH nano comments 15May2008.pdf

JV NIOSH nano omments 15May20.

To Whom It May Concern:

Attached are my comments on the NIOSH Strategic Plan for Nanotechnology (NIOSH-134).

with kind regards,

john

John Volckens
Assistant Professor
Environmental and Radiological Health Sciences Colorado State University
1681 Campus Delivery
Fort Collins, CO 80523-1681

Ph: (970)491-6341
Fx: (970)491-2940

Colorado State University

Department of Environmental and Radiological Health Sciences

College of Veterinary Medicine and Biomedical Sciences
1681 Campus Delivery
Fort Collins, Colorado 80523-1681
Phone: (970) 491-6341
Facsimile: (970) 491-2940
john.volckens@colostate.edu

Date: 15 May 2008

To: Dr. John Howard
Director, National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

From: John Volckens
Assistant Professor, Environmental Health
Colorado State University

Re: Review of *Strategic Plan for NIOSH Nanotechnology Research*

Dr. Howard,

Attached are my comments on the NIOSH Strategic Plan for Nanotechnology Research. I believe this plan needs serious improvement and that only a fundamental shift in the NIOSH paradigm for intramural research will do so. Please feel free to contact me if you have additional questions regarding these comments.

With Kind Regards,

John Volckens

General Comments:

In this document NIOSH has identified many of the salient occupational health 'needs' related to the growing nanotechnology industry. These needs help define 'goals' that NIOSH has subsequently laid out. However, very little substance for an actual *plan of attack* is provided. Many of the issues and questions surrounding nanotechnology have been known for years. What is needed from NIOSH is a document that explicitly states HOW these questions will be answered. As is, the document reads like a tourist map highlighting points of interest but lacking roads, distances, and direction.

There are no testable hypotheses to accompany any of the stated performance measures. In fact, there are only three hypotheses in the entire document and two of them are posed by extramural researchers. The lack of a *scientific method* approach towards answering the basic and applied questions surrounding nanotechnology does not instill much confidence that any of these goals will be satisfactorily achieved. Some of the intramural research approaches put forth are innovative and carry specific objectives. However, there is a difference between *objective-driven* research and *hypothesis-driven* research – the latter carries a significantly higher probability of contributing to the advancement of scientific knowledge. Furthermore, most of the intramural projects are not tied to specific performance goals, hypotheses, or highlighted issues. Others approaches lack direction and innovation and, even if completed, may only perpetuate the continuing uncertainty that has plagued nanotechnology risk assessment since its inception. How does NIOSH plan to follow this proposed 'roadmap' without employing hypothesis-driven research?

In many places, reference is given to the measurement of 'airborne nanomaterials'. That descriptor is vague and potentially misleading, as airborne nanoparticles can be generated by biogenic (e.g., sea salt and forest fires), incidental (i.e., fossil fuel combustion), and engineered processes alike. NIOSH has been charged with addressing the occupational health issues surrounding *engineered nanoparticles.* While incidental and biogenic nanoparticles may pose human health risks, exposures to such non-engineered nanoparticles have occurred for decades. Consequently, more effort should be made towards measuring concentrations of *engineered nanoparticles* in workplace air and towards discerning such nanoparticles from biogenic and incidental ones. Ambient and indoor air contains thousands of nanoparticles in each cubic centimeter, however, that does not mean that any of these particles originated from an engineered source. The primary need in the measurement arena is for a method that can identify and quantify engineered nanoparticles in environments where many confounders exist, as both biogenic and incidental nanoparticles are present in the majority of workplace atmospheres.

Specific Comments:

> **Intermediate Goal 5.1. Extend existing measurement methods.** Evaluate current methods for measuring airborne mass concentrations of respirable particles in the workplace and determine whether these mass-based methods can be used as an interim approach for measuring nanomaterials in the workplace and to maintain continuity with historical methods.

The answer to this question is no. How can a respirable aerosol measurement possibly discern the fraction of aerosol mass contributed by airborne nanoparticles, when mass follows the cube of particle diameter? A 4 μm particle, which is captured by respirable sampler with near 50% efficiency, has 65,000 times the mass of a 100 nm particle and 1,000,000 times the mass of a 40 nm particle. The prospect of respirable size sampling being applicable for nanoparticle measurement, by mass, would only be valid when the sampled aerosol size distribution is below a few hundred nanometers. Such a scenario is extremely rare in industry (perhaps only in clean-room operations). Spending resources on an attempt to evaluate and adapt an ineffectual method, regardless of whether it has historical continuity or only represents a band-aid approach for the interim, is a waste of tax dollars.

> **Performance Measure 5.1.** Within three years evaluate the correlation between particle number, surface area, mass, and particle size distribution airborne measurement results and provide guidance for sampler selection based on the nanomaterial of interest.
>
> Continue to conduct measurement studies of nanoparticles in the workplace over the next five years and establish a suite of instruments and protocols for nanoparticle measurement in the workplace.

Determining the correlations between existing measurement methods is a waste of time. Correlations between particle number, surface, and mass concentration are a mathematical construct based primarily on the airborne particle size distribution and secondarily on particle morphology and composition. Therefore, effort should be given towards evaluating (or developing) methods that can discern size, shape, and composition together. As mentioned before, it is the issue of confounding by particles of varying origin that propagates uncertainty in exposure assessment. The vast majority of existing methods are largely irrelevant because they cannot identify engineered nanoparticles from others types. Furthermore, no standard reference 'nanoparticle aerosol' exists to serve as a basis for comparison and evaluation. Therefore, cross-comparisons from separate experiments or differing workplace environments will be highly variable and thus, unreliable. How a 'selection guide' is to be developed from this aim is unclear.

> Continue with refining the NIOSH method 5040 specifications for the collection of elemental and organic carbon for application to the collection of carbon nanotubes and nanofibers.

What is the rationale for this effort? A thermo-optical method cannot specifically identify carbon nanotubes and nanofibers from other combustion aerosols collected on a filter (and likely present in industrial workplace air).

> **Intermediate Goal 5.2. Develop new measurement methods.** Expand the currently available instrumentation by developing and field

testing methods that can accurately measure workplace airborne exposure concentrations of nanomaterials using metrics associated with toxicity (e.g., particle surface area, particle number).

First, there are no established reference protocols for even determining nanoparticle toxicity either in vivo or in vitro. Shouldn't an in vitro screening procedure first be developed with an established particle type and cell line so that separate research groups can standardize and qualify their results? Second, even if the toxicity were established, that does not guarantee that a measurement metric can be developed to reliably measure the 'toxicity' of workplace air. For example, measurements of number and surface area concentrations (as proposed in 5.2) are confounded by a lack of specificity.

Intermediate Goal 5.3. Validation of measurement methods.
Develop testing and evaluation systems for comparison and validation of nanoparticle sampling instruments and methods.

Performance Measure 5.3. Within three years publish procedures for validation of nanoparticle sampling instruments and methods.

This is a valid goal but how is it going to be achieved? Furthermore, what aspects of nanoparticle measurement do you propose to validate (counting efficiency, aspiration efficiency, source specificity, sizing accuracy)? What is the standard reference aerosol and sampling method to be used?

Intermediate Goal 1.2 Worker exposures.
Quantitatively assess exposures to nanomaterials in the workplace including inhalation and dermal exposure. Determine how exposures differ by work task or process.

This goal is not attainable with current technology. How can this aim be achieved without a proven exposure assessment technique that can distinguish engineered nanoparticles from incidental and biogenic ones?

Performance Measure 6.5. Within three years publish a document on the suitability of control banding approaches for nanomaterials.

This goal is premature and depends on successful achievement of almost all of the goals shown above. Control banding approaches require input on relative toxicity and generation/release rate for classification into specific bands. To date, almost no information exists in this area and I don't expect it to be generated in three years time.