

Title Page

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1. List of Terms and Abbreviations

OEL = occupational exposure limit

GWU = George Washington University

2. Abstract

Title: Strategies for setting OELs for engineered nanomaterials

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An important mission of NIOSH-CDC is to generate scientific information to substantiate risk assessment and management of workplace hazards. Animal toxicology studies and a 'large number' of high throughput *in vitro* studies have consistently observed an association between exposure to engineered nanomaterials and adverse health effects. Less is known, however, about the dose-response or time course of response to inhaled nanomaterial and very little is known about the chronic effects of inhaled nanomaterials. While this information is being developed, there is little guidance to inform industrial hygienists how to efficiently set occupational exposure limits (OELs) for nanotechnology products currently being manufactured. Recently published papers indicate that scientists and industrial hygienists are struggling with this issue, yet none of the numerous national and international nanoparticle meetings held over the last 10 years, have focused on this issue. The topic for our conference on nanomaterial OELs arose because of this need and stakeholders and industrial hygienists suggested that developing a workshop that discussed establishing strategies for developing OELs for nanomaterials would be critical at this time. A diverse group of industry, academic, government, and non-government stakeholders was approached and all agreed to organize a workshop focused solely on setting OELs for nanomaterials.

We recruited a focused group of speakers to meet and discuss strategies for setting OELs for nanomaterials. The individual critical issues were assigned to the first ½ day of the meeting and the remaining day and a half were devoted to presentations by individuals representing a diversity of stakeholders. Full participation of stakeholders, speakers, moderators, and audience occurred and appropriate time for questions, answers, and discussion was allocated for each session, although evaluation metrics suggested that more time should have been designated for discussion periods. Student scribes took notes throughout the meeting and an audio recording was taken and later transcribed. Both were used in the preparation of a manuscript that has been accepted for publication. In addition, powerpoint presentations for each speaker have been provided to the public via a website.

3. Section 1

Significant Findings and Translation of Findings

The 2 day conference was a success in terms of anticipated outcomes. The conference was a unique collaboration between many stakeholders and financially supported by a NIOSH R13 grant, an NSF grant, the American Chemistry Council (ACC), and George Washington University (the host institution).

1. It was well attended by stakeholders (total = 58) in government (n= 17), industry (n = 28), labor (n = 1), and academics (n = 12) with the majority of attendees coming from industry and government. Thus, the organizing committee was successful in reaching the target audience.
2. As anticipated, the general consensus of the speakers and attendees was that non-traditional risk assessment methods must be developed to ensure worker safety in the nanotechnology field.

Outcomes

1. A manuscript reviewing the presentations and these non-traditional risk assessment methodologies was prepared by the organizing committee and has been accepted for publication.
2. Based upon the deliberations developed at the conference, a member of the organizing committee, Dr. Tsai, proposed a follow-up symposium which was accepted for the 2014 annual industrial hygiene meeting in Arizona.
3. The slide presentations have been made available on a website maintained by ACC.

4. Section 2

Scientific Report

We organized a focused group of stakeholders to meet and discuss strategies for setting OELs for nanomaterials. The individual critical issues were each assigned approximately ½ day for presentations and discussions. Full participation of stakeholders, speakers, moderators, and audience was expected and appropriate time for questions, answers, and discussion was allocated in each session.

The workshop was useful in 2 ways. First, it brought together 4 groups of stakeholders who are beginning to conduct nanomaterial risk assessments on their own and permit them to 'compare notes' on successful and unsuccessful approaches to utilizing available toxicology and exposure assessment data to establish OELs for engineered nanomaterials. The second, and potentially more important, goal of this workshop was to introduce toxicology researchers to risk assessment problems and solutions and to discuss the development of guidelines to developing appropriate databases for risk evaluations of nanomaterials. This meeting was extremely timely because of NIOSH's recent decision to develop OELs for individual nanomaterials. Before risk assessment on other nanomaterials proceeds much further, and if done on an individual basis at a very slow pace, we proposed to initiate communication among nanomaterial risk assessors, industrial hygienists, and researchers and discuss issues critical to facilitating the development of OELs. Thus, the planned conference was an extremely strong match with NIOSH's research and risk assessment goals in nanotechnology.

A program committee was charged with developing the meeting format, inviting the speakers, finalizing the schedule, logistical arrangements related to workshop site, participant travel, and on site facilities, as well as soliciting financial backing, advertising, and conference registration. Program committee members, along with their affiliations (listed below), were a diverse group of individuals representing the stakeholders to whom it is most critical to develop OELs for nanomaterials (i.e., industry, non-governmental organizations, government agencies, and academia). The committee was also diverse in terms of membership (4 academic, 2 industry, and 2 government members), which balanced any inherent biases of participants.

The meeting was held at George Washington University on Sept 11 and 12, 2012. Audio recordings of the meetings were taken as were meeting notes by student scribes. Conference calls were held by the organizing committee after the meeting and a manuscript for publication was prepared and has been accepted for publication. In addition, a follow-up symposium has been accepted for the annual AIHce meeting in Arizona. Furthermore, attendees evaluated the meeting and gave it high scores.

Publication: Workshop Report: Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials. Steven C. Gordon, John H. Butala, Janet M. Carter, Alison Elder, Terry Gordon, George Gray, Philip G. Sayre, Paul A. Schulte, Candace S. Tsai, Jay West (*Regulatory Toxicology and Pharmacology*, accepted).