Some Key Elements for Nanomaterial Exposure Assessment and Management to Advance Sustainable Manufacturing

EH&S Panel II Discussion
Workshop on Enabling the Carbon Nanomaterials Revolution
Gaithersburg, Maryland
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The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of company names or products does not constitute endorsement by NIOSH.
Some background about NIOSH

The National Institute for Occupational Safety and Health is:

the U.S. Federal agency **responsible** for **conducting research** and **making recommendations** for the **prevention of work-related illness, injury, disability, and death.**

www.cdc.gov/niosh 2
We participate in the National Nanotechnology Initiative (NNI).
NIOSH Strategic Plan for Nanotechnology Research and Guidance

- NIOSH Intermediate and long-term objectives
- Performance measures
- Timeline for nanotechnology research
- Capabilities and gaps for nanotechnology measurements

NIOSH Publication 2010-105

www.cdc.gov/niosh/topics/nanotech/
NIOSH Approaches and Progress

NIOSH Publication 2009-125

Approaches to Safe Nanotechnology
Managing the Health and Safety Concerns Associated with Engineered Nanomaterials

NIOSH Publication 2010-104

Progress Toward Safe Nanotechnology in the Workplace
A Report from the NIOSH Nanotechnology Research Center
Project Updates for 2007 and 2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

• Progress in 10 key areas
• Continuing project plans
• Opportunities for collaboration

www.cdc.gov/niosh/topics/nanotech
Interim Guidance for the Medical Screening of Workers PotentiallyExposed to Engineered Nanoparticles

• **Current Intelligence Bulletin 60:**
  Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles

NIOSH Publication 2009-116

www.cdc.gov/niosh/docs/2009-116/
Key Elements of Risk Management

Are they hazardous?

Can they be measured?

Can they be controlled?

Hazard Identification
“Is there reason to believe this could be harmful?”

Exposure Assessment
“Will there be exposure in real-world conditions?”

Risk Characterization
“Is substance hazardous and will there be exposure?”

Risk Management
“Develop procedures to minimize exposures”
It makes sense to manage nanoparticles as a component of a traditional Radiation or Chemical Hygiene Program.

- Basic Rules and Procedures
- Chemical Procurement, Distribution, and Storage
- Environmental Monitoring
- Housekeeping, Maintenance, and Inspections
- Medical Program
- Personal Protective Apparel and Equipment
- Records
- Signs and Labels
- Spills and Accidents
- Training and Information
- Waste Disposal
Current Challenges

- The traditional assessment and management strategy requires an occupational exposure limit (OEL).

- OELs for radioactive materials are based on a unified concept of dose.

- Such a unifying concept is not available for nanoparticles.

- How can an effective chemical hygiene program for nanotechnology be developed and implemented in the absence of comprehensive OELs?

- What control approaches are feasible and effective?
We are partnering to develop a comprehensive risk management scheme to:

- Anticipate,
- Recognize,
- Evaluate,
- Control, and
- Confirm

appropriate control of potential health risks for nanotechnology

by applying a science-based approach to understanding and managing the critical elements over which we have control.

A robust framework and approach

Risk Management Decision-Making Framework

Anticipate
Recognize
Evaluate
Control
Confirm

Documentation and Improvement

With a variety of delivery opportunities

Anticipate

Confirm

Do it right...
Do it safe...

Train for it.
Document it.
Improve it.

Recognize

Control

Evaluate

Don’t cause A RECC
Nanoinformatics 2010

A Collaborative Roadmapping Workshop

Participants: Workshop Materials (login required)

Nanoinformatics 2010 is a collaborative roadmapping and workshop project at which informatics experts, nanotechnology researchers, and other stakeholders and potential contributors will jointly develop a roadmap for the area of nanoinformatics. By doing so, it will accelerate the responsible development and use of nanotechnology. Workshop themes include:

- Data Collection and Curation
- Tools for Innovation, Analysis, and Simulation
- Data Accessibility and Information Sharing

Nanoinformatics involves the development of effective mechanisms for collecting, sharing, visualizing, modeling, and analyzing information relevant to the nanoscale science and engineering community. It also involves the utilization of information and communication technologies that help to launch and support efficient communities of practice. Nanoinformatics is necessary for comparative characterization of nanomaterials, for design and use of nanodevices and nanosystems, for instrumentation development and manufacturing processes. Nanoinformatics also fosters efficient scientific discovery and learning through data mining and machine learning techniques.

Nanoinformatics 2010 is open to all members of the nanoinformatics community and will be organized and governed by that community. Contact the program committee to get involved.

The Nanoinformatics Roadmap is currently under development and is expected for release in early 2011. Stay tuned!

Thank you to all of our speakers!

- George Adams, Network for Computational Nanotechnology
- Andrei Nel, UCLA
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- Sylvia Spengler, NSF
- Vincent Caputo, Nanobusiness Alliance
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- Stacey Harper, Oregon State University
- Gretchen Bruce, Intertox
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- Sumit Gangwal, EPA
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- Michele Ostroz, RTI
- Guillermo Lopez-Como, Institute of Health “Carlos III”
- Derek Stewart, Cornell University

www.nanotechinformatics.org
Nanoinformatics
(a working definition)

• The **science and practice** of determining which information is relevant to the nanoscale science and engineering community,

• and then **developing and implementing effective mechanisms**

• for **collecting, validating, storing, sharing, analyzing, modeling, and applying** that information.
What are some useful frameworks and paths forward for advancing sustainable manufacturing for nanomaterials?
A Life-Cycle Approach for Instrumentation
Four Steps for Community Action

- Engage the community
- Inform the interested
- Reward the responsive
- Understand and incentivize the reluctant
Suggested Informatics Guidelines for Preventing Injury and Disease*

1. Emphasize literacy and develop critical thinking;
2. Develop and use real-life data examples;
3. Stress conceptual understanding rather than mere application of procedures;
4. Foster continuous improvement and active discussions;
5. Use technology for developing conceptual understanding and for analyzing and sharing information (e.g., modeling and simulation, databases, wikis, etc.);
6. Use assessments to improve and evaluate the efficacy and impact of these activities.

*as adapted by Mark Hoover from the American Statistical Association (ASA) “Guidelines for Assessment and Instruction in Statistics Education (GAISE)” which are available at http://www.amstat.org/education/gaise/.
The matrix can be used to clarify what elements the stakeholders need and what elements they can provide.
## Purpose of the Assessment

### BASIC AEROSOL CHARACTERIZATION
Understanding relevant physicochemical and biological properties of the aerosols of interest

<table>
<thead>
<tr>
<th>WORKER HEALTH PROTECTION</th>
<th>ENVIRONMENTAL MONITORING</th>
<th>PROCESS QUALITY ASSURANCE AND CONTROL</th>
<th>EMERGENCY PREPAREDNESS AND RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensuring that worker exposures are within allowed limits and As Low As Reasonably Achievable (ALARA)</td>
<td>Ensuring that environmental releases of aerosols are within allowed limits and ALARA for environmental and public health concerns</td>
<td>Ensuring that processes and process controls are operating properly</td>
<td>Providing a basis for appropriate actions when things go wrong</td>
</tr>
</tbody>
</table>

### DEMONSTRATION OF COMPLIANCE
Documenting that administrative and regulatory requirements are met

### RESEARCH
Advancing a comprehensive understanding of aerosol behavior, measurement, and control

Hoover, 2011 (Adapted from Hoover and Newton, 1993)

*Can foster synergisms and multiuse opportunities.*
# Graded Approach to Exposure Assessment

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Screening and Detection</td>
<td>Comprehensive Characterization and Assessment</td>
<td>Routine Monitoring and Control</td>
</tr>
<tr>
<td>• Process knowledge</td>
<td>• Composition</td>
<td>• A necessary and sufficient subset of Level 1 and 2 methods for the</td>
</tr>
<tr>
<td>• Gross mass or activity counting</td>
<td>• Elemental and chemical</td>
<td>material and situation of interest</td>
</tr>
<tr>
<td>• Optical particle counting</td>
<td>• Particle size</td>
<td></td>
</tr>
<tr>
<td>• Condensation particle counting</td>
<td>• Physical</td>
<td></td>
</tr>
<tr>
<td>• Microscopy</td>
<td>• Aerodynamic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thermodynamic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Electrical mobility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Exposure Concentrations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Peaks, averages, variability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Biophysical properties</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Shape, surface area, solubility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Other factors relevant to the assessment</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from Hoover, 2011

*Essential for cost and feasibility*
Welcome to the GoodNanoGuide-OHS Expert Matrix

The GoodNanoGuide is structured along a conceptual framework for occupational risk management designed to control and minimize exposure to engineered nanomaterials in the presence of uncertainty. Each organization should have a management structure to assess and minimize risk. In this section, the GoodNanoGuide has established a matrix in which the potential handling hazards of nanomaterials are rows labeled by the leftmost column, and the various physical forms of the nanoparticles are in four vertical columns.

<table>
<thead>
<tr>
<th>Nanoparticles in:</th>
<th>Dry Powder</th>
<th>Liquid Dispersion</th>
<th>Solid Polymer Matrix</th>
<th>Nonpolymer Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Step:</strong> Identify</td>
<td>Potential Hazard</td>
<td>Potential Hazard</td>
<td>Potential Hazard</td>
<td>Potential Hazard</td>
</tr>
</tbody>
</table>
| **Second and Third Steps:** Risk Assessment and Management
| Material Unpacking | Exposure Potential | Exposure Potential | Exposure Potential | Exposure Potential |
| | Controls | Controls | Controls | Controls |
| Synthesis | Exposure Potential | Exposure Potential | Controls | Controls |
| | Controls | Controls | Controls | Controls |
| Weighing and Measuring | Exposure Potential | Exposure Potential | Exposure Potential | Exposure Potential |
| | Controls | Controls | Controls | Controls |
| Dispersing | Exposure Potential | Exposure Potential | Controls | Controls |

www.goodnanoguide.org
The Nanotechnology Field Research Team Update

In 2006, NIOSH established a Nanotechnology Field Research Team to expand its knowledge and understanding of the potential health and safety risks that workers may encounter during the research, production, and use of engineered nanomaterials. This effort has complimented NIOSH’s extensive laboratory-based research program, as well as helped NIOSH identify and more fully understand the variety of work processes used to generate and manufacture engineered nanomaterials. It has also provided NIOSH with the opportunity to observe and evaluate work practices and engineering controls used to ensure worker health and safety in the nanotechnology industry.

NIOSH has conducted site visits to several facilities around the country that are involved in the research, manufacture, or use of various types of nanomaterials including, metal and metal oxide nanoparticles, carbon nanofibers, electrically conducting nanofibers, quantum dots, fullerenes, and nanocomposites. As a result, NIOSH obtained valuable information that is being used to assist in developing workplace guidance documents to protect nanotechnology workers from occupational injury and illness, and has learned that:

- Basic particle counting and sizing instruments can be used to identify emissions from nanomaterial processes,
- Careful interpretation of the particle data is needed to differentiate between incidental (background) and process-related nanoparticles, and
- Engineering controls do minimize workplace exposure to engineered nanoparticles.

Companies interested in receiving a visit by the Field Research Team are encouraged to contact NIOSH. All site visits are initiated by the respective companies and are completely voluntary. This program is fully funded by NIOSH; therefore, there is no monetary cost to the participant. Three companies who have voluntarily received site evaluations from the NIOSH Field Research Team were recently interviewed by Nanowork, LLC for its August/September 2007 issue of Nanorisk (www.nanorisk.org/). Overall, they described the collaboration as beneficial, and encouraged other companies to take advantage of NIOSH’s expertise, services, instrumentation, and unbiased assessments.

For more information about occupational safety and health topics pertaining to engineered nanomaterials, including fact sheets about the Field Research effort and other nanotechnology research programs, please visit the NIOSH nanotechnology topic page at www.cdc.gov/niosh/topics/nanotech. To discuss the possibility of receiving a site evaluation by the NIOSH Field Research Team, contact Charles Geraci, Ph.D., CIH at (513) 553-8950, CGeraci@cdc.gov or Mark Methner, Ph.D., CIH at (513) 841-4325, MMethner@cdc.gov.

Collaboration with NIOSH

- Share knowledge
- Use expertise
- Build experience
- Partner
Questions?

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Additional slides related to the group discussion of “quadrant approaches” to understanding and advancing basic and applied research
A Quadrant Approach to Alignment of Perception and Reality

The "snake oil" quadrant

The "seat belt" quadrant

The "smoking is bad" quadrant

The "childhood immunization" quadrant

Draft for discussion (Hoover, Mathews, and other contributors, 2010)
Draft Issue Evaluation Matrix for *(insert variable)* in *(insert situation)*

- **Inappropriate outcomes are likely**
  - Advantage: Outcomes are avoided
  - Disadvantage: Opportunities may be missed

- **Appropriate outcomes are likely**
  - Advantage: Opportunities are increased
  - Disadvantage: Inappropriate outcomes are avoidable

*Draft for discussion* (Hoover, Mathews, and other contributors, 2010)