Response to Public Comments

NIOSH Current Intelligence Bulletin (CIB)
"Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles"
(12-14-07 draft)

Questions posed by NIOSH during public review and to Peer Reviewers

1) Do the data support the conclusions on the document?
2) Are the conclusions appropriate in light of the current understanding of toxicological data?
3) Is medical surveillance appropriate at this time for workers with potential exposure to engineered nanoparticles; if so, what form(s) of medical surveillance are specific for such workers?
4) What are the potential benefits, adverse impacts, and limitations of medical screening of workers potentially exposed to engineered nanoparticles?
5) What are the potential benefits, adverse impacts, and limitations of establishing an exposure registry for workers exposed to engineered nanoparticles?

The following presents a summary of pertinent comments and the NIOSH response to those comments:

Stakeholder/Public Review Comments

The stakeholder/public comments are summarized below with the NIOSH response:

1. **Mr. John Muller – Navy/Marine Corp Public Health Center**

a) **Comment** - suggestion concerning creation of "action levels" (presumably an exposure level – such as an air concentration) for nanoparticles that would be some set percentage of the action level for the non-nanoparticle sized agent of the same type.

Response – not enough scientific data to support this action. No change to document.

b) **Comment** – has NIOSH planned outreach to workers at universities?

Response- NIOSH has had, and continues to perform, extensive outreach in assisting industry in identifying and controlling workplace exposures to engineered nanoparticles; the reviewers' comment about workers at universities is a very good point and focused outreach to those groups may need special emphasis. No change to document required.

2. Mr. Ali Mohammad –Nanophase Co.

Comment – When referencing the IARC status for TiO_2, the reference should specifically state that the status is as "non-published monograph" because this has regulatory implications.

Response – the reference in the document is correct and IARC's evaluation of TiO_2 can be located on their website. No change to document required.

3. Mr. John DiLoreto – SOCMA Nanotechnology SME Coalition

Comment – agrees with NIOSH approach.

Response – no change to document required.

4. Mr. Dave Ortlieb – United Steel Workers International

Comment – [summary of comments]: The reviewer's provide well presented and detailed comments summarizing a plan (consisting of a series of activities and recommendations) that differs from that presented in the NIOSH document. The three main parts of the suggested plan are: a) develop and recommend a basic medical screening protocol for workers with potential exposure to nanosized materials; b) implement an ongoing nanoparticle toxicity review group; c) develop a national nanotechnology health surveillance program.

Response – The proposed activities and recommendations have been thoroughly considered and debated by members of the NIOSH Nanotechnology Research Committee (NTRC) and members of the NIOSH NTRC Surveillance Working group (which included input from external scientists who participated in the development of this document). NIOSH shares the concern expressed by these reviewers regarding the potential for adverse health effects related to occupational exposure to engineered nanoparticles. However, we have concluded that insufficient scientific and medical evidence now exists to recommend specific medical screening of workers potentially exposed to engineered nanoparticles; similarly, insufficient evidence exists for NIOSH to recommend implementation of a national surveillance program. NIOSH is committed to updating relevant guidance as more is learned concerning potential health effects related to occupational exposure to engineered nanoparticles. The

NIOSH NTRC has an ongoing toxicity review process as a component of it's' research program.

No change to document.

5. Mr. Paul Wambach, Department of Energy

Comment – States that the NIOSH document is 'well-reasoned' guidance. One suggestion – expand Section 3.1 to summarize the full scope of activities that occur within a medical surveillance program as practiced in current occupational medicine practice.

Response – In the work leading up to the preparation of this document, the Surveillance Working Group of the NIOSH NTRC had developed background material that addresses this comment. We agree with the reviewer that this type of material might be helpful to current practitioners of occupational health. After extensive review and input by stakeholders and scientific peer reviewers this document has been specifically limited to guidance related to medical screening. Future efforts from NIOSH may involve guidance concerning the broader topic of occupational health surveillance. No change to document.

6. Dr. Robert McDonald, Giner Inc.

Comment – Reviewer is concerned about lack of guidance concerning precautions on handling nanomaterials including carbon nanotubes.

Response – The NIOSH NTRC agrees that this type of guidance is important. NIOSH has extensive, and periodically updated, guidance that is available on the internet ("Approaches to Safe Nanotechnology" – available at http://www.cdc.gov/niosh/topics/nanotech/safenano/). No change to document.

7. Mr. Henry Pineda, Health Science Associates

Comment – suggests use of the term "nanoconiosis."

Response – not relevant to this document. No change to document.

8. Mr. John Balbus, Environmental Defense Fund

Comment

a) Expresses strong support for exposure registry. The NIOSH NTRC has opened this debate and is currently seeking input on this topic.

b) Second primary comment involves support for NIOSH to make a recommendation that companies with existing surveillance programs for workers extend those programs to workers potentially exposed to nanoparticles.

Response – This is the subject of the Recommendation found in Section 5.3; the document encourages employers to continue to use established medical surveillance programs to collect data that may be informative concerning potential adverse health effects of engineered nanoparticles. No change to document required.

9. Dr. David Warheit, DuPont

Comment – Expresses support for the NIOSH recommendation – 'the feasibility and merit of medical screening is dependent upon identification of specific disease endpoints {associated with exposure}....'

Response – no change to document required.

10. Ms. Katie Slavin, American Nurses Association

Comment – This reviewer expressed support for "medical surveillance" and an exposure registry for workers exposed to engineered nanoparticles.

Response – no change to document required.

11. Dr. Samantha Dozier, PETA

Comment – The comments primarily deal with issues related to use of animals in product testing, and are not directly relevant to this document.

Response – no change to document required.

12. Ms. Maude Bullock, for the US EPA Safety, Health and Environmental Management Division

Comment – These comments were also presented at the public meeting held in Cincinnati, OH, January 30, 2008. There are two primary comments which are summarized here: a) NIOSH should adopt a conservative approach and clearly recommend medical screening until data are more definitive; b) in the absence of specific medical tests {useful for screening workers potentially exposed to nanoparticles}, NIOSH should develop recommendations for providing routine medical evaluation for workers potentially exposed to nanoparticles.

Response - The response for #4 (above) is relevant here also. We agree that medical surveillance is a key part of a comprehensive occupational health program. As hazard (toxicity) data are generated and evaluated by NIOSH scientists and others, the need

for medical screening and recommendations for medical evaluations based on potential exposure to engineered nanoparticles must be continually reevaluated. NIOSH is committed to updating relevant guidance on medical screening as more is learned concerning potential health effects related to engineered nanoparticles. No change to document.