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NIOSH Docket Office (CDC)

From: Shelby.David@epamail.epa.gov [Shelby.David@epamail.epa.gov] **Sent:** Wed 1/30/2008 8:29 AM
To: NIOSH Docket Office (CDC)
Cc:
Subject: 115 - NIOSH Interim Guidance Nanoparticles
Attachments: Comments NIOSH Nano Med Screening 1-30-08.doc(59KB)

Good morning,

Attached are the oral comments for Maude Bullock (EPA) presentation at the public conference. I have called and left messages to ask if anything needed to accompany the word document in reference to slides(ppt) or how this should be sent?

(See attached file: Comments NIOSH Nano Med Screening 1-30-08.doc)

Respectfully submitted,

please call if you have any questions.

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Preliminary Comments

on

National Institute for Occupational Safety and Health Request for Public Comment on the Draft Current Intelligence Bulletin (CIB): Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles

(Docket Number NIOSH-115)

Prepared by:
U.S. Environmental Protection Agency
Office of Administration and Resources Management
Office of Administration
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Submitted to:
NIOSH Docket Office
Robert A. Taft Laboratories
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Cincinnati, Ohio 45226

January 30, 2008

Preliminary EPA Comments on NIOSH Draft Current Intelligence Bulletin (CIB): *Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles* (November 2007)

The U.S. Environmental Protection Agency, Office of Administration and Resources Management, Office of Administration's Safety, Health and Environmental Management Division (SHEMD) is charged with protecting the Agency's employees and assets, and the environment in which the Agency does its work. Pursuant to our charter, SHEMD is pleased to respond to the National Institute for Occupational Safety and Health (NIOSH) request for public comment on the draft Current Intelligence Bulletin (CIB) titled, "Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles." The following comments constitute a preliminary review of the draft CIB. To facilitate the review, the Agency considered the following five questions presented by NIOSH. The Agency also intends to submit more detailed written comments by the February 15, 2008 deadline.

1. Do the data cited support the conclusions of the document?

Throughout the draft CIB, NIOSH repeatedly states that the available scientific evidence is insufficient to recommend specific medical screening of workers potentially exposed to nanoparticles; yet, NIOSH recommends that employers "consider" medical surveillance to assess whether there is an increased frequency of adverse respiratory and cardiovascular effects. EPA suggests that NIOSH modify the approach taken in the interim guidance document. Although the available data are insufficient for a definitive hazard determination for workers occupationally exposed to nanoparticles, NIOSH should adopt a conservative approach and clearly recommend medical screening until the data are better developed and more definitive.

Historically, medical surveillance has often been implemented after workers have developed health problems, as in the case of workers exposed to asbestos. EPA believes that, as an emerging industry, nanotechnology offers a unique opportunity to take a responsible approach to employee health. Providing medical surveillance to nanotechnology workers at this stage may identify subtle health effects in individuals, well before potentially serious health problems develop in the population of exposed workers.

EPA concurs that medical screening (also referred to as medical monitoring) is only part of a comprehensive safety and health management program. However, medical screening is a critical component to ensure the health of employees who may be exposed to an agent whose health effects are not known. In the absence of specific medical screening tests, NIOSH should nonetheless develop recommendations for providing routine medical evaluations to workers potentially exposed to nanoparticles.

It is essential that employees be tracked to identify early symptoms or subtle changes in health status that could signal potentially serious health effects from exposure to nanoparticles. EPA recommends a reasoned approach that strikes a balance between offering specific medical tests that may provide no benefit and conducting no medical screening at all. At a minimum, employees potentially exposed to nanoparticles must be provided with an opportunity to consult with an occupational physician on a regular basis.

2. Are the conclusions appropriate in light of the current understanding of the toxicological data?

NIOSH states that there is insufficient evidence to support specific medical screening tests to identify preclinical changes associated with exposure to engineered nanoparticles. The draft CIB emphasizes that much more research is needed before NIOSH can recommend specific screening tests. Despite the lack of adequate toxicological data, EPA believes that some guidance on general medical approaches for monitoring potentially exposed workers is required. Such guidance should not be delayed until evidence of symptoms and/or adverse health effects occurs.

EPA requests that NIOSH provide further guidance on the elements and frequency of routine medical screening for employees potentially exposed to engineered nanoparticles, as well as guidance on worker participation in such programs. Until the data collected justify specific medical screening tests, EPA recommends data collection via medical screening that would indicate changes in overall worker health. This approach provides for an early warning framework so that the employee and management can determine, to the best extent practicable, the potential influences on a workers' health status.

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?

As stated in the responses to questions #1 and #2, at a minimum, employees potentially exposed to nanoparticles must be provided with an opportunity to consult with an occupational physician on a regular basis.

In addition, EPA requests that NIOSH provide further guidance on the content and frequency of routine medical screening (e.g., spirometric testing, chest radiograph, EKG, physical examination of the respiratory system and the skin, etc.) for those workplaces using engineered nanoparticles of materials that are NOT addressed by the medical surveillance requirements of current OSHA standards or NIOSH recommendations. Such screening should be designed to track changes in health status that may be related to exposure.

In addition, workplace exposure assessment protocols would add a very meaningful element to this condition

All workers in medical screening programs should be provided with information about the purpose of the programs, the potential benefits of participation, and the program procedures (e.g., the routine tests included and how the test results are used, actions that may be taken based on the results, who has access to the routine screening results and those from follow-up or more detailed medical evaluations, and how confidentiality is maintained).

In addition, routine medical screening results should be periodically aggregated and evaluated by a knowledgeable individual to identify patterns of worker health that might be associated with nanoparticle exposures. Routine aggregate assessments of medical screening data should be used in combination with evaluations of industrial hygiene exposure data to identify measures needed to protect workers.

Guidance is also requested regarding worker participation in such programs. For example, should all workers who are potentially exposed to nanoaerosols or have potential skin contact with nanoparticles be included in an occupational medical screening program or, should priority be given to workers who may be at highest risk, such as all workers exposed to nanoaerosols above a designated concentration? Should workers with preexisting respiratory or cardiovascular diseases be included in nanoparticle medical screening programs? What about those who may have been previously exposed to asbestos or other respiratory hazards or those with potential exposure to nanoparticles who also smoke cigarettes or other tobacco products?

If additional information regarding the content of routine medical screening is not provided because the content of such screening must be determined on a case-by-case basis, then the CIB should discuss this issue and provide guidance on what criteria should be considered in determining the screening content (especially since data regarding possible health outcomes are quite limited).

NIOSH should also provide more guidance for employers trying to decide whether to do non-specific medical screening. Such guidance should include a more in depth discussion of the pros, cons, and limitations of medical screening.

In addition to further guidance on medical screening programs, EPA also requests that NIOSH provide some guidance pertaining to the management of potential health/medical concerns related to nanoparticle exposure. Such guidance should include information for both employees and qualified health care providers (e.g., when should a worker undergo additional or more frequent medical evaluations and what should be the contents of those evaluations?).

4. What are the potential benefits, adverse impacts, and limitations of medical screening of workers potentially exposed to engineered nanoparticles?

The potential benefits, adverse impacts, and limitations of medical screening of workers potentially exposed to engineered nanoparticles may include the following:

Potential Benefits:

- Identifies early health changes and symptoms that may be associated with nanoparticle exposures (before the worker would typically seek clinical care for symptomatic disease) and possible health trends within groups of exposed workers
- Provides more intensive medical monitoring and evaluation of existing exposure controls when early health changes or symptoms are identified
- Informs workers of potential health risks (or the lack of information regarding health risks) and promotes an understanding of the need for and support of nanoparticle exposure controls
- May benefit workers if questions arise at a later date about health effects related to nanoparticle exposures

Adverse Impacts:

- Increased concern, undue worry, and anxiety among workers
- Difficulty interpreting the results (i.e., are the results due to nanoparticle exposure or not?)
- False positives
- Adverse effects of the screening tests (e.g., exposure to radiation from chest x-rays)
- Unnecessary medical expenses (screening tests and additional diagnostic evaluations)
- Including more workers in the medical screening program than might otherwise be necessary (if more data on adverse health effects were available)
- Lost worker productivity due to time away from work for medical screening
- Delaying self-referral or denying symptoms on health questionnaires if the reporting of symptoms leads to involuntary job reassignment or loss of wages, benefits, or seniority

Limitations of Medical Screening:

Conducting medical screening tests without clearly defined health end points may not be useful because of the inability to associate positive test results with nanoparticle exposures. Medical screening alone would not typically be used to establish associations between exposures to nanoparticles and adverse health effects. In addition, new screening tests and biomarkers of exposure will likely need to be developed for engineered nanoparticles.

5. What are the potential benefits, adverse impacts, and limitations of establishing an exposure registry for workers exposed to engineered nanoparticles?

An exposure registry for workers exposed to engineered nanoparticles cannot be an alternative to medical surveillance. EPA supports the establishment of an exposure registry, provided that:

- The registry complies with HIPPA and OPM requirements for employee medical records
- There is a waiver process whereby employees may opt out of the registry
- Enrollment and review criteria are determined by a peer review process
- A process is in place for employers to access their data in the registry
- The registry resides at a non-regulatory agency
- The organization operating the registry does not dictate what employers must do regarding their employees (e.g., testing and research)
- There is no additional expense to employers

EPA does not support an exposure registry that would require a commitment to perform special testing protocols, where such procedures are over and above those already in place at EPA, unless there is a clear scientific basis for doing so.

Potential benefits, adverse impacts, and limitations of an exposure registry for workers exposed to engineered nanoparticles may include the following:

Potential Benefits:

- Proactive approach to monitoring worker health
- Heightened employee awareness (also could be a drawback)
- Better understanding of how exposure affects worker health
- Ability to identify and track subtle symptoms and emerging syndromes
- Mechanism for notifying participants of the results of research related to their exposure
- Means to facilitate epidemiologic research (e.g., in ascertaining adverse health effects from low-level exposure over a long period of time)

Adverse Impacts:

- Increased concern, undue worry, and anxiety among workers
- Issues of privacy and confidentiality for individual workers
- Potential discrimination (e.g., health/life insurance)

Limitations:

- Costs (management and term of the registry)
- Ability to track participants into the future (e.g., attrition due to refusals, unable to locate, unable to contact)

Summary

EPA believes that, as an emerging industry, nanotechnology offers a unique opportunity to take a proactive and responsible approach to protecting worker health. Medical surveillance is an essential part of a comprehensive safety and health management program. In the case of nanotechnology, such surveillance is necessary to ensure the health of employees who may be exposed to materials whose potential health effects are not known. In the absence of specific medical screening tests, EPA urges NIOSH to develop a reasoned approach that strikes a balance between offering specific medical tests with no clear benefit and conducting no medical screening at all.