

Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials: A Labor Perspective

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Definition

According to the US National Technology Initiative a process or product is properly described as nanotechnology if it is characterized by all of the following:

- Researching and developing technologies that work at the atomic, molecular or macromolecular level of the scale of 1 to 100 nanometers**
- Involving structures, devices and systems that have novel properties and functions because of their scale**
- Controlling or manipulating materials at the atomic level**

What is New about Nanotechnology?

- **Nanomaterials have different properties from bulk chemicals because of**
 - **Scale**
 - **Surface area per unit of mass**
 - **Quantum effects**
- **The physical, chemical, and biological properties of materials at the nanoscale differ in fundamental and valuable ways from bulk matter.**
- **It is *our ability* to measure, manipulate and process at the nanoscale that is new**

Some Characteristics that Engineered Nanomaterials Share with Other Emerging Technologies

- **Rapid introduction**
- **Broad distribution**
- **Complexity and range of materials**
- **Complex materials flows/multiple sources**
- **Hard to study and characterize risks**
- **Knowledge is limited, uncertain, and indeterminate regarding:**
 - **Cumulative and interactive effects**
 - **Potential effects from low level exposures**

Penetration of Nanotechnology in Automobile and Automotive Parts Manufacturing

- **Market for nano tire additives is already mature.**
- **Markets for nanoclay composites, wear and friction-resistant nanocoatings and mechanically enhanced nanocomposites are maturing.**
- **Many other nanomaterials are in the research and prototype stages, where occupational exposure, albeit to fewer workers, still occur.**
 - **Many of these are expected to enter the market within the next five years.**

Nanomaterials that have already Entered the Automotive Market

- metal oxide nanopowder paint additives
- nanomagnetic fluid components
- anti-bacterial interior nanocoatings
- nanoclay polyurethane foams
- thermally conductive nanocoatings
- nanopowder catalysts and fuel cell additives
- carbon nanotube electrostatic paint
- nanofiber composites
- nanofluid coolants
- nanometal soldering additives
- anti-scratch nanocoatings
- anti-corrosion nanocoatings
- nanofiber engine filters and air filters

Potential Hazards of Engineered Nanomaterials

- **Size, shape, and strength create new hazards – new distribution; higher surface to mass, higher reactivity**
- **Hazards depend on:**
 - **Small size**
 - **Shape**
 - **Purity**
 - **Solubility**
 - **Surface area**
 - **Chemical composition**
 - **Aggregation**
 - **Dissolution and degradation (during release)**

Potential Hazards of Engineered Nanomaterials

- **Greater surface areas means increased bioactivity**
- **Inhaled nanoparticles reach deeply into the respiratory tract**
- **Nanoparticles can pass the blood/brain barrier¹ and some evidence of passage of blood testis barrier².
These properties can be therapeutic or toxic**
- **Small size and shape leads to rapid uptake into cells and more effective transport to target organs.**
- **Nanomaterials may be “carriers” for other more toxic molecules.**

¹JM Koziara, PR Lockman, DD Allen and RJ Mumper (2003). In Situ Blood–Brain Barrier Transport of Nanoparticles. *Pharmaceutical Research*: 20(11), 1772-1778

²Lan Z, Yang WX. Nanoparticles and spermatogenesis: how do nanoparticles affect spermatogenesis and penetrate the blood-testis barrier. *Nanomedicine (Lond)*. 2012Apr;7(4):579-96.

Petrochemical Revolution

- Produced many benign and beneficial substances. *The same can be expected for many nanomaterials.*
- Also produced tetraethyl lead, DDT and Benzene. *We can expect that some nanomaterials will be bad actors as well*
- Lesson: technological revolutions must be accompanied by regulatory regimes that can adequately distinguish between benign and harmful technologies and can restrict harmful technologies *before* exposure is widespread

Reactive Policy: Making the Same Mistake Again

- **Develop technology without constraints and fix problems once they occur**
- **Wait until we have perfect evidence before establishing OELs**
- **Treat uncertainty and lack of information about harm as evidence of safety**
- ***This amounts to taking no action until the body count is indisputably large***

Lessons from Past Policy Mistakes

- Investigate potential hazards of a new technology before it gets widely introduced
- Assume that, when dealing with complex technologies, hazard information will always be incomplete
- Act on partial and/or accumulating knowledge
- Design technologies with an eye towards potential health, safety, environmental implications

Setting Nanomaterial OELs

- **Develop ways to rapidly assess hazard and degree of concern**
- **Prioritize for immediate action those uses of greatest concern**
- **Develop lists of nanomaterials of concern**

Uncertainty in Setting Nanomaterial OELs

- **Information is always incomplete and more so for new materials**
- **OELs may need to be revised as additional information becomes available**

Control Banding May Offer Methods for Dealing with Incomplete Information and Uncertainty

CB Nanotool Risk Level Matrix

| | | Probability | | | |
|----------|--------------------|---------------------------|---------------------|----------------|-------------------|
| | | Extremely Unlikely (0-25) | Less Likely (26-50) | Likely (51-75) | Probable (76-100) |
| Severity | Very High (76-100) | RL 3 | RL 3 | RL 4 | RL 4 |
| | High (51-75) | RL 2 | RL 2 | RL 3 | RL 4 |
| | Medium (26-50) | RL 1 | RL 1 | RL 2 | RL 3 |
| | Low (0-25) | RL 1 | RL 1 | RL 1 | RL 2 |

RL 1: General Ventilation

RL 2: Fume hoods or local exhaust ventilation

RL 3: Containment

RL 4: Seek specialist advice

Paik, S, Zalk, D, and Swuste, P. (2008) Application of a pilot control banding tool for risk level assessment and control of nanoparticle exposures. *Annals of Occupational Hygiene* 52 (6): 419-428.

Livermore Probability Scores

- Estimated amount of material used (25 pts)
- Dustiness/mistiness (30 pts)
- Number of workers with similar exposure (15 pts)
- Frequency of operation (15 pts)
- Duration of operation (15 pts)

Livermore Severity Scores

- **Nanomaterial: 70% of Severity Score**
 - Surface Chemistry (10 pts)
 - Particle Shape (10 pts)
 - Particle Diameter (10 pts)
 - Solubility (10 pts)
 - Carcinogenicity (7.5 pts)
 - Reproductive Toxicity (7.5 pts)
 - Mutagenicity(7.5 pts)
 - Dermal Toxicity (7.5 pts)
- **Parent Material: 30% of Severity Score**
 - Occupational Exposure Limit (10 pts)
 - Carcinogenicity (5 pts)
 - Reproductive Toxicity (5 pts)
 - Mutagenicity (5 pts)
 - Dermal Toxicity (5 pts)

(Maximum points indicated in parentheses)

Handling Missing Information

- For a given hazard category, the Livermore group gave an unknown rating 75% of the value of a high hazard rating, which is higher than a medium rating
- The group assigned a risk level of 3 (second highest) to substance for which all hazards are unknown. Risk level 3 requires containment.
- If one risk category is high and all others are unknown, the substance was assigned to the highest risk level
- The authors indicated that this system was an incentive to seek information.

Summary

- **Learn from pasts mistakes**
- **Act before there are countable bodies**
- **Reduce and prevent exposure while information is still incomplete**
- **Control banding may be a way of controlling exposures with incomplete information**