Control Banding Approach to Safe Handling of Nanoparticles

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NIEHS panel: Control Banding and nanotechnology and its implications for workers and worker training

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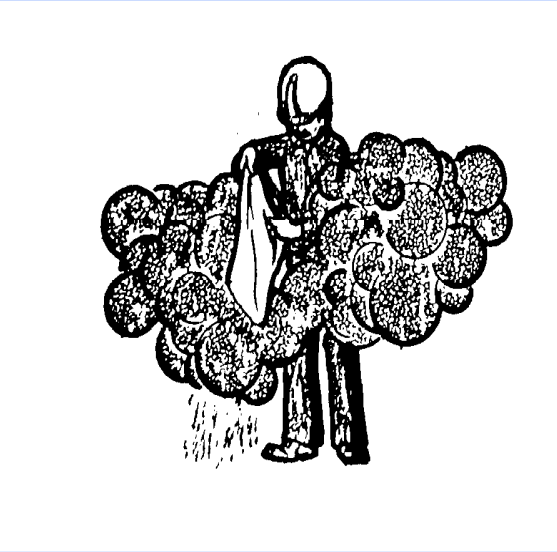
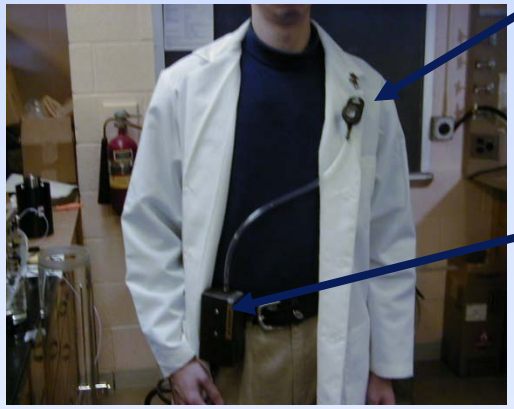
Overview

- Challenges in Traditional IH Approach
- Advantages of Control Banding for Nano
- Development and Application of CB Nanotool
- Worker participation

Traditional IH Approach

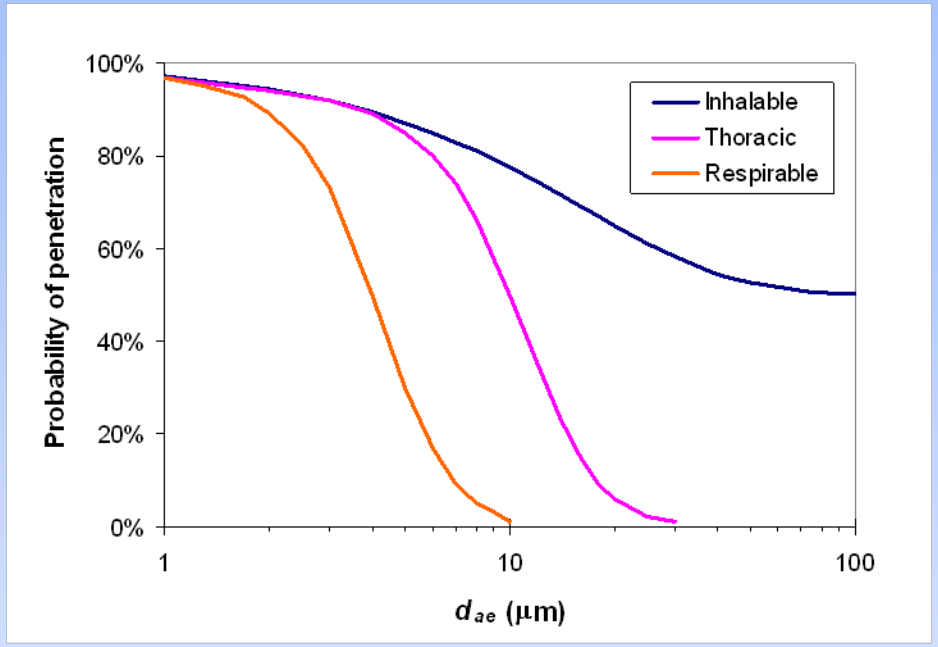
- Personal air sampling
  - Collect air samples from worker's breathing zone
  - Compare concentration of particles of interest with exposure limits
  - Implement control measures to reduce concentrations below exposure limits





Traditional IH Assumptions

- Sampled concentrations are representative of what the worker is breathing
- Exposure index pertaining to health effects is known
- Analytical methods are available to quantify exposure index
- Exposure levels at which particles produce adverse health effects are known



inhalable

thoracic

respirable

What can we do?

- 3 of the 4 assumptions are not met for nanoparticles
  - A long way to go before traditional IH approach can be relied upon as effective risk assessment
- Is there an alternative approach for risk assessment?
  - Yes! → Control Banding

CONTROL BANDING IS AN ALTERNATIVE APPROACH TO TRADITIONAL IH

Overview

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- Control Banding for Nano
- Development and Application of CB Nanotool
- Worker Participation

Control Banding for Nano

* Maynard, AD. (2007) Nanotechnology: the next big thing, or much ado about nothing? AnnOccHyg 51(1);1-12.

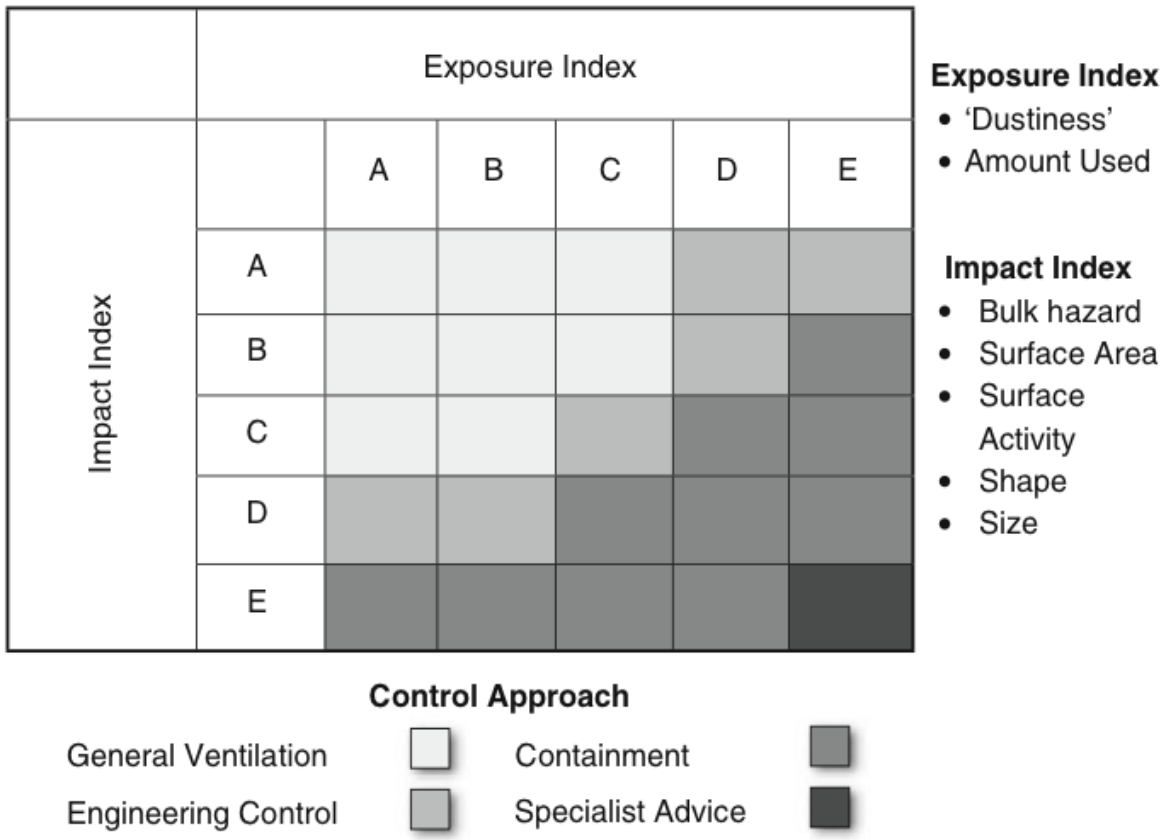

Fig. 7. Conceptual interpretation of how a control-banding type of approach might be applied to airborne engineered nanomaterials.

Factors that Favor Control Banding (CB) for Nano

- Alternative to traditional IH
- Efficacy of conventional controls
  - Fits well with a four band control outcome
- Product and Process Based – designed for use at the non-expert, worker level
- Successful application in many EU countries and historically in the pharmaceutical industry (e.g., COSHH Essentials, Stoffenmanager)
  - However, pharmaceutical's banding is intended for use by experts

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CB Nanotool Concept and Pilot

- While there were theories of how CB could be applied to nano, there were no comprehensive nano ‘tools’ available at the time

- Goal
  - Explore feasibility of CB concept by developing pilot tool, utilizing existing knowledge on nanoparticle toxicology
  - Apply CB Nanotool to current R&D operations at LLNL

CB Nanotool Risk Level Matrix

Probability

Severity	Extremely Unlikely (0-25)	Less Likely (26-50)	Likely (51-75)	Probable (76-100)
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

CB Nanotool: Treating Unknowns

- For a given hazard category, should an “unknown” rating be given the same weight as a “high hazard” rating?
  - Due to scarcity of data, most operations would require highest level of control
- Decided to give an “unknown” rating 75% of the point value of “high” rating. This is higher than a “medium” rating.
- The default control for operation for which everything is “unknown” is Containment (Risk Level 3). If even one rating is “high” with everything else “unknown”, resulting control would be Seek Specialist Advice (Risk Level 4).
  - Provided incentive for responsible person to obtain health-related data for the activity

CB Nanotool (v2): Severity Factors

- Nanomaterial: 70% of Severity Score
  - Surface Chemistry (10 pts)
  - Particle Shape (10 pts)
  - Particle Diameter (10 pts)
  - Solubility (10 pts)
  - Carcinogenicity (6 pts)
  - Reproductive Toxicity (6 pts)
  - Mutagenicity (6 pts)
  - Dermal Toxicity (6 pts)
  - Asthmagen (6 pts)
- Parent Material: 30% of Severity Score
  - Occupational Exposure Limit (10 pts)
  - Carcinogenicity (4 pts)
  - Reproductive Toxicity (4 pts)
  - Mutagenicity (4 pts)
  - Dermal Toxicity (4 pts)
  - Asthmagen (4 pts)

(Maximum points indicated in parentheses)

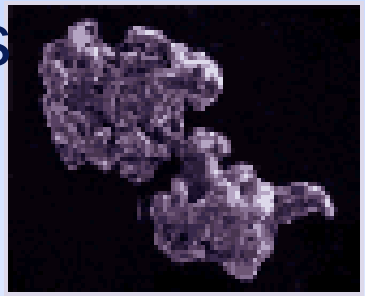
CB Nanotool(v2): Probability Factors

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

Particle Shape (nanomaterial)

- Tubular/fibrous:
  high aspect ratio
  (e.g., carbon nanotubes)

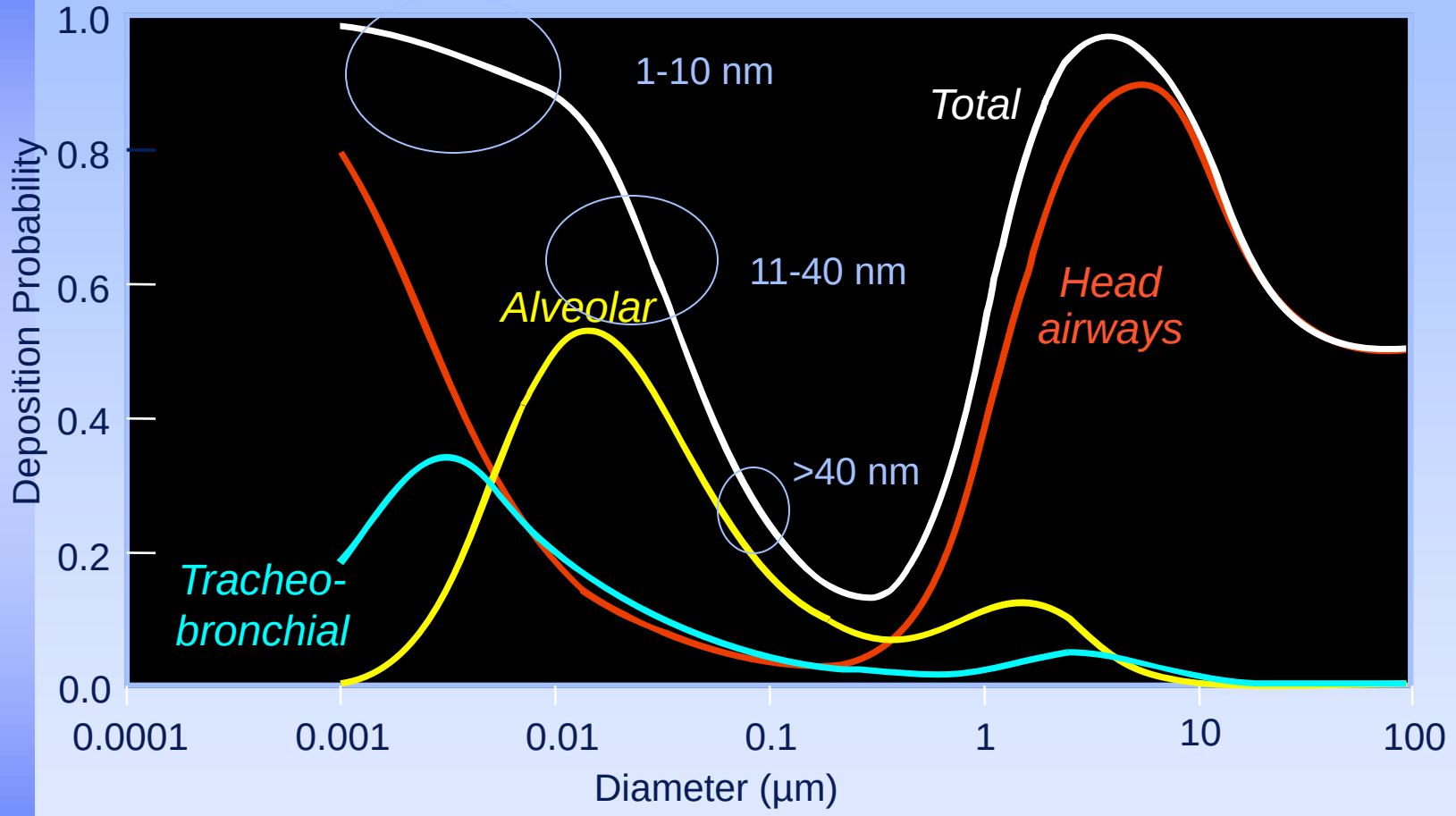
- Irregular shapes:
  generally more surface
  area than compact particles
  (e.g., iron powders)



Tubular/fibrous: 10 pts Anisotropic: 5 pts Compact/spherical: 0 pts

Unknown: 7.5 pts

Particle Diameter (nanomaterial)



1-10 nm: 10 pts 11-40 nm: 5 pts >41 nm: 0 pts Unknown: 7.5 pts

ICRP (1994) model: adult, nose breathing, at rest. Courtesy of CDC-NIOSH.

Surface Chemistry (nanomaterial)

- Particle surface free radical activity
  - Surface Chemistry (10 pts)
  - Ability to generate reactive oxygen species, oxidative stress responses
  - Toxicological studies – Bronchoalveolar lavage fluid collected from rodents: analyzed for markers of inflammation, lung tissue damage, antioxidant status, etc.
  - Auger spectroscopy

High: 10 pts Medium: 5 pts Low: 0 pts Unknown: 7.5 pts

Solubility (nanomaterial)

- Insoluble particles
  - Titanium dioxide, PTFE, $BaSO_4$
  - Causes inflammatory response
  - May penetrate skin, may translocate into brain

- Soluble particles
  - Potential systemic effects through absorption into blood

Insoluble: 10 pts Soluble: 5 pts Unknown: 7.5 pts

Other Tox Effects (nanomaterial)

- Carcinogenicity
  - e.g., Titanium dioxide (IARC Group 2B potential carcinogen)

    Yes: 6 pts No: 0 pts Unknown: 4.5 pts
- Reproductive toxicity – mostly unknown

  Yes: 6 pts No: 0 pts Unknown: 4.5 pts
- Mutagenicity – mostly unknown

  Yes: 6 pts No: 0 pts Unknown: 4.5 pts
- Dermal toxicity – mostly unknown
  - Either cutaneous or through skin absorption

    Yes: 6 pts No: 0 pts Unknown: 4.5 pts
- Asthmagenic potential – mostly unknown

  Yes: 6 pts No: 0 pts Unknown: 4.5 pts

MOST TOXICOLOGICAL DATA PERTAINING TO NANOSCALE IS UNKNOWN

Severity Factors of Parent Material

- Toxicological properties of parent material may provide insight into nanomaterial toxicity
  - 30% of total severity score is based on parent material characteristics

- Bulk hazard (Parent material)
  - Is there an established occupational exposure limit?

<10 μg/m^3: 10 pts
>1 mg/m^3: 0 pts

10-100 μg/m^3 : 5 pts
Unknown: 7.5 pts

101-1000 μg/m^3 : 2.5 pts

Severity Factors of Parent Material

- Carcinogenicity

  Yes: 4 pts No: 0 pts Unknown: 3 pts
- Reproductive toxicity

  Yes: 4 pts No: 0 pts Unknown: 3 pts
- Mutagenicity

  Yes: 4 pts No: 0 pts Unknown: 3 pts
- Dermal toxicity
  - Either cutaneous or through skin absorption

    Yes: 4 pts No: 0 pts Unknown: 3 pts
- Asthmagenic potential – mostly unknown

  Yes: 4 pts No: 0 pts Unknown: 3 pts

Probability Factors

- Pertain to probability of exposure, irrespective of toxicological effects

  - Estimated amount of material used

  >100 mg: 25 pts 11-100 mg: 12.5 pts 0-10 mg: 6.25 pts Unknown: 18.75 pts

  - Dustiness/mistiness

  High: 30 pts Medium: 15 pts Low: 7.5 pts None: 0 pts Unknown: 22.5 pts

  - Number of employees with similar exposure

  >15: 15 pts 11-15: 10 pts 6-10: 5 pts 1-5: 0 pts Unknown: 11.25 pts

  - Frequency of operation

  Daily: 15 pts Weekly: 10 pts Monthly: 5 pts Less than monthly: 0 pts

  - Duration of operation

  >4 hrs: 15 pts 1-4 hrs: 10 pts 30-60: 5 pts <30 min: 0 pts Unknown: 11.25 pts

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Activities at LLNL (examples)

- Weighing of dry nanopowders in glovebox
- Flame synthesis of garnet ceramic nanoparticles by liquid injection
- Synthesis of carbon nanotubes and metal oxide nanowires onto substrates within tube furnace
- Deposition of liquid-suspended nanoparticles onto surface using low voltage electric fields
- Sample preparation of various nanomaterials by cutting, slicing, grinding, polishing, etching, etc.
- Use of gold nanoparticles for testing carbon nanotube filters
- Etching nanostructures onto semiconductors
- Addition of quantum dots onto porous glass
- Growth of palladium nanocatalysts
- Synthesis of aerogels
- Machining (e.g., turning, milling) of aerogels and nanofoams for laser target assembly
- Sample preparation and characterization of CdSe nanodots and carbon diamonoids

CB Nanotool vs IH Judgment

- Application to current operations
  - 36 operations at LLNL previously evaluated by field IHs
    - For 21 activities, CB Nanotool recommendation was equivalent to existing controls
    - For 9 activities, CB Nanotool recommended higher level of control than existing controls
    - For 6 activities, CB Nanotool recommended lower level of control than existing controls

CB Nanotool as LLNL Policy

- Overall (30 out of 36), CB Nanotool recommendation was equal to or more conservative than IH expert opinions
- LLNL decided to make CB Nanotool recommendation a requirement
- CB Nanotool is an essential part of LLNL's Nanotechnology Safety Program

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Worker Participation

- Control Banding can be used as effective hazard communication tool – risk level determination is straightforward
- CB Nanotool allows worker to suggest changes to reduce overall score (e.g., change to less hazardous material, change amount handled, etc.)
- CB Nanotool evolves as information on nanoparticle health effects evolves

Some notes for CB Nanotool

- Information on health effects from nanoparticle exposure is evolving – relative importance of factors may change
- Ranges of values for a given factor correspond to ranges one would expect in small-scale R&D operations (e.g., amounts used, number of employees, etc.)
- Score for a given rating within a factor can be set according to the level of risk acceptable to the institution
- Some qualitative ratings can be bolstered or eventually replaced with quantitative ratings

Publications

- Paik, S.Y., Zalk, D.M., 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.

- Zalk, D.M, Paik, S.Y., and Swuste, P. (2009) Evaluating the Control Banding Nanotool: a qualitative risk assessment method for controlling nanoparticle exposures. *Journal of Nanoparticle Research*, 11(7):1685-1704.

Acknowledgments

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Your attention is appreciated!

Questions?