Application of a pilot control banding tool for risk level assessment and control of nanoparticle exposures (submitted to Annals of Occupational Hygiene on March 11, 2008)

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ABSTRACT

Control Banding (CB) strategies offer simplified solutions for controlling worker exposures to constituents that are found in the workplace in the absence of firm toxicological and exposure data. These strategies may be particularly useful in nanotechnology applications, considering the overwhelming level of uncertainty over what nanomaterials and nanotechnologies present as potential work-related health risks, what about these materials might lead to adverse toxicological activity, how risk related to these might be assessed, and how to manage these issues in the absence of this information. This study introduces a pilot CB tool or 'CB Nanotool' that was developed specifically for characterizing the health aspects of working with engineered nanoparticles and determining the level of risk and associated controls for five ongoing nanotechnology-related operations being conducted at two Department of Energy (DOE) research laboratories. Based on the application of the CB Nanotool, four of the five operations evaluated in this study were found to have implemented controls consistent with what was recommended by the CB Nanotool, with one operation even exceeding the required controls for that activity. The one remaining operation was determined to require an upgrade in controls. By developing this dynamic CB Nanotool within the realm of the scientific information available, this application of CB appears to be a useful approach for assessing the risk of nanomaterial operations, providing recommendations for appropriate engineering controls, and facilitating the allocation of resources to the activities that most need them. [LLNL-JRNL-401987]

INSTRUCTIONS

Severity Score: Sum of all severity factors. Maximum score is 100. Out of the 100 pts, 70 points are based on characteristics of the nanomaterial and 30 points are based on characteristics of the parent material. Thus, more weight is given to nanoscale characteristics. 0-25: Low severity, 26-50: Medium severity, 51-75: High severity, 76-100: Very high severity.

1. Surface reactivity – Surface chemistry is known to be a key factor influencing the toxicity of inhaled particles. Particle surface free radical activity is the primary factor that influences the material's overall surface reactivity. Points will be assigned based on a qualitative judgment of whether the surface reactivity is high, medium, or low. Research studies will be consulted, when available, to make the judgment. High: 10 pts, Medium: 5 pts, Low: 0 pts, Unknown: 7.5 pts.

2. Particle shape – Studies have shown that exposure to fibrous particles like asbestos have long been associated with increased risk of fibrosis and cancer. Tubular structures, like carbon nanotubes, have also been shown to cause inflammation and lesions in rat lungs. Based on this information, the highest severity score is given to fibrous or tubular-shaped particles. Particles with irregular shapes (other than tubular or fibrous) are given a medium severity score because they typically have higher surface areas relative to isotropic (e.g. compact or spherical) particles. Tubular or fibrous: 10 pts, Anisotropic: 5 pts, Compact or spherical: 0 pts, Unknown: 7.5 pts.

3. Particle diameter – based on the ICRP curve, particles in the 1-10 nm range have a greater than approximately 80% chance of depositing in the lungs. Particles in the 10-40 nm range have a greater than approximately 50% possibility of depositing in the lungs and particles in the 41-100 nm range have a greater than approximately 20% possibility of depositing in the lungs. Based on this ability to deposit in the lungs (regardless of the region of deposition) and the fact that smaller particles have a higher overall surface area compared to larger particles for a given mass concentration, the following points are assigned to a given particle size range and used to determine the severity score. 1-10 nm: 10 pts, 11-40 nm: 5 pts, <41-100 nm: 0 pts, Unknown: 7.5. pts.

4. Solubility – several studies have shown that poorly soluble inhaled nanoparticles can cause oxidative stress, leading to inflammation, fibrosis, or cancer. Since soluble nanoparticles can also cause adverse effects through dissolution in the blood, severity points are assigned to soluble nanoparticles as well, but to a lesser degree than for insoluble particles. Insoluble: 10 pts, Soluble: 5 pts, Unknown: 7.5 pts.

5. Carcinogenicity – points are assigned based on whether the nanomaterial is carcinogenic or not. Yes: 7.5 pts, No: 0 pts, Unknown:5.625 pts.

6. Reproductive toxicity – points are assigned based on whether the nanomaterial is a reproductive hazard or not. Yes: 7.5 pts, No: 0 pts, Unknown:5.625 pts.

7. Mutagenicity – points are assigned based on whether the nanomaterial is a mutagen or not. Yes: 7.5 pts, No: 0 pts, Unknown:5.625 pts.

8. Dermal toxicity – points are assigned based on whether the nanomaterial is a dermal hazard or not. Yes: 7.5 pts, No: 0 pts, Unknown:5.625 pts.

9. Toxicity of parent material – the bulk material of some nanoparticles have established occupational exposure limits. While it is known that the toxicity of particles at the nanoscale can differ significantly from their larger counterparts, this provides a good starting point for understanding the toxicity of the material. Points are assigned according to the OEL (occupational exposure limit) band of the bulk material. 0-1 mcg/m^3: 10 pts, 2-10 mcg/m^3: 5 pts, 11-100 mcg/m^3: 2.5 pts, Unknown: 7.5 pts.

10. Carcinogenicity of parent material – points are assigned based on whether the parent material is carcinogenic or not. Yes: 5 pts, No: 0 pts, Unknown: 3.75 pts.

11. Reproductive toxicity of parent material – points are assigned based on whether the parent material is a reproductive hazard or not. Yes: 5 pts, No: 0 pts, Unknown: 3.75 pts.

12. Mutagenicity of parent material – points are assigned based on whether the parent material is a mutagen or not. Yes: 5 pts, No: 0 pts, Unknown: 3.75 pts.

13. Dermal hazard potential of parent material – points are assigned based on whether the parent material is a dermal hazard or not. Yes: 5 pts, No: 0 pts, Unknown: 3.75 pts

Probability Score: Sum of all exposure factors. Maximum score is 100. These factors determine the extent to which employees may be potentially exposed to nanoscale materials, primarily through inhalation, but also through dermal contact.
0-25: Extremely unlikely, 26-50: Less likely, 51-75: Likely, 76-100: Probable.

1. Estimated amount of chemical used during task. >100 mg: 25 pts, 11-100 mg: 12.5 pts, 0-10 mg: 6.25 pts, Unknown: 18.75 pts.

2. Dustiness/mistiness – points are assigned according to dustiness/mistiness level of material. Until further guidance is provided on quantifying dustiness/mistiness levels, points will assigned based on an estimate of relative dustiness/mistiness level. When "None" is chosen for dustiness/mistiness level, this automatically causes the overall probability score to be "Extremely Unlikely", regardless of what the other probability factors are. High: 30 pts, Medium: 15 pts, Low: 7.5 pts, None: 0 pts, Unknown: 22.5 pts.

3. Number of employees with similar exposure – points are assigned according to the number of employees authorized for the activity. >15: 15 pts, 11-15: 10 pts, 6-10: 5 pts, 1-5: 0 pts, Unknown: 11.25 pts.

4. Frequency of operation – points are assigned according to the frequency of the operation. Daily: 15 pts, Weekly: 10 pts, Monthly: 5 pts, Less than monthly: 0 pts, Unknown: 11.25 pts

5. Operation duration – points are assigned according to the duration of the operation. >4 hours: 15 pts, 1-4 hours: 10 pts, 30-60 min: 5 pts, Less than 30 min: 0 pts, Unknown: 11.25 pts.

Overall Risk Level

Based on the severity score and probability score, the following table is used to determine the overall risk level of the activity:

Severity \ Probability	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