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LLNL-JRNL-421516

Control Banding and Nanotechnology Synergist

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December 16, 2009

The Synergist

The average Industrial Hygienist (IH) loves a challenge, right? Okay, well here is one with more than a few twists. We start by going through the basics of a risk assessment. You have some chemical agents, a few workers, and the makings of your basic exposure characterization. However, you have no occupational exposure limit (OEL), essentially no toxicological basis, and no epidemiology. Now the real handicap is that you cannot use sampling pumps, cassettes, tubes, or any of the media in your toolbox, and the whole concept of mass-to-dose is out the window, even at high exposure levels. Of course, by the title, you knew we were talking about nanomaterials (NM). However, we wonder how many IHs know that this topic takes everything you know about your profession and turns it upside down. It takes the very foundations that you worked so hard in college and in the field to master and pulls it out from underneath you. It even takes the gold standard of our profession, the quantitative science of exposure assessment, and makes it look pretty darn rusty. Now with NM there is the potential to get some aspect of quantitative measurements, but the instruments are generally very expensive and getting an appropriate workplace personal exposure measurement can be very difficult if not impossible. The potential for workers getting exposures, however, is very real, as evidenced by a recent publication reporting worker exposures to polyacrylate nanoparticles in a Chinese factory (Song et al. 2009).

With something this complex and challenging, how does a concept as simple as Control Banding (CB) save the day? Although many IHs have heard of CB, most of their knowledge comes from its application in the COSHH Essentials toolkit. While there is conflicting published research on COSHH Essentials and its value for risk assessments, almost all of the experts agree that it can be useful when no OELs are available (Zalk and Nelson 2008). It is this aspect of CB, its utility with uncertainty, that attracted international NM experts to recommend this qualitative risk assessment approach for NM. However, since their CB recommendation was only in theory, we took on the challenge of developing a working toolkit, the CB Nanotool (see Zalk et al. 2009 and Paik et al. 2008), as a means to perform a risk assessment and protect researchers at the Lawrence Livermore National Laboratory. While it's been acknowledged that engineered NM have potentially endless benefits for society, it became clear to us that the very properties that make nanotechnology so useful to industry could also make them dangerous to humans and the environment. Among the uncertainties and unknowns with NM are: the contribution of their physical structure to their toxicity, significant differences in their deposition and clearance in the lungs when compared to their parent material (PM), a lack of agreement on the appropriate indices for exposure to NM, and very little background information on exposure scenarios or populations at risk. Part of this lack of background information can be traced to the lack of risk assessments historically performed in the industry, with a recent survey indicating that 65% of companies working with NM are not doing any kind of NM-specific risk assessment as they focus on traditional PM methods for IH (Helland et al. 2009). The good news is that the amount of peer-reviewed publications that address environmental, health and safety aspects of NM has been increasing over the last few years; however, the percentage of these that address practical methods to reduce exposure and protect workers is orders of magnitude lower.

Our intent in developing the CB Nanotool was to create a simplified approach that would protect workers while unraveling the mysteries of NM for experts and non-experts alike. Since such a large part of the toxicological effects of both the physical and chemical properties of NM were unknown, not to mention changing logarithmically as new NM research continues growing, we needed to account for this lack of information as part of the CB Nanotool's risk assessment. We chose a standardized 4 X 4 risk matrix (see figure 1) as our starting point, working with the severity parameters on one axis and the probability parameters on the other. The development of the severity axis was certainly the hardest part of our effort. This required the dissection of NM and its physicochemical properties which are often unknown, adding information on the PM which is far more available, and somehow scoring these input factors in a manner that appropriately weighted each factor. We decided to give unknown input factors a score of 75% of the points for each category, because otherwise the instinct of considering it as extremely dangerous would kick in and the highest level of control would almost always be the outcome. Balancing a conservative approach with a reasonable scientific estimate was the best way to not stifle research ingenuity, yet still protect workers. The probability axis was much easier to develop and score as this fits well with traditional IH knowledge. The details of the CB Nanotool go far beyond this, but we give the basics here.

Severity Factors

Based on the literature available prior to publication of the CB Nanotool, the list of factors below was considered to determine the overall severity of exposure to NM. The research and logic behind both the composition and scoring distribution of all these factors can be found in our publications (see Zalk et al. 2009 and Paik et al. 2008). These factors influence the ability of particles to reach the respiratory tract, their ability to deposit in various regions of the respiratory tract, their ability to penetrate or to be absorbed through skin and their ability to elicit biological responses systemically. The division of severity factor points taken cumulatively is 70% for the NM and 30% for the parent material (PM). Research to date does not contraindicate the potential for engineered NM to be more toxic than its PM. The individual factors that make up the NM severity factors are as follows:

Surface chemistry NM: surface chemistry is known to be a key factor influencing the toxicity of inhaled particles. Points are assigned based on a knowledge of whether the surface activity of the nanoparticle is high, medium or low.
High: 10 Medium: 5 Low: 0 Unknown: 7.5

Particle shape NM: points are assigned based on the shape of the particle. The highest rating is given to fibrous or tubular-shaped particles based on toxicological studies. Particles with irregular shapes (anisotropic) have higher surface areas than isotropic or spherical particles and therefore are given the next highest rating.
Tubular, fibrous: 10 Anisotropic: 5 Compact/ spherical: 0 Unknown: 7.5

Particle diameter NM: points are assigned based on the particles' deposition in the respiratory tract, regardless of the region in the respiratory tract.

1 – 10 nm: 10 11 – 40 nm: 5 < 41 – 100 nm: 0 Unknown: 7.5

Solubility NM: poorly soluble, inhaled nanoparticles can cause oxidative stress, leading to inflammation, fibrosis, or cancer. Since soluble NM can also cause adverse effects through dissolution in the blood, points are assigned to soluble NM as well, but to a lesser degree.
Insoluble: 10 Soluble: 5 Unknown: 7.5

Carcinogenicity NM: points are assigned based on whether the nanomaterial is carcinogenic or not, regardless of whether the material is a human or animal carcinogen. Little information is available.
Yes: 6 No: 0 Unknown: 4.5

Reproductive toxicity NM: points are assigned based on whether the nanomaterial is a reproductive hazard or not. Little information is available of this factor.
Yes: 6 No: 0 Unknown: 4.5

Mutagenicity NM: points are assigned based on whether the nanomaterial is a mutagen or not. Little information is available of this factor.
Yes: 6 No: 0 Unknown: 4.5

Dermal toxicity NM: points are assigned based on whether the nanomaterial is a dermal hazard or not. Little information is available of this factor.
Yes: 6 No: 0 Unknown: 4.5

Asthmagen NM: points are assigned based on whether the nanomaterial is an asthmagen or not. Little information is available of this factor.
Yes: 6 No: 0 Unknown: 4.5

Toxicity PM: although research agrees that NM can be more toxic than PM, knowledge of the PM toxicity is a good starting point for understanding the NM toxicity. Points are assigned according to the OEL of the bulk material.
< 10 μgm^{-3}: 10 10 – 100 μgm^{-3}: 5 101 – 1 mgm^{-3}: 2.5 > 1 mgm^{-3}: 0 Unknown: 7.5

Carcinogenicity PM: Points are assigned based on whether the PM is carcinogenic or not.
Yes: 4 No: 0 Unknown: 3

Reproductive toxicity of PM: points are assigned on whether the PM is a reproductive hazard or not.
Yes: 4 No: 0 Unknown: 3

Mutagenicity of PM: points are assigned on whether the PM is a mutagen or not.
Yes: 4 No: 0 Unknown: 3

Dermal hazard potential of PM: points are assigned on whether the PM is a dermal hazard or not

Yes: 4 No: 0 Unknown: 3

Asthmagen PM: points are assigned based on whether the PM is an asthmagen or not.
Yes: 4 No: 0 Unknown: 3

The overall severity score is determined based on the sum of all the points from the severity factors. The maximum score is 100. An overall severity score of 0-25 was considered low severity; an overall severity score of 26-50 was considered medium severity; an overall severity score of 51-75 was considered high severity; and an overall severity score of 76-100 was considered very high severity.

<u>Probability Factors</u>

The probability scores are based on factors determining the extent to which employees may be potentially exposed to NM.

Estimated amount of NM used during operation: for NM embedded on substrates or suspended in liquid, the amount is based on the mass of the NM itself and not the substrate or liquid portion.
> 100 mg: 25 11 – 100 mg: 12.5 0 – 10 mg: 6.25 Unknown: 18.75

Dustiness/mistiness: since employees are potentially exposed to nanoparticles in either dry or wet form, this factor encompasses both dustiness and/or mistiness of the NM. Knowledge of the operation (e.g., handling dry powders versus liquid suspensions of nanoparticles) would be a means to estimate dustiness/mistiness. A CB Nanotool design feature is that a rating of ´none´ for dustiness/mistiness level (and only for this factor) automatically causes the overall probability score to be “Extremely Unlikely”, regardless of the other probability factors, since the other factors will not be relevant if no dust or mist is being generated.
High: 30 Medium: 15 Low: 7.5 Unknown: 22.5

Number of employees with similar exposure: points are assigned by the number of employees assigned to this activity. More employees means a higher probability of employees being exposed.
> 15: 15 11 - 15: 10 6 - 10: 5 Unknown: 11.25

Frequency of operation: points are assigned based on the frequency of the operation, as more frequent operations are more likely to result in employee exposures.
Daily: 15 Weekly: 10 Monthly: 5 Less than monthly: 0 Unknown: 11.25

Duration of operation: points are assigned based on the duration of the operation, as longer operations are more likely to result in employee exposures.
> 4h: 15 1 – 4 h: 10 30 – 60 min: 5 < 30 min: 0 Unknown: 11.25

The overall probability score is based on the sum of all the points from the probability factors. The maximum score is 100. An overall probability score of 0-25 was considered extremely unlikely; an overall probability score of 26-50 was considered less likely; an overall probability score of 51-75 was considered likely; and an overall probability score of 76-100 was considered probable. Based on the severity score and probability score for an operation, the overall level of risk and corresponding control band is determined by the matrix shown in Figure 1.

The outcome of taking on this challenge by developing the CB Nanotool can be found in our first published article (Paik et al, 2008). Much to our surprise, the CB Nanotool generated quite a large amount of interest, particularly among international organizations including the International Labor Organization and the World Health Organization. CB for work with NM is now recommended by many countries worldwide, including: Canada, Australia and the Netherlands. Our co-author, Paul Swuste of the Delft University of Technology, was vital in obtaining high-profile European opportunities for presenting our work. All of a sudden, it became apparent that many experts were considering our qualitative CB approach to be as good and – dare we say – possibly better than the quantitative risk assessment approach that currently exists. By that time, the questions and further challenges began presenting themselves as more NM professionals became aware of our CB toolkit. This led to our latest article (Zalk et al, 2009), where we thoroughly evaluated the CB Nanotool in its entirety to address these questions. This whole process of professional questioning and evaluation of our qualitative methods provided an opportunity to improve the tool, resulting in version 2 of the CB Nanotool (version 2 is presented above), and shine a new, positive light on CB. Good things happen when IHs take on challenges.

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ACKNOWLEDGEMENT

This work was performed under the auspices of the U.S. Department of Energy by Lawrence Livermore National Laboratory under Contract DE-AC52-07NA27344, LLNL-JRNL-####.

Figure 1. Risk level (RL) matrix as a function of severity and probability scores. Control bands are based on overall risk levels.

Probability Score

Severity score		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

Control bands by risk level:

RL 1: General Ventilation
RL 2: Fume hoods or local exhaust ventilation
RL 3: Containment
RL 4: Seek specialist advice