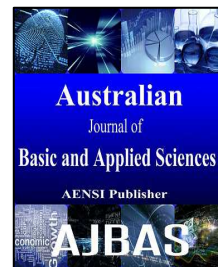




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A Review of Control Banding and Traditional Industrial Hygiene Sampling Methods for Determining Risk Assessment of Engineered Nanomaterials in the Workplace

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ABSTRACT

The properties of engineered nanomaterials (ENM) are increasingly being developed and used for technological developments. At present there is a high level of uncertainty about the health risks associated with manufactured nanomaterials. The traditional industrial hygiene (IH) exposure assessment strategy for nanomaterials is highly tailorable to most situations and workplace environments and enables effective and efficient exposure management while control banding (CB) allows an appropriate level of risk control that could be established and can be reassessed according to developing scientific and technical knowledge of the products and processes involved. The article discusses the method for both types of assessments using previously published scientific literature.

INTRODUCTION

Engineered Nanomaterials (ENM) are currently being used in numerous electronic, pharmaceutical, automotive, aerospace, and other applications (Paik *et al.*, 2008). An estimated \$1 trillion worth of products worldwide will incorporate nanotechnology and its components by 2015. The industry would employ about two million workers in nanotechnology. These estimates are based on a broad industry survey conducted in the United States, Europe, Asia, and Australia (Studer *et al.*, 2015). Research in nanoscale technologies is growing rapidly worldwide. Lux Research has projected that new emerging nanotechnology applications will affect nearly every type of manufactured product through the middle of the next decade, becoming incorporated into 15% of global manufacturing output, totaling \$2.6 trillion in 2014 (“Approaches to Safe Nanotechnology Managing the Health and Safety Concerns Associated with Engineered Nanomaterials – NIOSH,” 2009).

There are various means by which humans could be exposed to these ENM, but exposure possibilities during particle manufacturing and handling processes are among the most important as the concentrations may potentially be the highest (Brouwer *et al.*, 2009) (Bujak-Pietrek, 2010). The exposures can involve a wide range of sizes, shapes, concentrations and exposure frequencies and durations. The surface properties (e.g., surface potential, particle size, and surface area) play a dominating factor in determining the toxicity of ENM (Pompe, 2007). Based on their surface properties, nanomaterials can cause reactions in the body, stay inert, and/or interact with the body. ENMs generated in working conditions can reach high exposure concentrations, up to several hundred micrograms per cubic meter (Oberdörster *et al.*, 2005).

The skin has a surface area of 1.5 m², the digestive system is of 200 m² and the respiratory system is of a total surface area of 140 m² (Studer *et al.*, 2015). In occupational working conditions the exposure to ENM can

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reach high exposure concentrations, up to several hundred micrograms per cubic meter (Nikodinovska *et al.*, 2015). In the workplace, airborne particles in the range of microscale to nanoscale can be inhaled into the body. ENM which are suspended in the air pose the biggest threat to the body's respiratory system because they can be broken down into respirable sized particles (Pompe, 2007). The size of ENM was confirmed as the key parameter in the deposition of ENM into the lung. The smaller the particles, the deeper they can travel into the lung (Methner *et al.*, 2009).

Due to their unique size and characteristics, ENM have raised a concern for their influence on human health and ecological systems (Nikodinovska *et al.*, 2015). Anticipating, recognizing, evaluating, and controlling those exposures are the key challenges for an industrial hygienist. Categorization strategies are necessary to enable government regulatory bodies and industries to better predict the risks posed by the ENM. This will also allow the prioritization that is (hazard, exposure and surface properties) required to estimate their potential risk while minimizing time consuming and expensive in vivo studies or traditional risk assessments (Methner *et al.*, 2009), (Peters *et al.*, 2008).

Currently, very few tools and methods are available for regulatory authorities to allow material categorization according to potential human health risk (Bujak-Pietrek, 2010), (Methner *et al.*, 2009). The high risk materials should be targeted for additional scrutiny and material categories that pose the least risk can receive expedited review. NIOSH has presented a tool, Nanoparticle Emission Assessment Technique (NEAT) which allows a semi-quantitative evaluation of processes and tasks in the workplace where releases of ENM are possible (Brouwer *et al.*, 2009), (Methner *et al.*, 2009), (Methner *et al.*, 2010).

With the high level of uncertainty about the risks associated and non-availability of Occupational exposure limits (OELs) for the major number of ENM, the Control Banding (CB) method presents an alternative solution. CB is based on simple input information regarding hazards and exposure to processes and the materials involved (Paik *et al.*, 2008) (Methner *et al.*, 2009), (Liu *et al.*, 2014), (Riediker *et al.*, 2012). An industrial hygienist can provide a detailed evaluation of the hazard classification based on published literature and toxicological data provided by the manufacturers of the materials. Such a full hazard assessment can be fed into a Control Banding process in order to provide a hazard band (based on risk levels) for substances. This allows quick decisions by non-technical staff. It is therefore designed to tend towards elevated protection levels (Brouwer *et al.*, 2009), (Riediker *et al.*, 2012), ("Synergist - Control Banding & Nanotechnology," 2010).

Traditional Industrial Hygiene Methods For Determining Exposure, Risk And Health Assessment Of Enms At Workplace:

Nanomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles (nanoparticles). They may also come into contact with the skin or be ingested. Most workplace air monitoring studies are focused on activities, tasks, and processes related to production, operation and/or use of ENM ("Approaches to Safe Nanotechnology Managing the Health and Safety Concerns Associated with Engineered Nanomaterials – NIOSH," 2009).

Exposure to airborne ENM via inhalation route leads to deposition in the various compartments of the respiratory tract according to three important parameter groups: aerodynamic and thermodynamic nanoparticle properties, breathing pattern, and the three-dimensional geometry and structure of the respiratory tract. Deposition probability of nanoparticles below a thermodynamic diameter of 500 nm increases with decreasing size because of the increasing diffusion velocity leading to an increased deposition in the small airways and the alveoli, in particular. Below 20 nm, the location of deposition of nanoparticles changes to the upper respiratory tract because of their even higher diffusion velocity (Riediker *et al.*, 2012), (Luo *et al.*, 2015), (Oberdörster *et al.*, 2005), (Peters *et al.*, 2006).

Quantitative Measurement (Personal Exposure) Using Traditional Ih Methods:

For sampling exposures to ENM, the samples are obtained with an air sample from the worker's breathing zone using a sampling pump (Brouwer *et al.*, 2009), (Albuquerque *et al.*, 2015). Respirable samplers allow mass-based exposure measurements to be made using gravimetric and/or chemical analysis. Currently no commercially available personal samplers are designed to measure the particle number, surface area, or mass concentration parameters. Low-pressure cascade impactors that can measure particles to 50 nm and larger may be used for static sampling since their size and complexity prohibit their use as personal samplers ("Occupational Exposure to Titanium Dioxide - NIOSH," 2009).

But still, for ENM an appropriate quantitative measure of exposure has not yet been established by any international scientific community on what the relevant index of exposure is (NIOSH, 2006; ISO, 2007), (Brouwer *et al.*, 2009). NIOSH recommends airborne exposure limits of 2.4 mg/m³ for fine TiO₂ and 0.3 mg/m³ for ultrafine (including engineered nanoscale) TiO₂ as TWA concentrations for up to 10 hr/day during a 40-hour work week and the NIOSH Method 0600 for sampling airborne respirable particles [NIOSH 1998]. It has determined that ultrafine TiO₂ is a potential occupational carcinogen but that there are insufficient data at this time to classify fine TiO₂ as a potential occupational carcinogen ("Interim Guidance for Medical Screening and

Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles - NIOSH," 2009), ("General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories - NIOSH," 2012).

Real Life Scenario Of Traditional Method Application For TiO₂ Enm:

Brian Curwin *et al.*, for NIOSH, collected area samples and personal dust samples for titanium dioxide TiO₂ ("Occupational Exposure to Titanium Dioxide - NIOSH," 2009). The samples were collected from seven facilities which included small, medium and large scale ENM production facilities during different job tasks of production and handling. There were no statistically significant differences between facilities and processes. But when they analysed, a pattern was formed on how the non-specific metrics might relate to the amount of particle collected. For example, the total particle number concentration and surface area concentration were higher for production than handling. The higher potential for exposure to workers occurred during the handling process. However in this study, the sample size was small, and there was no clear method for determining personal exposure and therefore, most of the samples collected were area samples ("Occupational Exposure to Titanium Dioxide - NIOSH," 2009), ("Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles - NIOSH," 2009).

A study that was done by Ji Jun Ho *et al.* in a laboratory at Korea which was used to manufacture TiO₂ nanoparticles using various real-time aerosol detectors (Ji *et al.*, 2015). The monitors were set up in two locations to differentiate task or process based exposure from background measurements. The TiO₂ nanoparticles were produced through a flame synthesis process and collected by a bag filter system and ten measurements were made sequentially at both the inlet and outlet using real time detectors. The simulation of this release was done using a commercial computational fluid dynamics (CFD) software FLUENT. The results showed that during the manufacturing process, high concentrations of TiO₂ nanoparticles were measured mainly as a result of low collection efficiency of the bag filter and low flow rate of the receiving extraction hood. The results were confirmed by the CFD simulation, which predicted that large amounts of nanoparticles would be released from the bag filter system. For this study, no personal samples were taken and real time detectors should not be considered as a substitute for traditional sampling. They can be used but as a surrogate, especially when sampling nuisance dusts or well characterized dust or when monitoring for time varying levels of dusts to detect peaks or point sources and cannot be compared meaningfully against exposure limits (Plog and Quinlan, 2002).

Another research study in Korea was done on exposure assessment of workplaces manufacturing nanosized TiO₂ and nano silver (Lee *et al.*, 2011). Personal sampling, area monitoring, and real-time monitoring using a scanning mobility particle sizer (SMPS) and dust monitor were conducted at workplaces where the workers handled these nanomaterials. The results were found to be below the Korean OEL and ACGIH values. The results from the TiO₂ operation exceeded NIOSH REL for ultrafine particles and it did not exceed REL in terms of an 8 h time-weighted average.

One other exposure study was conducted by Heinz Kaminski *et al* in eight industrial work areas in production plants of TiO₂ and Al₂O₃ nanoparticles (Kaminski, 2015). This was done mainly to examine the correlation between the existing background measurement strategies and to derive a first assessment of possible exposure to workers. The results from this study may be used to validate the fact that a second measurement location to calculate the background particle concentration is necessary, in addition to the personal or area sample at the work area (over a period of 8 hours). Theoretically measurements at the background measurement location should mirror the area surrounding the work area to be investigated and 'no work activity' particle concentrations (size distributions) at work areas can be calculated from those at the background measurement location. However, based on the results obtained in this study, the measured results were above the theoretically calculated results which suggest that there could be interferences from an auxiliary process located nearby to the background particle measurement location (Kaminski, 2015).

Qualitative Measurement of Potential Exposure To Enm Developed By Niosh:

Currently, there are very few sampling methods that can be used to characterize exposure to ENM. NIOSH has developed the Nanoparticle Emission Assessment Technique (NEAT) to qualitatively determine the release of engineered nanomaterials in the workplace. This approach may be helpful to others for the initial evaluation of workplaces where ENM are manufactured or used. This method compares particle number concentrations and relative particle size at the potential emission source to background particle number concentrations and particle size, providing a semi-quantitative means for determining the effectiveness of existing control measures in reducing engineered nanoparticle exposures. Studies have been performed using this method and this procedure utilizes portable direct-reading instrumentation supplemented by filter-based air samples. However the accuracy of the results was found to vary with the accuracy of these direct-reading instruments (Methner *et al.*, 2010).

Control Banding (Cb) Method of Enm Banding At Workplace:

Control banding is a qualitative or semi-quantitative approach for managing health and safety risks. It was

developed by professionals in the pharmaceutical industry for evaluating the risk of contaminants without an OEL or for which there are few toxicological data (Paik *et al.*, 2008), (Sargent and Kirk, 1988), (Fleury *et al.*, 2013), (Zalk and Heussen, 2011). These new products were classified to 'bands' (Zalk and Heussen, 2011), (Rose *et al.*, 2011). These bands were then defined according to the hazard level of known products similar to those used, taking into account the assessment of exposure at the work station (Fleury *et al.*, 2013), (Rose *et al.*, 2011).

Traditionally, particles concentration in the worker breathing zone is measured by using a sampling pump, which uses forces such as particle inertia and gravity in order to force nanoparticles to follow the sampled air into the sampler line. However, the gravitational field is considerably weak for ENM (Albuquerque *et al.*, 2015). Although some studies suggest that total surface area concentration may be a better exposure index than traditional mass concentration for ENM, no international scientific community has reached consensus (Albuquerque *et al.*, 2015), (NIOSH, 2006), (Guseva Canu *et al.*, 2015).

CB takes into account the procedures implemented, the quantities handled, the duration and frequency of operations performed, and the intrinsic properties of the materials involved, particularly their physical form. Hazard and toxicological data of ENM are still largely unavailable and it currently appears to be impossible to perform tests on a case-by-case basis for a wide variety of nanomaterials (Albuquerque *et al.*, 2015), (Schulte *et al.*, 2008).

In addition to this, a large part of the toxicological effects of both the physical and chemical properties of ENM were not only unknown but were also changing logarithmically (Fleury *et al.*, 2013), (Albuquerque *et al.*, 2015), (Schulte *et al.*, 2008). Given the limited amount of information about health risks that may be associated with nanomaterials, taking measures to minimize worker exposures is deemed necessary. In this case the risk assessment is even more difficult due to the many uncertainties related to both the identification of potential hazards and the characterisation of exposure (Nikodinovska *et al.*, 2015), (Oberdörster *et al.*, 2005), (Zalk and Heussen, 2011), (Albuquerque *et al.*, 2015). These uncertainties have led to the use of control banding approaches to assessing risk levels and guidance for controls for nanomaterials in workplaces.

Application of Control Banding For Measurement of Nanoparticles At Workplace:

Precautionary Matrix, Stoffenmanager Nano, NanoSafer, the ANSES, ISO 12901-2 approach and the Guidance are the tools which are available presently to characterise nanomaterial using CB method (Riediker *et al.*, 2012), ("Synergist - Control Banding & Nanotechnology," 2010). The risk evaluation principle of the control banding model is based on simplified modelling techniques and methods for calculating weighted scores. This evaluation includes three main aspects ("Synergist - Control Banding & Nanotechnology," 2010):

1. Classification of substances according to the risk level.
2. Assessment of workers' exposure: potential exposure and risk assessment.
3. Selection of the control and prevention approach based on a risk score calculated by combining the risk and exposure indexes

Control banding and other risk banding approaches can provide structured frameworks for evaluating nanomaterial exposure risks and making risk management decisions in the absence of OELs or other standards; however, recommended outcomes may differ depending on the model (Michele N, 2014). 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 (Fleury *et al.*, 2013), (Juric *et al.*, 2015).

Real Life Scenario of Cb Nanotool Method Application

The CB nanotool developed by Paik and Zalk have a qualitative risk assessment with CB method which is simple, affordable and is also a comprehensive way for risk assessment of ENM (Paik *et al.*, 2008). The tool uses most easily accessible parameters, such as chemical form, particle size/dimensions, particle shape, surface reactivity, solubility, aggregation or agglomeration potential, dustiness potential, purity of material, flammability, flash point, substrate toxicity, LD₅₀, mutagenicity, carcinogenicity, reproductive toxicology, dermal effects, bioaccumulation potential and other limited available data on the toxicity of ENM. The results were found to be in agreement with findings of other studies on effective role of size, shape, solubility and surface area of ENM on toxicity level of ENM (Paik *et al.*, 2008). In addition to this the CB Nano Tool outcomes have been compared with occupational hygienists' evaluations and show a good agreement (Paik *et al.*, 2008), (Fleury *et al.*, 2013). However, much of the initial research and development (R&D) in ENM were still performed in academic research laboratories and the quantity of ENMs used tends to be less than those used in industry (Paik *et al.*, 2008). Furthermore, academic practices tend to be less standardized than typical industrial processes. This means that engineering controls which are commonly used in industry may not be practical to apply in academic laboratory research settings.

A study was conducted to evaluate six task based exposure samples in a semiconductor manufacturing

environment. Data on the material hazard and exposure/emission potential that were available onsite were collected from a review of documentation and this information was subjected to ANSES, CB nanotool, ISO 12901-2 and Precautionary Matrix tools. There were differences in the specific input parameters used by the four approaches, as well as how the same property was applied or measured and its relative importance in the tools. Application of the ANSES approach resulted in the lowest control level for all six scenarios evaluated, while CB nanotool indicated a risk level of either 1 or 2 out of 4 tasks evaluated. The controls recommended by the ISO 12901-2 approach were more conservative (increase of at least one band) than the other two control banding models for five of the six tasks evaluated. Precautionary Matrix recommended a review of existing measures for all exposure scenarios evaluated except for one task. However for this study, comparisons from model application were based on a small sample size and a narrow scope and the results did not comprise of a consensus outcome among multiple users (Michele N, 2014).

Another study was done in 2014 to assess and control exposure of nanoparticles emitted during MAG (Metal Active Gas) welding operations by using CB nanotool. Risk assessment was mainly based on chemical composition of the filler material, shielding gas and base material to be welded. The results from the study show that the recommended protection measures were considered adequate (engineering control which comprised of local exhaust ventilation) (Albuquerque *et al.*, 2015), (João Gomes *et al.*, 2014). However, this approach is qualitative and somewhat general as only a few parameters were considered for evaluation.

Conclusion:

The absence of well defined OELs as well as a lack of understanding of available monitoring equipment and analytical methods hinder exposure monitoring efforts (Methner *et al.*, 2009), (Methner *et al.*, 2010), ("Synergist - Control Banding & Nanotechnology," 2010). The methods of protection used for chemicals include some that are suitable for the handling of nanomaterials (Paik *et al.*, 2008), (Brouwer *et al.*, 2009), (Zalk and Heussen, 2011). Industrial hygienists must adopt a conservative approach and not assume that health and safety data for a non-nanomaterial would also hold true for its nanoscale version, until an OEL is established (Methner *et al.*, 2009), (Methner *et al.*, 2010). When all the required data become available, the control banding approach can be viewed on the same platform as quantitative risk assessment (Paik *et al.*, 2008), (Nikodinovska *et al.*, 2015). Control banding is not intended to replace traditional risk evaluation methods, but is instead a complement to them ("Synergist - Control Banding & Nanotechnology," 2010). Additional studies are needed to investigate potential adverse health effects from exposures to ENM, the ranges of associated doses, and the scenarios where such exposures may occur in the workplace. Complementing this, the CB methods was also found to be consistent with industrial hygiene professional judgment (Paik *et al.*, 2008), (Zalk and Heussen, 2011). The exposure assessment, risks and health issues presented in this review study indicate that at present, a few ENM can be approached as a logical subset of traditional exposure assessment and CB approach. The main challenge for both the methods is to provide a consistent and effective exposure assessment.

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