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Can Control Banding be Useful for the Safe Handling of Nanomaterials? A Systematic Review

Adrienne Eastlake, MS, REHS/RS[1], **Ralph Zumwalde, MS**[2], and **Charles Geraci, PhD, CIH**[1]

[1]Nanotechnology Research Center, National Institute for Occupational Safety and Health

[2]RCS Corporation

Abstract

Objectives—Control banding (CB) is a risk management strategy that has been used to identify and recommend exposure control measures to potentially hazardous substances for which toxicological information is limited. The application of CB and level of expertise required for implementation and management can differ depending on knowledge of the hazard potential, the likelihood of exposure, and the ability to verify the effectiveness of exposure control measures. A number of different strategies have been proposed for using CB in workplaces where exposure to engineered nanomaterials (ENMs) can occur. However, it is unclear if the use of CB can effectively reduce worker exposure to nanomaterials. A systematic review of studies was conducted to answer the question "can control banding be useful to ensure adequate controls for the safe handling of nanomaterials."

Methods—A variety of databases were searched to identify relevant studies pertaining to CB. Database search terms included 'control', 'hazard', 'exposure' and 'risk' banding as well as the use of these terms in the context of nanotechnology or nanomaterials. Other potentially relevant studies were identified during the review of articles obtained in the systematic review process. Identification of studies and the extraction of data were independently conducted by the reviewers. Quality of the studies was assessed using the Methodological Index for Non-Randomized Studies (MINORS). The quality of the evidence was evaluated using Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Results—A total of 235 records were identified in the database search in which 70 records were determined to be eligible for full-text review. Only two studies were identified that met the inclusion criteria. These studies evaluated the application of the CB Nanotool in workplaces where ENMs were being handled. A total of 32 different nanomaterial handling activities were evaluated in these studies by comparing the recommended exposure controls using CB to existing exposure controls previously recommended by an industrial hygienist. It was determined that the selection of exposure controls using CB were consistent with those recommended by an industrial hygienist

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CORRESPONDENCE, Adrienne Eastlake, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS-C14, Cincinnati, Ohio, 45226, Phone: 513-533-8524, Fax: 513-533-8588, aeastlake@cdc.gov.

CONFLICT OF INTEREST
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for 19 out of 32 (59.4%) job activities. A higher level of exposure control was recommended for nine out of 32 (28.1%) job activities using CB while four out of 32 (12.5%) job activities had in place exposure controls that were more stringent than those recommended using CB. After evaluation using GRADE, evidence indicated that the use of CB Nanotool can recommend exposure controls for many ENM job activities that would be consistent with those recommended by an experienced industrial hygienist.

Conclusion—The use of CB for reducing exposures to ENMs has the potential to be an effective risk management strategy when information is limited on the health risk to the nanomaterial and/or there is an absence of an occupational exposure limit (OEL). However, there remains a lack of evidence to conclude that the use of CB can provide adequate exposure control in all work environments. Additional validation work is needed to provide more data to support the use of CB for the safe handling of ENMs.

Keywords

Nanomaterials; Control Banding; Nanotechnology; Systematic Review

INTRODUCTION

The traditional approach to protecting worker health has been the measurement of worker exposures to potentially hazardous agents (NIOSH, 2009b). Measurements of worker exposures to these agents are typically compared to occupational exposure limits (OELs) to determine if existing control measures provide adequate protection. Reliance on this approach has become increasingly difficult due to the growing number of potentially hazardous materials in the workplace that do not have OELs (Garrod & Rajan-Sithamparanadarajah, 2003). Nanoscale materials are becoming commercially available, and in many cases these nanomaterials have not been well characterized with regard to their potential toxicity. Their introduction into the workplace has created a challenge in assuring that their development, manufacture, production, and use can be performed safely. Given the limited information about the health risks associated with occupational exposure to these nanomaterials, individual companies, trade associations, and government agencies have instituted various risk management strategies to protect the health of workers who may come into contact with these materials.

The International Organization for Standardization (ISO) has developed nomenclature and terminology for defining nanomaterials (International Organization for Standardization (ISO), 2008). According to ISO, nanomaterials are comprised of nano-objects which have one, two, or three external dimensions in the size range from approximately 1–100 nanometers (nm). These materials can be produced as nanoscale powders or as suspensions incorporated in materials and devices. Because of their small size and low density, aerosolization of these materials can occur during their production, use, and disposal creating a risk for inhalation and dermal exposure (Castranova, 2011).

The large and rapidly growing number of types and structures of nanomaterials (e.g. nanoparticles, nanofibers, nanotubes) has presented a major challenge as it is impossible to perform toxicological evaluation on each nanomaterial prior to potential worker exposure.

These data limitations include: 1) the absence of information on the relationship between size, structure, and physical and chemical properties on toxicity, 2) the uncertainty of lung deposition and clearance of particles from the lung, including transport to other organs, 3) no consensus on relevant indices of exposure (e.g., mass, surface area, particle size/number), and 4) lack of workplace exposure information and populations at risk (i.e. higher risk workers, pregnant women, children) (Creutzenberg et al., 2012; Kan et al., 2012; Khandoga et al., 2010). Only a few types of nanomaterials (i.e., titanium dioxide, carbon nanotubes and nanofibers) have undergone extensive toxicological evaluation. Results from animal studies with titanium dioxide and other poorly soluble, low-toxicity particles of fine and ultrafine (nanoscale) sizes have shown adverse pulmonary responses in exposed rats, including persistent pulmonary inflammation and lung tumors (Donaldson, 2009; NIOSH, 2011; Oberdörster, 2002; Poland et al., 2012). Similar toxicological responses (e.g., pulmonary inflammation, fibrosis) have also been observed in rats and mice exposed to carbon nanotubes and nanofibers (NIOSH, 2013a). Since it is unlikely that a full assessment of bioactivity can be conducted for every possible type of nanomaterial, Kuempel, Castranova, Geraci, and Schulte (2012) have suggested that risk management strategies (e.g., workplace exposure controls) could be developed for specific groups of nanomaterials that exhibit similar relationships between physical and chemical properties and their resultant bioactivity.

Control of Workplace Exposures using Control Banding (CB)

Published studies have reported workplace factors that can increase the potential for worker exposure to engineered nanomaterials (ENMs), including: working with nanomaterials in liquid during pouring or mixing operations, generating ENMs in open systems, handling powders of nanostructured materials, and machining, sanding, drilling of ENM composites (NIOSH, 2009a). Available workplace exposure data indicate that airborne exposure to ENMs can be minimized at most processes and job tasks using engineering control techniques similar to those used in reducing exposures to fine dusts and other aerosols such as source enclosure and local exhaust ventilation systems (Evans, Ku, Birch, & Dunn, 2010; NIOSH, 2009a, 2013b; Old & Methner, 2008; Schulte, Geraci, Zumwalde, Hoover, & Kuempel, 2008; Tsai, Huang, & Ellenbecker, 2010). It has been suggested that the use of engineering control techniques as part of a CB strategy can assist businesses in reducing occupational exposures to ENMs (Brouwer, 2012; Maynard, 2007; NIOSH, 2013b; Paik, Zalk, & Swuste, 2008; Riediker et al., 2012; D. M. Zalk, Paik, & Swuste, 2009).

CB has been described as a qualitative or semi-quantitative approach to risk assessment and risk management that uses occupational exposure control strategies, based on predetermined exposure bands or other information on workplace exposures, to assist in reducing workers' exposures to potentially hazardous materials. In theory, CB incorporates a hierarchy of risk management approaches for controlling exposures to hazardous materials that typically includes: 1) containment of the potential hazard, 2) engineering controls, including local exhaust ventilation (LEV), 3) good occupational hygiene practices (which may include personal protective equipment (PPE)), and 4) the need to seek specialist advice depending on the particular CB strategy. Some CB strategies focus on the hazard potential of the material by assigning it a specific 'control band' based on the possible hazard severity of the material (e.g., captured by risk phrases or other indicators of toxicity) and in some cases, based on exposure potential (e.g., quantity used, volatility, dustiness). Other CB strategies focus on the task performed to assign exposure control options and PPE directly without the interim step of assessing the potential exposure. CB strategies can be applied in workplaces to reduce airborne exposures to hazardous materials (e.g., chemicals) where OELs may or may not exist for the materials of interest.

A number of CB strategies have been proposed for various workplace scenarios (e.g., small and large industries) in which different levels of expertise are required depending on the availability of hazard information (e.g., toxicology) and workplace exposure data. These strategies have been used in a number of countries, particularly in Europe, where such strategies often use a combination of “hazard bands” (i.e., hazard potential of the material) with “exposure potential” to determine the desired level of exposure control. The hazard and exposure information (e.g., risk phrases) typically gathered in this process is used to place materials into two to five different ‘levels’ or ‘bands’ based upon their risk characterization or risk phrases. These sets of levels or bands are combined in a matrix resulting in a control band that specifies a level of exposure control. One of the earliest attempts of banding risks for hazardous substances and their exposure controls was devised by the chemical industry to address the potential and severity of a catastrophic event at a large chemical plant (i.e. explosion, radiation, or chemical release) in the absence of complete hazard information (C Money, 2003). This strategy was later expanded by the pharmaceutical industry to address the control of exposures to potentially biologically active and toxic materials that had little or no toxicity information available (Naumann et al., 1996; Sargent & Kirk, 1988). This risk management model helped to establish performance-based exposure control limits (PB-ECLs) based on available toxicological and pharmacological information. These PB-ECLs were used to develop five hazard control categories in which specific engineering control and administrative procedures were recommended to control exposures (Farris, Ader, & Ku, 2006; Naumann et al., 1996; Tait, 2004). Other CB strategies have been proposed world-wide that differ in their application and the level of expertise required for their implementation and management (Alain Balsat, De Graeve, & Mairiaux, 2003; A Balsat, Mairiaux, & De Graeve, 2002; J. Cherrie, Schneider, Spankie, & Quinn, 1996; J. W. Cherrie & Schneider, 1999; Hashimoto et al., 2007; International Organization for Standardization (ISO), 2013; Jones & Nicas, 2006a, 2006b; Lee, Harper, Bowen, & Slaven, 2009; Lee, Slaven, Bowen, & Harper, 2011; Marquart et al., 2008; Chris Money et al., 2006; Schinkel et al., 2010; Tischer, Bredendiek-Kämper, & Poppek, 2003; Tischer, Bredendiek-KÄmper, Poppek, & Packroff, 2009; Van de Ven et al., 2010). Not all of these proposed CB strategies have been adequately described in the published literature. Although differences exist among strategies, all of them include the following elements: 1) the need to conduct appropriate hazard assessments to classify the potential hazard, 2) an assessment of worker exposures, 3) implementing and verifying the proper control measures, and 4) communicating to workers all risk management actions taken (D. Zalk & Nelson, 2008). All proposed strategies provide elements of risk assessment and management that can be customized to manage the handling of potentially hazardous materials in the absence of OELs (Chemical Industries Association (CIA), 1992; Gardner & Oldershaw, 1991; Guest, 1998; CD Money, 1992; Naumann et al., 1996; Russell, Maidment, Brooke, & Topping, 1998). These CB strategies have been adopted for different materials and industries, but the basic premise of the strategy remains the same (Brouwer, 2012).

Overview of CB Strategies for Nanomaterials

While it is important to characterize and manage the potential health risks associated with exposure to ENMs, the data to quantify the potential health concerns for the development of OELs are lacking. In the absence of such data, the use of CB strategies has been suggested as a pragmatic approach to manage the potential health risk resulting from exposure (Kuempel et al., 2012; Maynard, 2007; Schulte et al., 2008). A number of CB strategies have been proposed for use in workplaces where exposure to ENMs may occur. These nanomaterial specific strategies include, CB Nanotool, Precautionary Matrix, the French Agency for Food, Environmental and Occupational Safety (ANSES), Stoffenmanager® Nano, NanoSafer (Danish only) and Guidance (Cornelissen, Jongeneelen, & van Broekhuizen, 2011; Groso, Petri-Fink, Magrez, Riediker, & Meyer, 2010; Höck et al., 2008; Ostiguy, Riediker, Triolet, Troisfontaines, & Vernez, 2010; Paik et al., 2008; Riediker et al., 2012; Schneider et al., 2011; Van Duuren-Stuurman et al., 2012; D. M. Zalk et al., 2009). Brouwer (2012) reviewed each of these strategies for their scope and applicability, parameters for hazard and exposure banding, and classification in risk or control bands. Each strategy was found to represent different target users and applicability domains (i.e. laboratory versus small business). In addition, the amount and detail of information and professional knowledge required for implementing each strategy varied. ANSES, Stoffenmanager Nano, and Guidance were judged to be the most robust tools based on the amount of information required and the wide range of activities that could be evaluated by the strategies. Brouwer (2012) found that the CB Nanotool and ANSES strategies relied more on the need for safety and health expertise to use the tool, whereas both Stoffenmanager Nano and Guidance were intended to be used by non-experts. Brouwer (2012) concluded that while there remains uncertainty about how to select appropriate control bands in the absence of toxicology and exposure data for ENMs, several of the proposed strategies attempt to address this concern by: 1) taking a precautionary approach by assigning high hazard bands, and consequently assigning high risk or control bands, 2) identifying high-concern substances based on particle structure (e.g., fiber), or 3) identifying a single hazard parameter such as carcinogenicity to influence the selection of the control band.

Regardless of the CB strategy used, the uncertainty of the potential health risks of ENMs seems to result in a conservative hazard characterization that results in a high level of risk determination requiring a high level of exposure control that may not be necessary for all ENMs (Brouwer, 2012; Fleury, Fayet, Vignes, Henry, & Frejafon, 2013). Although each CB strategy has its own individual strengths, it is not possible to completely evaluate each CB strategy until their application has been applied and evaluated in more workplaces (Brouwer, 2012). A summary of the various ENM control banding strategies is presented in Table 1.

Various concerns have been raised regarding the inability to adequately characterize worker exposure to ENMs and the lack of information validating the effectiveness of exposure control strategies (C Money, 2003). In addition, there are a lack of OELs that are specific to the burgeoning number of ENMs currently in use in occupational settings. Juric, Meldrum, and Liberda (2015) have proposed the use of a Nanomaterial Occupational Exposure Management (NOEM) strategy to reduce exposures to ENMs. In the absence of OELs for ENMs, the NOEM strategy uses *Nano Reference Values* (*NRVs*) for evaluating the effectiveness of exposure controls used in a CB strategy. NRVs include a shift from the traditional toxicity-based hazard approach (risk = hazard x exposure) to a concern-based approach (risk = concern x exposure) (Hendrikx & van Broekhuizen, 2013). As toxicity information is not available for all ENMs, this approach is desirable as it takes into account existing toxicity information and places materials into hazard bands based on expected or anticipated toxic effects. NRVs provide an 8-hour time weighted average based on physicochemical attributes such as density, biopersistence, shape, and size (Hendrikx & van Broekhuizen, 2013).

METHODS

Search strategy

A systematic review of the literature was conducted to determine whether the use of CB strategies has been effective in reducing worker exposure to ENMs. A literature database search was performed on July 29, 2013 to identify records that describe control band(ing) and/or exposure band(ing) and/or risk band(ing). The following databases were searched: ProQuest ABI/Inform Complete™, Article bibliography, Compendex, ProQuest COS conference papers index, Defense Technical Information Center (DTIC®) online, Embase™ Biomedical Database, Health and Safety Science abstracts, NIOSHTIC-2, OSH References Collection, PapersFirst® Database, PubMed, Risk Abstracts, Toxicology Abstracts, Toxicology Literature Online (Toxline), Thomson Reuters Web of Science™, and WorldCat®. The complete list of search strategies for each database is available in Annex A. No publication date or publication status restrictions were imposed. All searches were limited to English. The following search terms were used to search PubMed: (Occupational Exposure OR Occupational) AND (Control Band OR Control Bands OR Control Banding OR Exposure Band OR Exposure Bands OR Risk Banding OR Hazard Band OR Hazard Bands) AND English.

The titles of all records obtained via search were independently assessed for relevance by two reviewers. Records were excluded if they did not contain a reference to control and/or exposure and/or risk banding. Records were also excluded if they corresponded to a PowerPoint presentation, a conference abstract, a thesis or dissertation, or a review article. Disagreements between the two reviewers were resolved by using all the records that each reviewer deemed appropriate for full text review. Each reviewer performed a review of the full-text of these records. During full-text review, articles were excluded if they did not apply control banding methodology to the use of nanomaterials.

Results from the literature search

All studies that described the application of CB in the workplace were considered. The only studies that were included were those that indicated the use of CB to evaluate activities involved in the handling of nanomaterials. Studies that were similar in task description were summarized and compared (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). A total of 226 records were identified through database searches. An additional 15 records were obtained from the ISO Control Banding approach (International Organization for Standardization (ISO), 2013). After removal of duplicate records, a total of 235 records were available for title review. A total of 165 records were removed based on the title if the record did not contain a reference to control and/or risk banding. Both reviewers independently reviewed all article titles for applicability. A list of 70 articles was generated that included all the articles that each reviewer recommended for full record review. Based on limitations (conference proceedings, abstracts, presentations, etc.) only 48 of these records were able to be obtained for full review. Two additional duplicate records were noted and removed at this time. Based on full record review, a total of 44 articles were excluded. The removed articles were either not nanomaterial specific or if they were nanomaterial specific, they did not apply CB strategies to nanomaterial exposures. Excluded records and the reason for exclusion are listed in Annex B. A flow diagram of the study selection process is given in Figure 1.

Data synthesis

Two studies were identified as being relevant to the use of CB (i.e., CB Nanotool) for controlling exposures to ENMs (Annex C). Data were extracted from these studies using a data extraction sheet that was developed and refined by the reviewers prior to the data collection process. The information that was extracted included: (1) task description, (2) name or description of nanomaterial, (3) current engineering control recommended by industrial hygienist and/or safety and health expert, (4) CB Nanotool severity band, (5) CB Nanotool probability band, (6) overall risk level without controls, (7) recommended engineering control based on CB Nanotool risk level, (8) did CB Nanotool recommend upgrading the engineering control currently in use, (9) and the version of CB Nanotool used. One reviewer extracted the data from the studies and the other reviewer checked the extracted data for accuracy. If any disagreements occurred between the reviewers they were resolved by discussion.

Quality of the Evidence According to MINORS and GRADE

Each reviewer independently generated an evidence profile for each of the two studies using the Methodological Index for Non-Randomized Studies (MINORS) checklist, results were discussed, and the risk of bias assessment profiles were generated (Slim et al., 2003). One reviewer extracted the data from the studies and the second reviewer checked the extracted data for accuracy. If any disagreements occurred between the reviewers they were resolved by discussion. It was determined that a score ≤ 50% of the total score of 16 points (uncontrolled) and of 24 points (controlled) would be considered high risk of bias (Annex D). Each study provided adequate information on the following criteria: 1) *a clearly stated study aim*: to determine how the CB Nanotool recommendations compared to those provided by an industrial hygienist; 2) *prospective collection of data*: all data were collected according to a protocol established before the beginning of the study, and 3*) endpoints appropriate to the aim of the study*: the criteria used to evaluate the outcome of the study was explained. Information on the following was provided in each study, but wasn’t considered to contain sufficient detail to be deemed adequate: 1) *inclusion of consecutive workplaces*: only a small number of activities were included in each study therefore leading to a small sample number; and 2) *unbiased assessment of the study endpoint*: exposure assessment data were either not provided or deemed not to support the recommendations of the industrial hygienist, therefore, indicating unsubstantiated conclusions. This information was rated based on the quality of the data provided in the record. No information was provided in the records to indicate that a score should be assigned based on the following criteria: 1) *loss of follow-up and follow-up period*: even though the CB Nanotool was altered between the studies, no reanalysis was performed on the activities performed in the initial study; and 2) *calculation of the study size*: statistical analysis of the study size was not performed. The following scores were used to rate the quality of evidence in the records reviewed: 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). If no information was provided in the record to meet the criteria, then a score of 0 was assigned. Using MINORS, each reviewer gave an evidence criteria score of 8 (8 out of a possible 16) for each study. This score indicates that the studies were at a high risk of bias for determining the usefulness of CB in controlling exposure to ENMs (Slim et al., 2003).

In addition, the risk of bias within the included studies was rated using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (GRADE Working Group, 2004). GRADE is a specific systematic review methodology that evaluates multiple dimensions of the study to include the following: risk of bias, consistency, directness, precision, and publication bias. For observational studies, such as those evaluated in this review, low quality of evidence was assumed if evidence was problematic in one or more of the following five domains: study limitations, inconsistency, indirectness, imprecision, and publication bias. If any problems were observed the quality was downgraded by one or more levels. If there were positive features in one or more of the following domains the quality was upgraded: a large effect, a dose response gradient, and possible biases underestimate the possible true effect. The following scores were used in evaluating the studies: 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). If no information was provided in the study to meet the criteria, then a score of 0 was assigned. The overall quality of the evidence conforming to the GRADE evaluation (Table 2) resulted in a rating of very low quality of evidence (Atkins et al., 2005; Atkins et al., 2004; GRADE Working Group, 2004; Guyatt, Oxman, Kunz, Falck-Ytter, et al., 2008; Guyatt, Oxman, Kunz, Vist, et al., 2008; Guyatt, Oxman, Vist, et al., 2008).

RESULTS

Study characteristics, risk of bias, and results

The 2008 study by Paik et al. (2008) introduced the CB Nanotool as a strategy for assessing the potential risk of working with ENMs and providing recommendations for appropriate engineering controls. The severity/probability matrix used in the CB Nanotool is similar to that used in the Control of Substances Hazardous to Health (COSHH) essentials. The CB Nanotool uses a numerical rating system of 1 to 4 based on definitions assigned to hazard severity and probability bands. The severity band is determined by answering questions about the physical-chemical characteristics of both the nanomaterial and the bulk form of the material. The answers have a set rating score based on what is known about the material.

The probability band is determined by answering questions about the potential worker exposure. This information is converted to a score. Summaries of the severity and probability scores and the associated maximum point values are listed in Table 3. The severity and probability scores were then applied to the matrix in Figure 2. A risk level (RL) is assigned to one of four different control bands: RL 1, General Ventilation; RL 2, Fume Hood or Local Exhaust Ventilation; RL 3, Containment; RL 4, Seek specialist advice. If the answer to any question was "unknown," that score was assigned a value that was 75% of the maximum value. In practice, assigning a 75% score on all questions (unknown nanotechnology-based task and product) would be translated by the CB Nanotool as RL 3, which would necessitate the use of exposure containment.

The 2009 study reported by D. M. Zalk et al. (2009) described revisions to the CB Nanotool scores based on input from a group of experts at Lawrence Livermore National Laboratory (see Table 2). The maximum number of points and associated ranking were altered to incorporate an asthmagen factor for both the nanomaterial and the bulk form of the material. The overall maximum severity score remained the same and no changes were made to the probability score.

The maximum number of points associated with the severity rating scale used for the CB Nanotool decreased from those published in 2008 (Paik et al., 2008) to those in 2009 (D. M. Zalk et al., 2009) for the following health concerns: carcinogenicity, reproductive toxicity, mutagenicity, and dermal toxicity. An additional health concern, asthmagen, was added for determining the severity score in the 2009 update of the CB Nanotool. This change in the allocation of points between the 2008 and 2009 studies created a minor difference but the results were considered marginal.

In the 2008 and 2009 studies a total of 32 nanomaterial handling activities were evaluated using the CB Nanotool (Paik et al., 2008; D. M. Zalk et al., 2009). These activities used different types of nanomaterials in different physical forms. The tasks varied in scope but could be grouped into the following job activities: synthesis or growth of material, sample preparation, product mixing or manipulation, and waste handling activities. The professional evaluation and judgment of an experienced industrial hygienist were used to determine the initial exposure control used for the job activity; quantitative exposure measurements were not taken. Following evaluation of the job activity and the assessment of the material being used, the recommended exposure control using CB Nanotool was compared to the in-place exposure control to verify whether the same level of exposure control would have been recommended. The results of how the recommendations for exposure control using CB Nanotool compared with those of expert judgment are presented in Table 4.

Narrative Summary of the Evidence Identified in the Systematic Review

Based on assessment of the 32 nanomaterial activities from the 2008 and 2009 studies (Annex E), it was determined that the exposure controls recommended by using the CB Nanotool were consistent with what was recommended by an industrial hygienist for 19 out of 32 (59.4%) job activities. The need for a higher level of exposure control was recommended nine out of 32 (28.1%) using CB while four out of 32 (12.5%) activities had exposure controls in place that were more stringent than those recommended using the CB

Nanotool. These data indicate that when directly compared to the recommendations by an industrial hygienist, the CB Nanotool provided: 1) a more conservative and protective control approach 28.1% of the time, 2) exposure controls that were consistent almost 60% of the time, and 3) recommendations for exposure control that were less stringent 12.5% of the time.

When all 32 job activities are consolidated into four categories (Table 5), differences in exposure controls recommended using professional judgement by the industrial hygienist and those recommended using CB Nanotool can be found. For example, use of the CB Nanotool appears to recommend a more conservative exposure control practice when handling nanomaterial waste which may have been due to the lack of ENM exposure information (unknown) for that activity. Consequently, by using “unknown” as a response when using the CB Nanotool, a potential ‘high risk level’ is assigned which triggers the use of a ‘high level of exposure control’ for that activity.

DISCUSSION

There was “low quality of evidence” from the Paik et al. (2008) and D. M. Zalk et al. (2009) studies when exposure controls recommended by the use of CB Nanotool were compared with those recommended by an experienced industrial hygienist. The following data limitations were identified from the evaluation:

- Field-based data was not available for validation of nanomaterial-specific methods to determine if controls provided sufficient worker protection.
- Available information did not provide sufficient evidence for characterizing the physical-chemical properties of the nanomaterials used in reported studies
- An absence of hazard data associated with a specific nanomaterial
- No indication of the exposure potential for each nanomaterial at job tasks/ processes
- No criteria/rationale provided as to why the industrial hygienist selected a particular exposure control strategy for a particular job task
- Studies assumed that exposure controls recommended by the industrial hygienist are the appropriate controls for the given job task. No data presented to verify that the exposure controls were reducing exposures to “acceptable exposure concentrations”
- Specific information was not provided on recommended engineering controls (i.e. air flow, size, the anticipated reduction in exposure concentrations)

Use of Other Control Banding Strategies

Various concerns have been raised regarding the efficacy of specific CB strategies because of limited information validating the effectiveness of these exposure control strategies (C

Money, 2003). Much of the published research on the strengths and weaknesses of CB has focused on the COSHH Essentials method and the ILO Toolkit (C Money, 2003). Russell et al. (1998) reported that the exposure control levels recommended in the COSHH Essentials strategy were frequently in agreement with, or more stringent than, expertly derived health-based OELs. These findings were similar to those reported by Bracker, Morse, and Simcox (2009) in which the application of COSHH Essentials exposure bands were in general agreement (65%) with the exposure evaluations conducted by a certified industrial hygienist. Tischer et al. (2003) also found reasonably good agreement between the COSHH Essentials exposure bands and measured airborne concentrations of solids and organic solvents (when used in medium quantities), but found that exposure concentrations could exceed predicted ranges when small quantities of organic solvents (medium/high volatility) were used. Lee et al. (2009) also found the COSHH Essentials to perform reasonably well for short-term task-based and full-shift exposures to organic chemicals in small and medium-sized businesses. However, Jones and Nicas (2006a), in their evaluation of vapor degreasing and bag filling operations, found that the use of exposure bands does not always provide consistent, or adequate margins of safety when used with control bands. Because of the high rate of under-control errors, Jones and Nicas (2006b) highlighted the need to evaluate the effectiveness of installed exposure control systems using capture efficiency and/or air monitoring measurements. In addition, they suggested that the use of CB strategies (such as COSHH Essentials or the ILO toolkit), instead of using health-based OELs, may not provide adequate worker protection. In a pilot study at the Lawrence Livermore National Laboratory, ‘preliminary control bands’ were established based on knowledge of the physical and chemical properties of the ENM including the particle size, morphology, agglomeration state, chemical composition, and solubility (Casuccio et al., 2010). The effectiveness of the recommended exposure control measures were subsequently evaluated by sampling worker exposure to ENMs. Sampling results indicated that the ‘preliminary control bands’ used by researchers to establish exposure controls resulted in airborne concentrations of ENMs that were low or unmeasurable.

A major difficulty to assessing the effectiveness of using CB strategies is the scarcity of data with which to validate available CB models, including the: 1) limited range of exposure situations with which to compare exposure predictions with actual exposure measurements; 2) difficulty in ascertaining the “reported control strategies (i.e., difficulty in classifying controls as control strategies 1, 2, 3 or 4), and; 3) difficulty in retrospectively characterizing the workplace and /or materials in use for comparison of predicted and actual exposures. Another concern that has been raised is that the use of CB may not take into account the variability in airborne exposure concentrations over a work shift and that providing exposure controls without performing exposure measurements would not provide an accurate representation of worker exposures and required controls (Kromhout, 2002).

Implications for Practice

Although further validation of CB strategies for ENMs is needed (e.g., model prediction and quantitative verification of exposures), the use of CB to reduce worker exposures to ENMs may serve as an alternative risk management practice for some processes/job tasks until a more comprehensive assessment can be made of the potential hazard and risk. CB strategies for ENMs have the potential to be entry-level tools for occupational risk management until more information becomes available on the health risks so that appropriate OELs can be developed. The selection of a specific CB strategy should take into account the level of expertise required to evaluate the hazard potential of the nanomaterial, and the availability of resources and information on: the quantity of material used, the potential volatility or dustiness of the material, the physical and chemical characteristics of the nanomaterial, the processes and/or job tasks in which workers are potentially exposed, and worker exposure data. Current efforts to create CB strategies for ENMs have been based almost entirely on the use and evaluation of CB strategies developed and used for reducing exposures to potentially hazardous chemicals. Given current knowledge about the physical and chemical characteristics of ENMs and their possible role in eliciting adverse health effects, use of CB for ENMs needs to be capable of making changes over time for both controls implemented and the managerial oversight to ensure the strategy reflects the most current hazard information. Essential to having a dynamic system for controlling occupational exposures is the development of a protocol that specifies how exposure assessments (actual or estimated) and controls will be validated to ensure that the CB strategy is performing as planned. Creating this system with a task force of health and safety professionals working in concert with managerial oversight and worker representation can help to facilitate the best use of a CB strategy to maximize its effectiveness, consistent application, and efficient use of resources (NIOSH, 2009b).

Implications for Research

The history of CB evolution, application, and evaluation indicates that CB strategies may not provide adequate solutions for the assessment and management of all occupational hazards. Currently, there are situations in which CB cannot provide the precision and accuracy necessary to protect worker health; alternatively, there are situations in which the use of CB may recommend a higher level of exposure control than is necessary (Van Duuren-Stuurman et al., 2012). Although CB is not intended to be a replacement for traditional exposure monitoring and the use of OELs, it can be an integral part of a tiered risk management strategy for controlling worker exposures to ENMs. However, questions remain regarding the validity of the information used in the hazard and exposure assessment component of the CB strategy due to limited published data. Conducting the following research would improve the usability and predictability of CB for nanomaterials:

- Develop an information resource so that small businesses can obtain assistance on interpreting hazard data for nanomaterials and information on implementing control measures
- Develop an information resource that provides data and guidance on the effectiveness of control technologies specific to nanomaterials
- Determine the feasibility of adopting the Globally Harmonized System (GHS) for the classification and labelling of chemicals and that efforts are taken to classify nanomaterial hazards to ensure that standardized hazard statements are available

- Develop training materials for professionals and small business operators on the implementation of CB strategies
- Develop protocols that can be used to validate each step of the CB strategy (e.g., exposure prediction, hazard classification, control recommendations).
- Evaluate errors that have been associated with CB hazard classification, exposure assessment, and control recommendations to determine the accuracy of the model
- Consider dermal absorption as a factor that might make an impact on the hazard classification and control solutions
- Develop strategies for addressing processes with combined chemical (nanomaterial) use, mixtures, and compounds of various compositions that can have additive or synergistic health consequences
- Develop task-based and industry sector toolkits (e.g., construction, healthcare, manufacturing) for nanomaterials

The application and validation of nanomaterial specific CB strategies has not been widely practiced and published. Additional quantitative data should be collected and made available to further validate these methods.

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ANNEXES

A. Complete search strategy for each bibliographic database

B. List of studies excluded at the full-text stage and the reason for exclusion

C. Relevant studies

D. Evidence profiles generated for the two studies using MINORS methodology

E. Summary of the task/activity results across the two selected studies

A. Complete search strategy for each bibliographic database

Strategy for PubMed

("Occupational Exposure"[Mesh] OR Occupational [TW]) AND (Control Band[TIAB] OR Control Bands[TIAB] OR Control Banding[TIAB] OR Exposure Band[TIAB] OR Exposure Bands[TIAB] OR Risk Banding[TIAB] OR Hazard Band[TIAB] OR Hazard Bands[TIAB]) AND English[lang]

Strategy for: RISK ABSTRACTS, TOXICOLOGY ABSTRACTS, HEALTH & SAFETY SCIENCE ABSTRACTS, TOXLINE, COS CONFERENCE PAPERS INDEX, EMBASE, ABI/INFORM, NTIS, NIOSHTIC-2

"Control Band" OR "Control Bands" OR "Control Banding" OR "Exposure Band" OR "Exposure Bands" OR "Exposure Banding" OR "Risk Banding" OR "Hazard Band" OR "Hazard Bands" OR "Hazard Banding"

(Eliminated Risk Band and Risk Bands – different meaning in penal system)

Strategy for: WorldCat, WordCat Dissertations, Papers First, Proceedings First

"banding" OR "risk banding" OR "hazard banding" OR "exposure banding"

Strategy for Web of Science

Topic= ("Control Band" OR "Control Bands" OR "Control Banding" OR "Exposure Band" OR "Exposure Bands" OR "Exposure Banding" OR "Risk Banding" OR "Hazard Band" OR "Hazard Bands" OR "Hazard Banding")

Refined by: Web of Science Categories= (PUBLIC ENVIRONMENTAL OCCUPATIONAL HEALTH OR TOXICOLOGY OR NANOSCIENCE NANOTECHNOLOGY OR ENGINEERING ENVIRONMENTAL) Timespan=All years. Databases=SCI-EXPANDED, CPCI-S, CPCI-SSH.

Strategy for Compendex

Expert Search

34 articles found in Compendex for 1884–2013: ((“Control Band” OR “Control Bands” OR “Control Banding” OR “Exposure Band” OR “Exposure Bands” OR “Exposure Banding” OR “Risk Banding” OR “Hazard Band” OR “Hazard Bands” OR “Hazard Banding”) WN ALL) +(((occupational risks) OR (risk management) OR (risk assessment) OR (nanostructured materials) OR (health risks) OR (hazards) OR (nanoparticles) OR (health hazards) OR (health) OR (industrial hygiene) OR (toxicity) OR (accident prevention)) WN CV) AND ((English) WN LA)

Strategy for DTIC

“control banding OR “exposure banding” OR “risk banding” OR “hazard banding”

Strategy for OSH References Collection (OSHLine; CISILO; HSELine; Canadiana)

“control banding” <OR> risk banding <OR> exposure banding

B. List of studies excluded at the full-text stage and the reason for exclusion

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C. Relevant studies

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D. Evidence profiles generated for the two studies using MINORS methodology

MINORS evidence profile for the following record: Paik S, Zalk D, Swuste P. (2008). Application of a Pilot control Banding Tool for Risk Level Assessment and control of Nanoparticle Exposures. Ann. Occup. Hyg. 52(6):419-428

Criteria	Score[a]
1. **A clearly stated aim**: the question addressed should be precise and relevant in light of available literature	**2**
2. **Inclusion of consecutive workplaces**: all workplaces potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)	**1**
3. **Prospective collection of data**: data were collected according to a protocol established before the beginning of the study	**2**
4. **Endpoints appropriate to the aim of the study**: unambiguous explanation of the criteria used to evaluate the main outcome, which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-address basis.	**2**
5. **Unbiased assessment of the study endpoint**: blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated.	**1**
6. **Follow up period appropriate to the aim of the study**: the follow up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events.	**0** **No follow up**
7. **Loss of follow up less than 5%**: all workplaces should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint.	**0** **No follow up**
8. **Prospective calculation of the study size**: information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing outcomes	**0**
Total	**8**

[a]Items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The highest achievable score is 16 for non-comparative studies.

MINORS evidence profile for the following record: Zalk D, Paik S, Swuste P. (2009). Evaluating the Control Banding Nanotool: a qualitative risk assessment method for controlling nanoparticle exposures. J. Nanopart. Res., 11:1685-1704.

Criteria	Score[a]
1. **A clearly stated aim**: the question addressed should be precise and relevant in light of available literature	**2**
2. **Inclusion of consecutive workplaces**: all workplaces potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)	**1**
3. **Prospective collection of data**: data were collected according to a protocol established before the beginning of the study	**2**
4. **Endpoints appropriate to the aim of the study**: unambiguous explanation of the criteria used to evaluate the main outcome, which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-address basis.	**2**
5. **Unbiased assessment of the study endpoint**: blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated.	**1**
6. **Follow up period appropriate to the aim of the study**: the follow up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events.	**0** **No follow up**
7. **Loss of follow up less than 5%**: all workplaces should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint.	**0** **No follow up**
8. **Prospective calculation of the study size**: information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing outcomes	**0**
Total	**8**

[a]Items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The highest achievable score is 16 for non-comparative studies.

E. Summary of task/activity results across the two selected studies

Task Description	Name or description of NM	Current Engineering control recommended by safety and health expert	CB Nanotool severity band	CB Nanotool probability band	Overall risk level without controls	Recommended engineering control based on control banding nanotool risk level	Version of Nanotool
Synthesis of metal foams	Metal NPs	Containment	High	Likely	3	Containment	2008
Flame synthesis	Ceramic NPs	Fume hood or LEV	Medium	Likely	2	Fume hood or LEV	2008
Synthesis within a tube furnace	Carbon nanotubes	Containment	High	Extremely unlikely	2	Fume hood or LEV	2008
Consolidation	Ceramic NPs	Fume hood or LEV	High	Likely	3	Containment	2008
Preparation/drying of sample	Uranium dioxide	Containment	High	Likely	3	Containment	2008
Synthesis of nanowires	Metal oxides	Containment	High	Extremely unlikely	2	Fume Hood or LEV	2009
Synthesis	Metal NPs	Fume hood or LEV	High	Less likely	2	Fume Hood or LEV	2009
Maintenance of a tube furnace	Metal NPs	Containment	High	Likely	3	Containment	2009
Surface deposition of NPs	Polymer and metal NPs	General ventilation	Medium	Extremely unlikely	1	General ventilation	2009
Composite manipulation	Various NPs	Fume hood or LEV	Medium	Extremely unlikely	1	General ventilation	2009
Pouring of water into NP slurry	Carbon nanotubes	Fume hood or LEV	High	Extremely unlikely	2	Fume hood or LEV	2009
Gold NP testing carbon nanotube filter	Gold NPs	General ventilation	Medium	Extremely unlikely	1	General ventilation	2009
Mixing and etching	Polystyrene spheres and NPs	General ventilation	Medium	Extremely unlikely	1	General ventilation	2009
Adding quantum dots to glass	Cadmium selenide, lead sulfide	Fume hood or LEV	High	Extremely unlikely	2	Fume hood or LEV	2009
Growth of palladium catalyst	Palladium nanocatalyst	Fume hood or LEV	High	Less likely	2	Fume hood or LEV	2009
Sample preparation and characterization	Gold and silver NPs	General ventilation	Medium	Less likely	1	General ventilation	2009
Sample preparation and characterization	Oxides of iron, aluminum, silicon dioxide, ceramic aerogels and nanopowders	Fume hood or LEV	Medium	Less likely	1	General ventilation	2009
Synthesis of aerogel	Zinc and titanium NPs	General ventilation	Medium	Extremely unlikely	1	General ventilation	2009
Synthesis of aerogel	Silica, iron, chromium, copper, zinc NPs	General ventilation	Medium	Extremely unlikely	1	General ventilation	2009
Synthesis and characterization	Quantum dots, iron oxide, gold, lead sulfide NPs	General ventilation	High	Less likely	2	Fume hood or LEV	2009
Sample preparation and characterization	Quantum dots	Fume hood or LEV	High	Less likely	2	Fume hood or LEV	2009
Sample preparation and characterization	Carbon diamonoids	Fume hood or LEV	High	Less likely	2	Fume hood or LEV	2009
Sample preparation and characterization	Gold and silver NPs	General ventilation	High	Less likely	2	Fume hood or LEV	2009
Preparation of nanofoam	Gold, copper, aluminum, nickel NPs	General ventilation	High	Extremely unlikely	2	Fume hood or LEV	2009

Task Description	Name or description of NM	Current Engineering control recommended by safety and health expert	CB Nanotool severity band	CB Nanotool probability band	Overall risk level without controls	Recommended engineering control based on control banding nanotool risk level	Version of Nanotool
Preparation of carbon nanotubes	Carbon nanotubes	General ventilation	High	Extremely unlikely	2	Fume hood or LEV	2009
Machining of aerogels and nanofoams	silica and tantulum aerogels, metal and carbon nanofoams	Fume hood or LEV	High	Less likely	2	Fume hood or LEV	2009
Waste dumping activities	Various NPs	General ventilation	High	Less likely	2	Fume hood or LEV	2009
Waste management and packaging	Various NPs	General ventilation	High	Less likely	2	Fume hood or LEV	2009
Analysis of NP waste samples	Various NPs	General ventilation	High	Less likely	2	Fume hood or LEV	2009
Waste management and packaging	Various NPs	General ventilation	High	Less likely	2	Fume hood or LEV	2009
Purification and functionalization	Carbon nanotubes	Fume hood or LEV	High	Extremely unlikely	2	Fume hood or LEV	2009

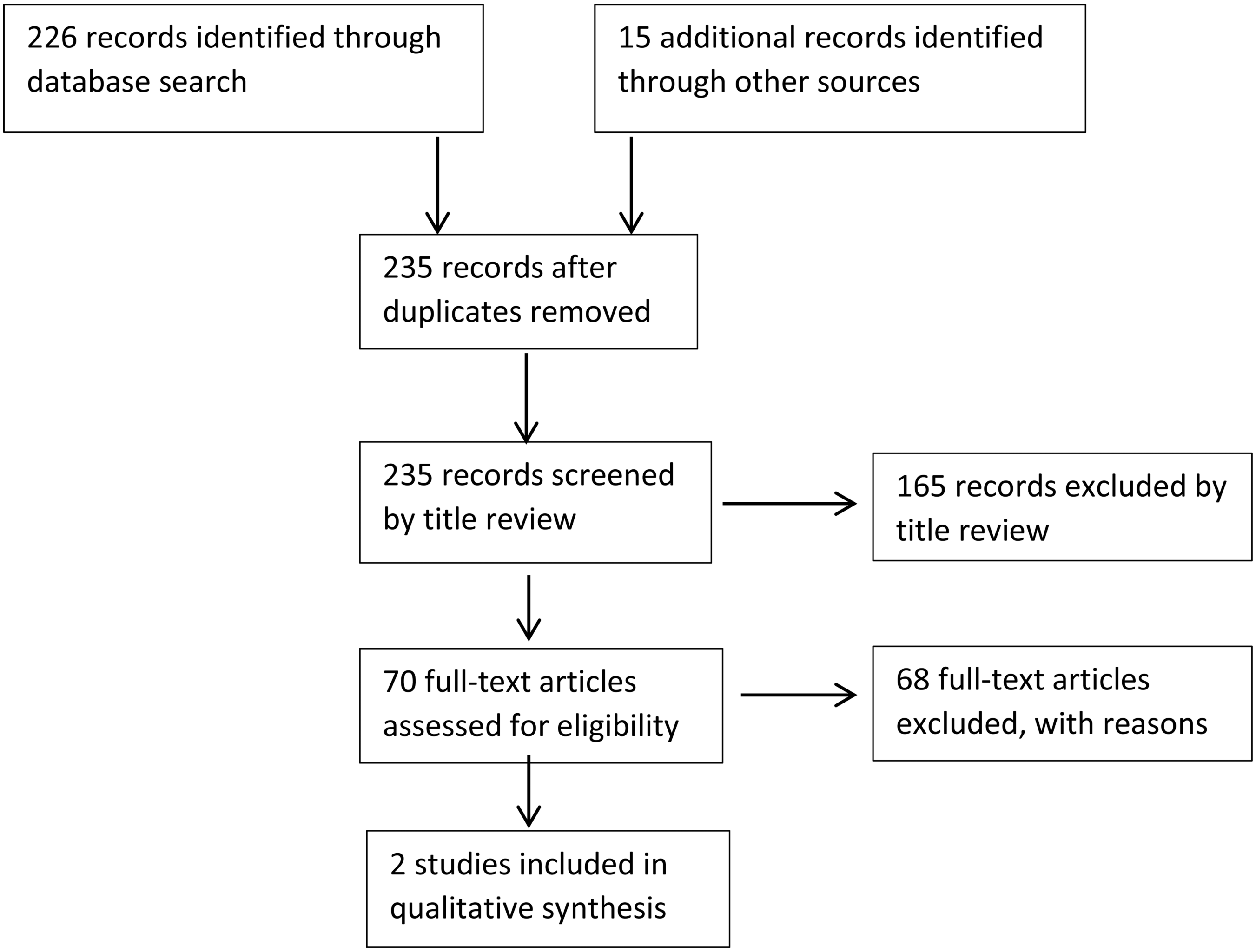

FIGURE 1.
Study selection in the form of a flow diagram

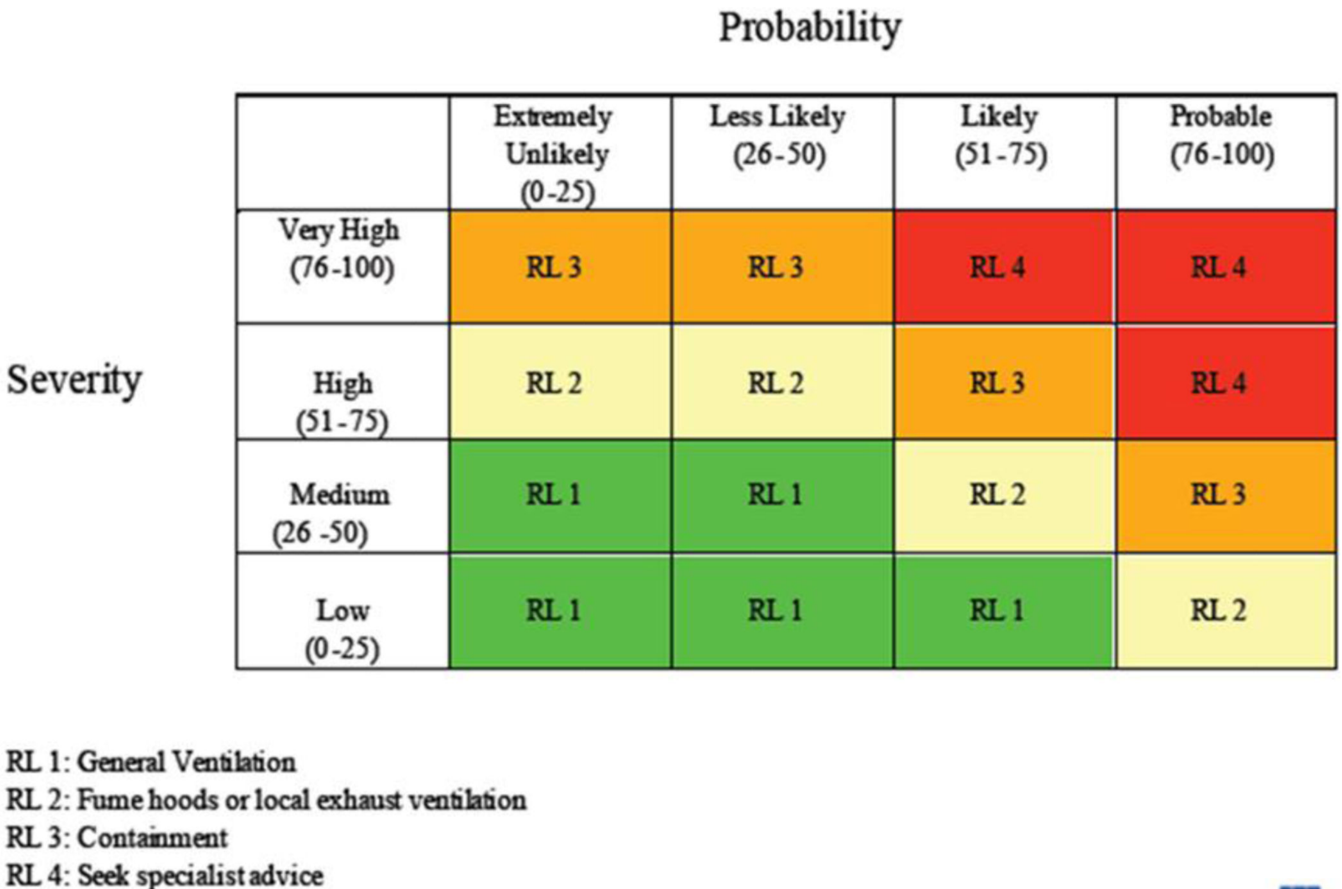

FIGURE 2.

Control banding nanotool matrix (Paik, Zalk, and Swuste 2008. Application of a Pilot Control Banding Tool for Risk Level Assessment and Control of Nanoparticle Exposures. Ann. Occup. Hyg. 52(6): 419-428.)

TABLE 1

Summary of characteristics of the various ENM control banding strategies

		Hazard Banding			Exposure Banding			Matrix	
		Allocation System							
Methodology	Language Availability	Decision tree approach	Score-based	Number of Hazard Bands	Emission Potential	Exposure Potential	Number of Exposure Bands	Number of Cont rol Bands	Number of Risk Levels
Stoffenmanager Nano	Dutch, French, English	✓	✓	5	✗	✓	4	✗	3
CB Nanotool	English	✗	✓	4	✓	✗	4	4	✗
Precautionary Matrix	German	✗	✗	1	✓	✗	1	2	✗
ANSES (France)	French & English	✓	✗	5	✓	✗	4	5	✗
Nanosafer	Danish	✓	✓	4	✗	✓	5	✗	5
ISO/TS12901- 2	English	✓	✗	5	✓	✗	4	5	4
Guidance	Dutch & English	✓	✗	3	✓	✗	3	3	✗

Adapted from Brouwer DH. Control banding approaches for nanomaterials. Ann of Occ Hyg. 2012; 56(5):506-14

✓ Used/addressed by tool

✗ Not used/addressed by tool

TABLE 2

Summary of GRADE evaluation

Comparison	Risk of Bias	Consistency	Directness	Precision	Publication Bias	GRADE Quality
CB versus Industrial Hygienist	*Two high risk observational studies:* **Downgrading**	*All results consistent:* **No downgrading**	*Direct comparison:* **No downgrading**	*Total number of activities small (32):* **Downgrading**	*Not detected in Review:* **No downgrading**	**Very Low Quality**

TABLE 3

Summaries of the severity and probability scores for included studies

Severity factor		**Maximum Points**	**Maximum Points**	**Maximum Severity Score**
Surface Chemistry	Nanomaterial	10	10	100
Particle Shape		10	10	
Particle Diameter		10	10	
Solubility		10	10	
Carcinogenicity		7.5	6	
Reproductive Toxicity		7.5	6	
Mutagenicity		7.5	6	
Dermal Toxicity		7.5	6	
Asthmagen		N/A	6	
Toxicity	Parent Material	10	10	
Carcinogenicity		5	4	
Reproductive Toxicity		5	4	
Mutagenicity		5	4	
Dermal Toxicity		5	4	
Asthmagen		N/A	4	
Probability factor		Maximum Points	Maximum Points	Maximum Probability Score
Estimated amount of nanomaterial		25	25	100
Dustiness/mistiness		30	30	
Number of employees with similar exposure		15	15	
Frequency of operation		15	15	
Duration of operation		15	15	

TABLE 4

Summary of studies of application of control banding to the use and/or handling of nanomaterials

Source	Number of activities evaluated	Number of task engineering controls consistent with what was recommended by the CB Nanotool
Paik, Zalk, & Swuste, 2008	5	• Three out of five were consistent with those recommended by the tool • One task was determined to need upgrading • One task's current controls exceeded what was recommended by the tool
Zalk, Paik, & Swuste, 2009	27	• 16 out of 27 controls were consistent with those recommended by the tool • 8 out of 27 controls were determined to need upgrading • Three of the tasks' current controls exceeded what was recommended by the tool

TABLE 5

Summary of the CB Nanotool recommended upgrades of exposure control based on type of job activity

Type of Task	CB Nanotool recommended upgrading of in-place exposure controls			
	Total	**Yes**	**No**	**% to upgrade**
Synthesis or growth of material	9	1	8	11%
Sample preparation	8	3	5	37.5%
Product mixing or manipulation	11	1	10	9%
Waste handling	4	4	0	100%