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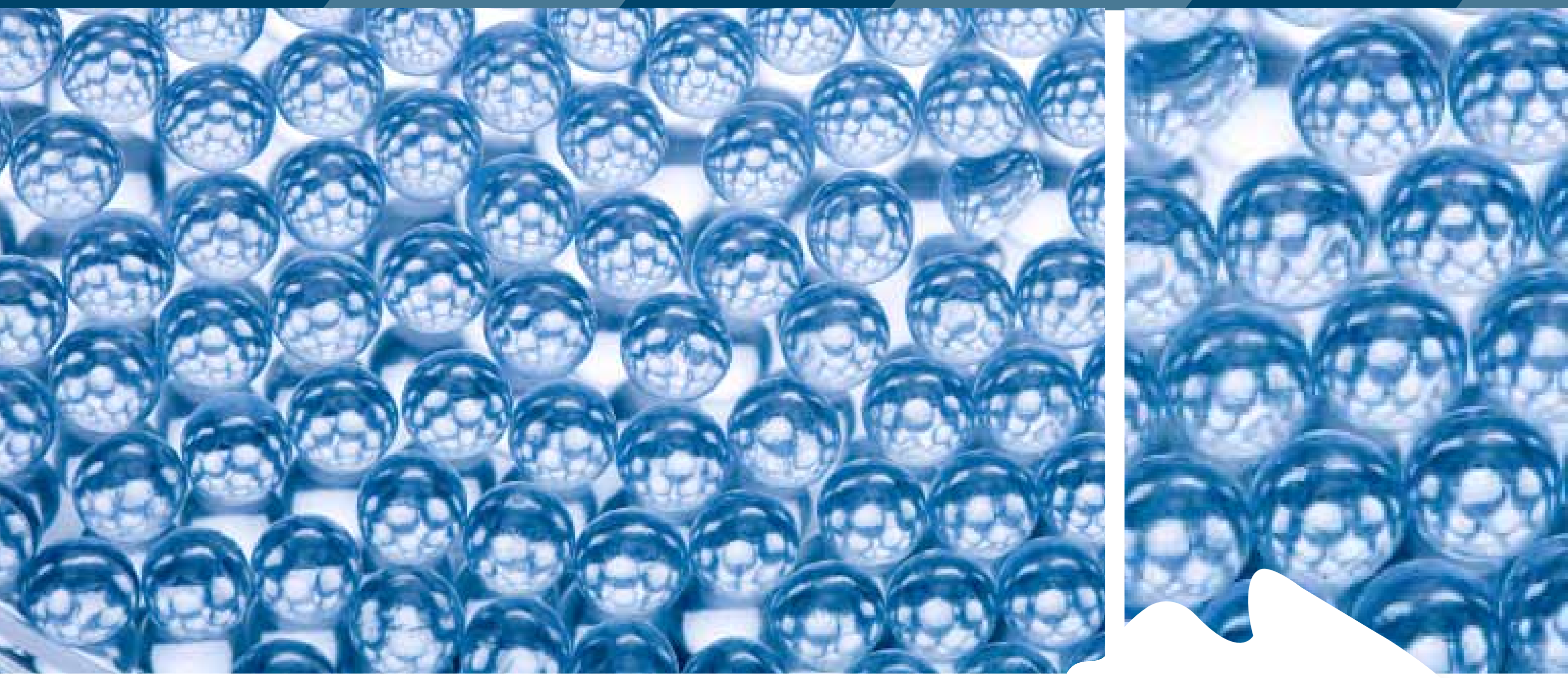
Engineered Nanomaterials:
Feasibility of establishing exposure standards and using control banding in Australia



August 2010

Engineered Nanomaterials: Feasibility of establishing exposure standards and using control banding in Australia

Acknowledgement

This review was commissioned by Safe Work Australia, through funding provided under the National Nanotechnology Strategy. The review was undertaken by the Monash Centre of Occupational and Environmental Health and the Australian Centre for Human Health Risk Assessment at Monash University, Melbourne, Australia. The review was undertaken by Dr Geza Benke, Dr Martine Dennekamp, Professor Brian Priestly and Professor Malcolm Sim from Monash University and Dr Howard Morris from Safe Work Australia.

This report has been reviewed by Safe Work Australia's Nanotechnology OHS Advisory Group, and Nanotechnology OHS Measurement Reference Group. The authors would like to thank Mr Peter McGarry (Workplace Health and Safety Queensland), Dr Jurg Schutz (CSIRO) and Dr Neale Jackson (RMIT University) for the comments provided.

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ISBN 978-0-642-33098-7 (Online PDF)
ISBN 978-0-642-33099-4 (Online RTF)

Executive Summary

The focus of this report is to investigate the feasibility of:

- establishing group-based Australian National Exposure Standards for engineered nanomaterials
- using control banding for engineered nanomaterials in Australia.

In December 2007, the British Standards Institution (BSI) published: "Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials" (the BSI Guide). The BSI Guide defines four hazard type groups for engineered nanomaterials, includes information on benchmark exposure levels (BELs) which are guidance on control levels for nanomaterials in those groups, and provides control guidance for those groups based on control banding. Investigating the feasibility of establishing group-based Australian National Exposure Standards and using control banding for engineered nanomaterials involved a detailed assessment of the groups, the BELs and the guidance based on control banding.

While there are some issues associated with the hazard type groups suggested in the BSI Guide, they appear to be practical groupings of nanomaterials. In relation to each of the BELs proposed in the BSI Guide for each of the hazard type groups, this report finds:

- The BEL for insoluble fibrous nanomaterials should be modified to 0.1 fibre/ml, rather than the 0.01 fibre/ml recommended in the BSI Guide, as there is no evidence that these nanomaterials are more toxic on a fibre-by-fibre basis than asbestos, and also, a higher number of fibres will be counted by electron microscopy which is needed to resolve fine fibres, e.g. carbon nanotubes. This BEL may also be applied to poorly soluble fibrous nanomaterials.
- There is currently limited scientific evidence to support a quantitative BEL for nanomaterials which are already classified in their larger form as carcinogenic, a reproductive toxin, asthmagenic or mutagenic (CMAR) of 0.1xWEL, as proposed in the BSI Guide. This was a recommendation based on prudence and a rule of thumb, and should be supported by following a precautionary approach until knowledge is enhanced.
- In regard to insoluble nanomaterials, there is toxicological evidence to support the BSI Guide recommendation of a quantitative BEL of 0.066xWEL for nanomaterials similar to TiO_2, but there is a lack of quantitative evidence for most insoluble nanomaterials. Combining the use of mass-based BELs and the particle number concentration BEL of 20 000 particles/ml may be the optimum approach. The particle size range over which a particle number concentration BEL should be measured needs to be defined.
- Although there is currently insufficient evidence to support the BSI recommendation of a quantitative BEL of 0.5xWEL for soluble nanomaterials, this may be prudent due to the possibility that the size, shape and surface chemistry of soluble nanoparticles may lead to increased dose rates, or doses to parts of the body not usually exposed to such materials. However, a number of soluble nanomaterials do not have bulk forms for which exposure limits are set.

If quantitative exposure limits or benchmark exposure levels are adopted, then one approach is to adopt them as BELs (guidance) initially, and convert to National Exposure Standards as further hazard, risk and measurement data become available.

There are a number of initiatives internationally to consider the control banding methodology as a means to effectively control nanomaterials in the workplace. Two control banding approaches examined in this report look promising:

- the *Control Banding Nanotool*, which has been specifically designed for control of nanomaterials
- use of the control banding guidance in the BSI Guide should enable organisations to reduce exposures below the BELs. Exposures below the BELs should be achievable using conventional engineering controls.

Control banding for the nanomaterial industry is likely to be a suitable risk control approach for managing nanoparticle exposure in many situations. Control banding is particularly favourable to the control of chemical hazards where there is limited toxicological information and workplace exposure limits are absent as is currently the case with engineered nanomaterials.

However, in general, Australian workplaces do not have wide experience of using the control banding approach for other hazards and this situation is likely to remain so until there is impetus nationally to accept the control banding approach in support of State, Territory and Commonwealth regulations. Therefore, if control banding is to be used, it should be used in combination with the conventional approach towards the assessment and control undertaken in the current jurisdictional regulations, including those existing for human carcinogens.

The use of both benchmark exposure levels and control banding, as proposed in the BSI Guide, are consistent with a precautionary approach to handling nanomaterials, as recommended by Safe Work Australia where limited information about hazards and risks is available.

There is a need to develop further capability of measuring nanomaterial exposures, which will also enable assessment of control against Benchmark Exposure Levels. The OECD Working Party for Manufactured Nanomaterials (WPMN) guidance for emissions measurement of nanomaterials appears to be a practical way to measure nanomaterial exposures in workplace settings. This is currently being validated by Queensland University of Technology and Workplace Health and Safety Queensland in a project commissioned by Safe Work Australia. Following completion of the validation, focus should be placed on dissemination of the methodology to occupational hygienists in Australia. The methodology can be used to assess performance against BELs.

Recent literature reviews and industry surveys (overseas) suggest that there is a need for guidance on the safe handling, control and disposal of nanomaterials in the industry. Currently, there are no Australian guides for safe handling and control of specific engineered nanoparticles that can be incorporated into the current legislation framework used within Australia. CSIRO is currently developing guidance for safe handling and disposal of carbon nanotubes for Safe Work Australia.

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1 Scope

Following on from the National Nanotechnology Strategy (NNS), the National Enabling Technologies Strategy (NETS) was established in 2009. NETS aims to "establish the environment that allows Australia to capture benefits of nanotechnology while addressing the issues impacting on successful and responsible development of nanotechnology". In support of the NETS, a Nanotechnology Work Health and Safety Program is being implemented by Safe Work Australia, with focus on the following areas:

- nanotechnologies and the Workplace Hazardous Substances Regulatory Framework
- understanding the hazardous properties of engineered nanomaterials
- evaluating the effectiveness of workplace controls
- emissions and exposure measurement capability
- supporting Australian nanotechnology organizations
- ensuring consistency with international approaches.

This project is one of a series of projects commissioned by Safe Work Australia in the Nanotechnology Work Health and Safety Program, with funding provided under the NNS. Of these projects, one recent report has involved a review of the literature of the toxicology and health hazards associated with engineered nanomaterials (Toxikos, 2009) and another reviewed the effectiveness of workplace controls to prevent exposures to engineered nanomaterials (RMIT, 2009).

The current project has been undertaken by the Monash Centre for Occupational & Environmental Health (MonCOEH) and the Australian Centre for Human Health Risk Assessment (ACHHRA) based at Monash University.

The main focus of this report is to investigate the feasibility of:

- establishing group-based Australian National Exposure Standards for engineered nanomaterials
- using control banding for engineered nanomaterials in Australia. This involves examining the appropriateness of control banding scheme for Australian businesses and organisations using engineered nanomaterials.

In December 2007, the British Standards Institution (BSI) published: *"Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials"* (the BSI Guide, BSI 2007). The BSI Guide provides guidance on the general approach to management of risks, information needs, hazard assessment, measurement of exposure, methods of control and disposal.

Investigating the feasibility of; (a) establishing group-based National Exposure Standards, and (b) the use of control banding for engineered nanomaterials involves a detailed assessment of the proposed benchmark exposure levels (BELs) and the control banding-based guidance in the BSI Guide.

2 Glossary

agglomerate: Group of particles held together by relatively weak forces, including van der Waals forces, electrostatic forces and surface tension.

aggregate: Heterogeneous particle in which various components are not easily broken apart.

BELs: benchmark exposure levels. These are not occupational exposure limits (OELs) or workplace exposure limits (WELs) but are intended as pragmatic guidance levels.

carbon nanotubes: Tiny tubes about 10 000 times thinner than a human hair consisting of cylinders of carbon hexagons. Abbreviation **CNT.**

CIH: Certified Industrial Hygienist.

control banding (CB): A strategy or process in which a single control technology (such as general ventilation or containment) is applied to one range or band of exposures to a chemical (such as 1-10 mg/m^3) that falls within a given hazard group (such as harmful by inhalation & irritating to respiratory system). The following four main control bands have been developed for exposure to chemicals by inhalation:

Band 1: Use good occupational hygiene practice and general ventilation

Band 2: Use local exhaust ventilation

Band 3: Enclose the process

Band 4: Seek expert advice.

This qualitative risk assessment and management approach focuses resources on exposure controls and defines appropriate measures to control risks.

COSHH[1] Essentials: A CB model developed by the British Health and Safety Executive (HSE) to assist small and medium-sized enterprises in complying with COSHH Regulations.

engineered (manufactured) nanomaterials: Nanoparticles having at least one dimension between approximately 1 nm and 100 nm, manufactured to have specific properties or composition. Abbreviation **ENP.** These contain only a few thousand or tens of thousands of atoms, rather than the millions or billions of atoms in particles of their bulk form. They are considered distinct from ultrafine particles (UFPs) for the purposes of this report insomuch as UFPs are not purposely produced.

fullerene: An allotrope of carbon characterized by a closed cage structure consisting of an even number of three coordinate carbon atoms without hydrogen atoms. This class was originally limited to closed-cage structures with twelve isolated five- membered rings, the rest being six- membered rings.

granuloma: Small nodules usually consisting of epithelioid macrophages surrounded by lymphocytes. When necrosis is evident internally this is termed 'caseating granulomas'- especially as observed with tuberculosis.

multi-walled carbon nanotubes: Carbon nanotubes (q.v.) which consist of more than one nanotube completely contained within another.

MWCNTs: Abbreviation for multi-walled carbon nanotubes.

nano: 10^{-9} or, alternatively, 0.000000001.

nanoaerosol: A collection of nanoparticles suspended in a gas.

nanoengineering: The construction of nanostructures and their components.

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[1] **Control of Substances Hazardous to Health**

nanomanufacturing: Integrated assembly of nano-elements into commercial products. This involves controlling position, orientation, and interconnectivity of the nano- elements.

nano-objects: materials with one (nanoplate), two (nanorod) or three (nanoparticles) dimensions in the nanoscale.

nanoparticle(s): Abbreviation: **NPs.**

nanopowder: Dry nanoparticles.

nanorod: nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger.

nanoscale: the size range between approximately 1-100nm (1 to 100 billionths of a metre).

nanoscience: The study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

nanospheres: Spheres ideally completely spherical and homogeneous in size at the nanoscale.

nanotubes: nanometre-diameter tubes composed of various substances including carbon, boron nitride, or nickel vanadate. Carbon nanotubes were discovered in 1991 by Sumo Iijima and resemble rolled up graphite.

nanowires: Molecular wires millions of times smaller in diameter than a human hair.

National Exposure Standard (NES): Safe Work Australia standard for maximum workplace exposure. Exposure standard means an airborne concentration of a particular substance in the worker's breathing zone, exposure to which, according to current knowledge, should not cause adverse health effects nor cause undue discomfort to nearly all workers (NOHSC 1995). The exposure standard can be of three forms; time-weighted average (TWA), peak limitation, or short term exposure limit (STEL).

NPs: Abbreviation for nanoparticles (q.v.), c.f. UFPs (q.v.).

pathogenic fibre dimensions: fibres being greater than 5um long, thinner than 3um and having an aspect ratio of greater than 3:1.

quantum dots: Nanometre sized particles of semiconductor crystalline material, that exhibit size dependent properties due to quantum confinement effects on the electronic states.

single walled carbon nanotubes: Carbon nanotubes (q.v.) which do not contain any material internally.

specific surface area: Ratio of the surface area to the mass of nanoparticles.

SWCNTs: Abbreviation for single-walled carbon nanotubes.

UFPs: Abbreviation for ultrafine particles (q.v.)

ultrafine particles: An anthropogenic or natural form of nanoparticle which is usually derived from combustion processes. An ultrafine particle is a particle with a nominal diameter (such as geometric, aerodynamic, mobility, projected-area or otherwise) of 100 nm or less. UFPs may have large variations in composition.

Workplace Exposure Limit (WEL): British guideline/standard for maximum workplace exposure over an 8-hour time weighted average (TWA) exposure. This term is used in the British Standards Institution (BSI) “Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials” (the BSI Guide). Equivalent to a US OSHA PEL (Permissible Exposure Limit), or Safe Work Australia 8-hour TWA National Exposure Standard.

3 Background

Nanotechnology is a rapidly growing field and research on the health effects of engineered (or manufactured)[2] nanomaterials has lagged behind industrial developments. Exposure to nanoparticles may occur in the workplace or from combustion or environmental sources in ambient air. Much has been published on exposure to nanoparticles (ultrafine particles) in the environment but less has been published on exposure to engineered nanomaterials in the workplace. This report concentrates on exposure to engineered nanomaterials in the workplace.

Nanotechnology worldwide

Regarding the number of companies working with nanotechnologies, the Nanotechnology Project (2010) reported that there are currently more than 1 200 nanotechnology companies, universities, government laboratories and organisations across all 50 US states. The Technology Transfer Centre (2007) reported over 300 nanotechnology companies in Europe, with Germany having the most companies (over a third) followed by the UK with almost 70. They also reported over 250 nanotechnology companies in the Asia-Pacific, with China having the most companies (more than 90), followed by South Korea, Japan and Australia. The most recent figures available for Australia (Invest Australia, 2007) indicate a network of 75 nanotechnology research organisations and around 80 nanotechnology companies. There are no data on the number of employees currently working in the nanotechnology industry, either globally or in Australia.

Engineered nanomaterials

Engineered nanomaterials are intentionally produced with specific properties or compositions in mind. These nanomaterials are different from incidental nanoparticles (also called ultrafine particles) as these are usually by-products of processes, such as from combustion or welding. Engineered nanomaterials consist of nano-objects which, according to the International Standards Organization (ISO/TS 27687:2008), are defined as materials with one, two or three dimensions in the size range from approximately 1-100nm (ISO 2008a). A nano-object with one dimension at the nanoscale is a nano-plate, that with two dimensions at the nanoscale is a nanotube (hollow nanofiber) or a nanorod (solid nanofiber) and a nano-object with three dimensions at the nanoscale is a nanoparticle. Nano-objects can also occur in a matrix as a nanocomposite, or they can occur in a gas or liquid.

Types of nanomaterials include fullerenes, carbon nanotubes, nanowires, metals and metal oxides and quantum dots. A more detailed explanation of these types of engineered nanomaterials can be found elsewhere, e.g. in the BSI Guide. The carbon nanotubes and nanowires are examples of two dimensional nanofibers and the fullerenes and quantum dots are examples of three dimensional nanoparticles.

Concerns related to possible health effects of exposure to nanomaterials

A major reason for concern related to exposure to nanomaterials is that there is some evidence that particles in the nano-state are more toxic than their larger counterparts of the same material (Faux et al, 2003). This is based on differences of nanoparticles compared to larger particles with regard to deposition, alveolar clearance, inflammatory response and granuloma formation. An added concern is that the toxicity of nanomaterials may be altered by changes to the surface chemistry (Royal Society / Royal Academy of Engineering, 2004). In addition there is emerging evidence that some nanomaterials which have fibre-like

[2] The terms *engineered nanomaterial* and *manufactured nanomaterial* are used interchangeably throughout this report.

dimensions show asbestos-like, length dependent pathogenic behaviour (Poland et al, 2008). A full review of the scientific evidence is beyond the scope of this report, but was the focus of the recent review published by Safe Work Australia (Toxikos, 2009). A follow-up review of more recent literature has been commissioned by NICNAS.

The Toxikos (2009) report analysed scientific literature from 2006 to 2009 and focused on the toxicity of a number of nanomaterials being researched, manufactured or used in Australia. Some key findings in the report include:

- there is no conclusive evidence to suggest that engineered nanomaterials have a unique toxicity, i.e. a different form of toxicity not seen with larger particles
- nanoparticles tend to be more bio-reactive, and hence potentially more toxic, than larger particles of the same material, and
- carbon nanotubes are potentially hazardous to health if inhaled in sufficient quantity.

However, chronic repeat dose studies have not been conducted for most engineered nanoparticles, so there is only limited understanding of potential long term effects.

4 Overview of the BSI Guide

In 2007 SAFENANO at the Institute of Occupational Medicine (IOM) in Edinburgh, Scotland prepared the document: (BSI PD 6699-2:2007) *"Nanotechnologies- part 2: Guide to safe handling and disposal of manufactured nanomaterials"* for the BSI Committee NT1/1, *Nanotechnologies.* The BSI Guide was published on 31 December 2007 in the UK and its use is yet to be critically examined. The BSI Guide describes manufactured nanomaterial types and characteristics and categorises nanomaterial hazard types into four groups. It gives details on risk evaluation, control, information on spillages and accidental release procedures, disposal procedures and prevention of fire and explosion.

There are 13 Clauses in the Guide, which are recommended to be used as a systematic approach to managing risks from nanoparticles (Table 1).

Two key elements to the BSI Guide are:

- the recommendations of quantitative Benchmark Exposure Levels (BELs) in Clause 8, and
- guidance for control of engineered nanoparticle exposure in the workplace based on control banding (Clause 8).

It is these two elements of the BSI Guide which are the principal subject of this report.

Table 1. Clauses in BSI Guide

Clause No.	Description
1	Outlines the scope of the document.
2	Briefly describes manufactured nanomaterials types, e.g. fullerenes, carbon nanotubes, nanowires, quantum dots and other nanomaterials, and characteristics.
3	The exposure and risk of nanoparticles are briefly discussed, with consideration given to health risks from inhalation, dermal and ingestion exposure. The risk of fire and explosion from nanoparticles is also discussed.
4	Outlines the general approach to managing risks from nanoparticles, with an eight step procedure in Figure 1. This is consistent with other generic approaches to management of risk in the workplace.
5	Briefly describes the identification and competence of the person conducting risk assessments, but gives little detail regarding qualifications and knowledge required.
6	Describes information collection requirements and emphasises that this is a key step in the risk assessment of nanoparticles. This section also stresses the need to not just identify the available information but also the information gaps, when collecting information.
7	Risk Evaluation. There are four groups defined to categorise nanomaterials: (a) Fibrous, (b) CMAR (any nanomaterial already classified in its larger particle form as Carcinogenic, Mutagenic, Asthmagenic or a Reproductive toxin), (c) Insoluble nanomaterials and (d) Soluble nanomaterials. Assessing risk involves exposure characterization, with an emphasis on the most serious risks to health. In section 7.3, the Guide suggests priorities for action on an identified risk.
8	Deals with the control of exposure, introducing the hierarchy of controls with a detailed discussion of the control types. Benchmark exposure levels (BELs) are then suggested for the four nanoparticle hazard types described in section 8.3. It is recommended that selection of a control should be as high in the control hierarchy as is technically and economically feasible. Figure 3 gives suggested control approaches for various generic tasks for the different nanoparticle hazard types. These control approaches are based on application of a Control Banding (CB) methodology. Minimum information, instruction and training for all employees likely to be exposed to nanomaterials are outlined in the final part of Clause 8. Part 8.4 includes the basic information used for the risk assessment and any further information that may assist in the safe use of nanomaterials.
9	Briefly describes health surveillance, and suggests that medical surveillance is not appropriate currently.
10	Deals with the measurement methods for evaluating controls and borrows a table from ISO/TR 27628:2007, to summarize the currently available methods and devices for direct measurement of number, mass and surface area concentration of nanoparticles. The sampling strategy section refers directly to advice from the National Institute for Occupational Health & Safety (NIOSH) in the USA, which in turn references the recommendations of Brouwer et al (2004). Brouwer recommended that a well designed ultrafine sampling strategy should include total particle number concentration and surface area concentration sampling. A limitation of the proposed sampling strategy is that it relies heavily upon static or area sampling, which has long been considered limited in comparison to personal sampling in the occupational setting (Ogden et al, 1993). Limitations are briefly discussed in clause 10.4 of the Guide.

Clause No.	Description
11	Deals with spillages and accidental releases of nanomaterials. The discussion considers primarily good work health and safety practices in the case of release of any chemical that is normally considered a hazardous substance. The principles of containment and controlled clean-up are outlined with involvement of outside agencies and emergency services if necessary.
12	Describes storage and disposal procedures for nanomaterial waste. Use of the British Guide on disposal of hazardous waste regulations (HWRO1) is recommended (Environment Agency, Great Britain 2005) together with the English List of Wastes Regulations 2005 (LoWR) (Great Britain 2005).
13	Briefly outlines prevention of nanoparticle fire and explosion. The Guide recommends that the management principles should be the same as those for the management of fine powders, dusts or dusty materials. Fire prevention should take into account existing legislation and the Guide recommends precautions be taken to avoid the risk of auto-ignition of nanoparticles.

5 Benchmark Exposure Levels

In the BSI Guide, benchmark exposure levels (BELs) have been recommended for four nanoparticle hazard types: fibrous nanomaterials; CMAR nanomaterials (nanomaterials which are already classified in their larger form as carcinogenic, a reproductive toxin, asthmagenic or mutagenic); insoluble nanomaterials; and, soluble nanomaterials. Although the four nanoparticle hazard types provide a summary of the common types of engineered nanomaterials which occur in industry, it should be noted that some nanomaterials may cross over between different hazard types. Therefore, it is appropriate to review the benchmark exposure levels recommended in the BSI Guide by hazard type sequentially, examine measurement of exposure, and examine whether exposure levels below the BELs are achievable in practice.

In Clause 8.3 the BSI Guide outlines how the benchmark exposure levels should be interpreted:

> *To help guide this process (selection of controls), the following benchmark exposure levels have been suggested for the four nanoparticle hazard types identified in 7.1. These are intended to provide reasonably cautious levels and are based in each case on the assumption that the hazard potential of the nanoparticle form is greater than the large particle form. This assumption will not be valid in all cases. Although these benchmark levels relate to current exposure limits, they have not been rigorously developed. Rather, they are intended as pragmatic guidance levels only and should not be assumed to be safe workplace exposure limits.*

Thus, BELs differ from exposure standards, which are generally based on known health effects and the results of epidemiological studies. The use of BELs supports a precautionary approach to the control of exposures.

The benchmark exposure levels in the BSI Guide have been summarised in Table 2 below. Columns 1 and 2 have been extracted from pages 9 and 14 of the BSI Guide and column 3 is sourced from additional information found in the literature. The workplace exposure limits (WELs) are for the bulk material of the various nanomaterial chemicals, but not all nanomaterials have bulk chemicals which have WELs.

Table 2. BSI categorisation of nanoparticle hazard types and example materials

Nanoparticle characteristic as per the BSI Guide grouping	**Suggested Benchmark Exposure Level (BEL)**	**Some types of engineered nanomaterials in each group**
Fibrous nanomaterials	0.01 fibres/ml	Carbon nanotubes, nanowires
CMAR nanomaterials	0.1x *WEL bulk material	Ni nanoparticles
Insoluble nanomaterials	0.066 x *WEL bulk material	Nanocrystals, quantum dots, ceramic oxides, metals
Soluble nanomaterials	0.5 x * WEL	Lipid-type nanoemulsions, dendrimer-type drug delivery systems

*WEL bulk material: Workplace Exposure Limit (i.e. Exposure Standard) for the bulk form of the chemical

5.1 BSI Guide nanoparticle hazard types

There is no universal agreement about the hazard type groupings of nanomaterials and the BSI Guide provides one of many possible groupings. The categories in the BSI Guide can be considered a useful simplification of nanomaterials of concern in the workplace, if the intent is to develop pragmatic and simple guidelines to avoid harm (Maynard, 2008). An alternative grouping could be based on engineered nanomaterials which; (a) do not exist in the bulk form, such as nanotubes and quantum dots, and (b) those which do exist in bulk, such as the metal oxides. A further alternative to the BSI hazard types is the approach described in a recent Swiss document (Höck et al, 2008), where a precautionary matrix for synthetic nanomaterials has been developed which begins with “specific framework conditions” which include size and agglomeration properties.

5.1.1 Fibrous nanomaterials

Fibrous nanomaterials are insoluble nanomaterials defined by their high aspect ratio. They would conform with the definition of regulated fibres as used for counting purposes according to the World Health Organization, Safe Work Australia, and the British Health & Safety Executive, which is a particle of length >5 µm, and diameter <3 µm, and with an aspect ratio (length to diameter) of >3:1 (Meldrum, 1996, NOHSC 2005a, Donaldson et al, 2006). The most common nanomaterials in this group are carbon nanotubes and nanowires.

Carbon nanotubes

Carbon nanotubes are attractive for commercial application due to, for example, the fact that they are around 100 times stronger than steel, but are only a fraction of the weight. The toxicity of fibres depends on length, diameter, surface activity and durability (Royal Society / Royal Academy of Engineering, 2004). *In vivo* and *in vitro* studies of these relatively new nanomaterials, first described by Iijima (1991), have been done in the past few years.

Two recent *in vivo* toxicological studies of the effects of nanotubes have attracted significant attention (Poland et al 2008; Takagi et al 2008). The Poland et al. (2008) reported that tests in mice showed that exposure to carbon nanotubes resulted in asbestos-like effects that may lead to mesothelioma. The study by Takagi et al (2008), utilising high doses of MWCNTs, also showed the potential for mesothelioma formation. Ichihara et al (2008) commented that carbon nanotubes need to be sufficiently biopersistent to be able to reach the mesothelium in sufficient numbers to cause mesothelioma following inhalation exposure. Recent findings clearly show that CNTs can migrate to the pleura following aspiration (Porter et al, 2009; Ryman-Rasmussen et al, 2009).

The potential mesothelioma hazard from carbon nanotubes was examined in detail by Toxikos (2009). For MWCNTs weight of evidence suggests that:

- long thin MWCNTs of pathogenic fibre dimensions present a mesothelioma hazard to workers if they are inhaled, and if sufficient numbers are in contact with mesothelial tissue
- data to date indicate that MWCNTs that are not of pathogenic fibre dimensions do not have this hazard.

To date, there are no data on the potential of SWCNTs or functionalised CNTs to cause pathogenic fibre-like responses, but there is no evidence that responses would be different to MWCNTs.

Thus as a precautionary default, Toxikos (2009) recommends that:

- all biopersistent CNTs, or aggregates of CNTs, of pathogenic fibre dimensions could be considered as presenting a potential fibrogenic and mesothelioma hazard, and
- manufacturing and handling procedures need to minimise workplace exposure to all respirable CNTs that physically resemble known fibrogenic materials.

Numerous other reports, e.g. a recent report (EMERGNANO, 2009), have also identified carbon nanotubes as a nanomaterial which is likely to have an adverse effect on human health. Reports also indicate that carbon nanotubes give rise to the most concern from a health and safety perspective. The report concluded that the precautionary principle should be invoked in this case. The precautionary principle means that measures should be taken to protect both worker and public health, even in the absence of clear scientific evidence of harm (Raffensperger and Tickner, 1999).

The EMERGNANO report also identified gaps in knowledge, and the need for ongoing research projects addressing CNTs. Safe Work Australia has commissioned a collaborative project for CSIRO, University of Edinburgh and the UK's Institute of Occupational Medicine to examine the durability and biopersistence of carbon nanotubes. Safe Work Australia has also contracted NICNAS to undertake a formal assessment for the health hazard classification of CNTs to clarify regulatory requirements for this nanomaterial.

Nanowires

Nanowires are electrically conducting or semi-conducting nanofibres, which can consist of carbon, metals, oxides, sulphides or nitrides. An example of nanowires is zinc oxide (ZnO) nanowires, which have drawn great interest due to their semiconducting nature and unique optical and piezoelectric properties. Nickel, copper, alumina and cadmium nanowires are all currently in limited production within the nanotechnology industry for potential use in electronics and photonics.

5.1.2 Nanomaterials classified as carcinogenic, mutagenic, asthmagenic or reproductive toxins (CMAR)

Nanomaterials classified as CMAR are nanoparticles already classified in their larger form as carcinogenic, a reproductive toxin, asthmagenic or mutagenic. Examples of CMAR nanomaterials are nickel nanoparticles or quantum dots which contain the carcinogen cadmium.

5.1.3 Insoluble nanomaterials

This category is defined as insoluble or poorly soluble nanomaterials not in the fibrous or CMAR category. Common nanomaterials in this group are quantum dots (which may also be CMARs), fullerenes, TiO_2, ZnO, Ag and CeO_2.

Quantum dots

Quantum dots (QDs), or nanocrystals, are semi-conductors which have unique optical properties making them useful in, among other purposes, diagnostic medical imaging. They are surrounded by one or more surface coatings (Ryman-Rasmussen et al, 2006), and can have a range of different functional groups attached. QDs are very diverse and cannot be studied in toxicology as one uniform group. The surface coating is important and it has been shown that quantum dot toxicity is dependent on the stability of the surface coating (Hardman, 2006; Powell, 2006).

Fullerenes

The most common form of fullerenes (Kroto et al, 1985) is a hollow sphere which contains 60 carbon atoms. Fullerenes have unique physical properties, as they retain their original shape after being exposed to extreme pressures. Fullerenes are hollow structured and can therefore be filled with different substances, which gives them potential for drug delivery. Other applications for fullerenes are in coatings, lubrication and hydrogen storage. From several recent toxicological studies of fullerenes it can be concluded that they appear to be less hazardous than other carbon-based nanoparticles (Baker et al, 2008; Fiorito et al, 2006; Hamilton et al, 2007, Toxikos 2009). The hazard is further decreased by the addition of functional groups which make the fullerene hydrophilic.

Titanium Dioxide (TiO_2)

Nanoscale TiO_2 has a wide range of applications, such as being used in paint and sunscreens. TiO_2 in general (not specifically nanoscale) has recently been classified as being a possible carcinogen (Group 2B) by the International Agency for Research on Cancer (IARC) in situations of high exposures. This classification is based upon high-dose inhalation studies in rats, where sufficient material reaches lungs to exceed the threshold load necessary for prolonged inflammation. Toxicological studies have shown that TiO_2 particles in the nanometer size range of less than 100nm may be more toxic than larger particles of the same material (Stone et al, 2007).

5.1.4 Soluble nanomaterials

Soluble nanomaterials as defined in the BSI guide are nanomaterials which do not belong in the fibrous or CMAR category and which are soluble. Most engineered nanomaterials have low solubility (Colvin, 2003). However, water soluble fullerenes have been found to be phototoxic (Colvin, 2003). Sayes et al (2004) also demonstrated the cytotoxicity of water-soluble fullerenes which disrupted normal cellular function through lipid peroxidation, responsible for cell membrane damage.

5.1.5 Comment on the groupings

Regarding groupings, points for consideration are:

- the fibrous group definition may be broadened to include both insoluble but also poorly soluble fibres
- the cut-off between poorly soluble and soluble is not defined. The groupings are made primarily based on inhalation hazards, and thus solubility may be examined by testing dissolution rates in simulated human lung fluid, such as artificial extracellular lung fluid (SUF) (Stefaniak and Chirila 2009).

5.2 Recommended BSI Benchmark Exposure Levels (BELs)

In the BSI Guide the following hazard type benchmark exposure levels have been recommended. Extracts from the Guide show the rationale used to recommend the BELs for the various levels (BSI Guide, Section 8.3, p.14).

Fibrous Nanomaterials

The most rigorous limit currently in place for fibres in air is 0.01 fibres/ml, used in the UK as the clearance limit in asbestos removal activities. A fibre is defined as a particle with aspect ratio greater than 3:1 and length greater than 5 000 nm. The counting method *used is phase contrast optical microscopy. The proposed benchmark for fibrous nanomaterials is 0.01 fibres/ml, as assessed by scanning or transmission electron microscopy.*

Nanomaterials classified as CMAR

The potentially increased solubility of CMAR materials in nanoparticle form could lead to increased bioavailability. To provide a margin of safety, a benchmark level of 0.1 × material WEL is suggested. Typically, this would be expressed as a mass concentration.

Insoluble Nanomaterials

For insoluble nanoparticles, work recently published by NIOSH [13] recommends exposure limits of 1.5 mg/m^3 for fine TiO_2 (particles greater than 0.1 µm in diameter) and 0.1 mg/m^3 for ultrafine particles as time-weighted averages. In the absence of other published approaches, this seems to be a reasonable basis to judge other nanomaterials. On this basis, a benchmark level of 0.066 × WEL is suggested. Typically, this would be expressed as a mass concentration.

An alternative would be to develop a benchmark based on particle number concentration. In the UK, current urban pollution is in the range 20 000 to 50 000 particles/ml. It is suggested that the lower end of this range 20 000 particles/ml discriminated from the ambient environmental particle concentration is an appropriate benchmark.

Soluble nanomaterials

For materials which are highly soluble in any case, nanoparticle forms are unlikely to lead to greater bioavailability. Nor are the types of effects associated with insoluble particles likely to occur. Therefore, for these materials, a benchmark of 0.5 × WEL is suggested.

5.3 Comment on the rationale given for BELs in the BSI Guide

The rationale for the benchmark exposure levels in the BSI Guide is essentially a precautionary approach. This is consistent with work health and safety standard setting in the workplace today in cases where inadequate data are available e.g. complex mixture exposure with many chemical components such as thermal decomposition products.

If one agrees with the hazard type groupings in the BSI Guide then it is reasonable to ascribe benchmark exposure levels since they give important guidance to industry. In a commentary on the BSI Guide, Maynard (2008) rightly states that it is important for industry to have benchmark exposure levels so that industry may justify actions to control exposure, especially costly ones. A discussion of the recommended BELs for each category of nanomaterials follows.

Fibrous Nanomaterials

In Australia, the National Exposure Standard (8-hour TWA) is 0.1 fibres/ml for occupational personal exposure to asbestos.

As reported above, the clearance limit for asbestos removal activities in the UK is 0.01 fibres/ml. In the document *Code of practice for the safe removal of asbestos 2nd edition* [NOHSC:2002(2005)], ‘Control levels’ for monitored airborne asbestos fibres are defined (Table 3 below, NOHSC, 2005b). ‘Control levels’ are airborne asbestos fibre concentrations which, if exceeded, indicate there is a need to review current control measures or take other action for the safe removal of asbestos and asbestos-containing materials from buildings and structures, plant and equipment, and vehicles. These control levels are occupational hygiene ‘best practice’, and are not health-based standards (they are below the concentration set in the National Exposure Standard for asbestos). The control levels should be used for the purposes of determining the effectiveness of control measures (NOHSC, 2005b).

Table 3 – Control levels and required actions for removal of asbestos

Control level (airborne asbestos fibres/mL)	Control / Action
<0.01	Continue with control measures
=>0.01	Review control measures
=>0.02	Stop removal work and find the cause

Given the potential for some forms of carbon nanotubes to show asbestos-like behaviour (Poland et al, 2008), it would therefore be prudent to treat fibrous nanomaterials with high levels of caution. However, there is no evidence to suggest that these forms of nanomaterials are more toxic than asbestos. The BEL is therefore unjustifiably restrictive and it would seem sufficiently prudent to have a benchmark exposure level for this group of 0.1 fibres/ml, which is equivalent to the 8-hour TWA for asbestos in Australia. Furthermore, the assessment of CNTs should be based on electron microscopy and not light microscopy (Donaldson et al, 2006), as light microscopy is not able to resolve thin CNTs. If this were to be undertaken in practice, then it would be expected that fibre counts with electron microscopy would be higher than the current results from light microscopy.

Nanomaterials classified as CMAR

The current Australian regulations already have exposure standards for macroscale versions of a number CMAR nanomaterials, e.g. nickel nanoparticles, or for elements within the nanomaterial that are CMARs on the macroscale, e.g. Cd in CdSe quantum dots.

There is a paucity of data on whether there is an enhancement of carcinogenic effects at the nanoscale for nanomaterials which are known to be carcinogenic in the larger particle state, e.g. Ni[3].

Thus a precautionary BEL of 0.1 x material WEL has been proposed. Maynard (2008) claims that based on current data, some nanoscale forms of such materials may require lower ceiling levels as they may be more capable of entering the body, penetrating to organs, and releasing material in a bioavailable form, than their non-nanoscale counterparts. An example of these effects could be the cadmium-containing quantum dots (QDs). However, the Toxikos report concluded that in many instances, QDs are recognised as foreign by the body and are sequestered by the reticuloendothelial system of the major organs, as are many other ENPs, but appear not to cause toxicity after intravenous injection (Toxikos 2009).

The Benchmark Exposure Level (BEL) suggested in the BSI Guide of 0.1 × material WEL is therefore a recommendation based on prudence, a precautionary approach and a rule of

[3] There is also a paucity of data on whether nanoparticles may be CMARs at the nanoscale but not in the larger particle state.

thumb. In time future toxicological studies will provide further evidence on the potential enhancement of known effects for the nanomaterial form.

Insoluble Nanomaterials

(a) Mass-based BELs

The BSI Guide suggested benchmark exposure levels for insoluble nanomaterials, which are referenced to the recommended NIOSH exposure limits for fine and ultrafine TiO_2 (NIOSH, 2005), that are based on detailed toxicological data. Dose–response relationships were examined for the endpoints of inflammation and lung tumour formation in rats. The NIOSH recommendations are for mass-based limits of 1.5 mg/m^3 for fine TiO_2 and 0.1 mg/m^3 for ultrafine TiO_2, and this is convenient for measurement by health and safety practitioners. The BSI Guide recommends a benchmark level of 0.066 x WEL, expressed as a mass concentration for insoluble nanomaterials generally. This is based on the ratio of NIOSH's proposed ultrafine TiO_2 exposure limit divided by the proposed fine TiO_2 exposure limit.

There is a question of whether this ratio can be extrapolated to all insoluble nanomaterials. For example, Maynard (2008) has suggested that a factor of 0.1 may be more appropriate, based on ZnO.

The proposed NIOSH exposure limit of 1.5 mg/m^3 for fine TiO_2 is based on measurement of the respirable particle fraction (NIOSH 2005). Therefore, a strict extrapolation of the (ultrafine/fine) exposure limit ratio to insoluble nanomaterials generally might be that:

*BEL=0.066*Exposure Standard/Limit for the respirable fraction.*

Using exposure standards for inhalable (inspirable) dust fractions may therefore be a further approximation, unless the standards are based on health effects from processes where the particles emitted are primarily respirable.

For application to insoluble nanomaterials where no specific National Exposure Standard has been assigned for a substance on the macroscale, the ACGIH's Threshold Limit Value (TLV) for respirable nuisance dust of $3mg/m^3$ may be an appropriate default exposure standard/limit to use for calculation of BELs.

The Australian National Exposure Standard for carbon black is $3mg/m^3$. A number of forms are nanoscale, and the material is engineered (manufactured). For a default respirable exposure standard of $3mg/m^3$, the BEL would be $0.066*3=0.2mg/m^3$. Thus, BELs calculated from the default exposure standard are precautionary.

Mass-based limits are convenient from the point of view of measurement, and especially for measurement of agglomerates or aggregates of nanomaterials (IFA 2009). However, since our knowledge of the hazards associated with nanoparticles is limited, there is the question of whether a scaling factor based on a mass limit is appropriate in all cases. In cases where similar reasoning can be used as for TiO_2 then this would seem a reasonable BEL.

(b) Particle-number based BELs

To supplement mass-based BELs, the authors of the Guide have also suggested the BEL of 20,000 particles/ml (discriminated from the background), which is a particle number concentration based limit. This would be applicable, for example, in cases where there is no WEL for the material.

IFA (2009) proposes the following number concentration-based benchmark levels for increases over the background exposure:

- *For metals, metal oxides and other biopersistent granular nanomaterials with a density of > 6 000 kg/m³, a particle number concentration of 20 000 particles/cm³ in the range of measurement between 1 and 100 nm should not be exceeded*
- *For biopersistent granular nanomaterials with a density below 6 000 kg/m³, a particle number concentration of 40 000 particles/cm³ in the measured range between 1 and 100 nm should not be exceeded.*

Relating to this matter, issues have been noted by Maynard (2008) about number concentration, and he suggests that particle number concentrations may be good for identifying sources of exposure, but not as a general tool for evaluating exposures to insoluble nanomaterials. IFA (2009) note issues associated with using number concentration-based benchmarks when considering agglomerates or aggregates of nanomaterials.

Given the lack of toxicological information for many insoluble nanomaterials, except for TiO_2, the recommended BELs for insoluble nanomaterials in the Guide are precautionary, but would be a reasonable recommendation. Combining the use of mass-based BELs and the particle number concentration BEL of 20 000 particles/ml may be the optimum approach.

If particle number BELs are applied, the question arises as to over what particle size range this particle concentration should be measured. A Condensation Particle Counters (CPC), e.g. the *P-Trak*, typically measures the particle number concentration which lies in the size range 20-1000nm. Thus, over this range, number concentration can be measured using a single instrument. This also captures the presence of nanoparticle agglomerates larger than 100nm in size, which can contribute to toxicity. Setting a benchmark with a measured range between 1 and 100nm, as in the IFA proposal, is more difficult to measure in practice.

Soluble nanomaterials

Soluble nanomaterials are expected to lose their nanostructure on contact with biological materials, and be cleared from the lungs if inhaled. Repeated inhalation of macroscale $NiSO_4.6H_2O$ did not result in accumulation of nickel in lungs of either rats or mice (Benson et al 1995). Nonetheless, a safety margin of 2-fold over the bulk material was suggested in the BSI Guide. Maynard (2008) suggests that this seems prudent where there is a possibility of new translocation routes and significantly enhanced dose rates. It is claimed that size, shape and surface chemistry of soluble nanoparticles may lead to increased dose rates, or doses to parts of the body not usually exposed to such materials. However to date, there have only been a limited number of studies of these factors.

For the soluble nanomaterial group, conventional risk assessment methodologies may be adequate. A safety margin of 2-fold over the bulk materials should be achievable in practice even if soluble nanomaterials are not found to be more toxic than their bulk material. An example is silver oxide nanoparticles. The National Exposure Standard is 0.01mg/m^3, and hence the BEL would be 0.005mg/m^3. However, a number of soluble nanomaterials (e.g. lipid-type nanoemulsions and dendrimer-type drug delivery systems) do not have bulk forms for which national exposure standards are set.

5.4 Can we measure nanoparticles to enable comparisons with the BSI proposed benchmark exposure levels?

In 2007 the International Organization for Standardization (ISO) published the Technical Report: ISO/TR 27628:2007 – *“Workplace Atmospheres – Ultrafine, nanoparticle and nano-*

structured aerosols - Exposure characterization and assessment" (ISO 2007). This standard addresses measurement and sampling of nanomaterials. The standard gives guidance on characterising exposure to occupational nanoaerosols, including exposure assessment strategies, though concluding with the statement that currently it is still unclear how exposure to nanoaerosols should be appropriately monitored. Although there is toxicity-based evidence that aerosol surface area is an appropriate exposure metric for low solubility particles[4], independent of particle size, there are also indications that particle number within specific particle size ranges may also be important.

More recently, the EMERGNANO report (2009) summarised measurement studies that had been reported in recent years. The report reviewed instrument development studies, instrument optimisation studies and measurement programs.

The OECD Working Party for Manufactured Nanomaterials (WPMN) published a document on *Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance (*OECD WPMN, 2009). This describes a procedure for the initial assessment to identify sources of emissions, and includes information on:

1. identifying potential sources of emissions – by walk-through survey
2. conducting particle number concentration sampling – by use of condensation particle counter (CPC) and optical particle counter (OPC) simultaneously, including background measurements and area sampling, before, during and after the task
3. conducting filter-based area and personal air sampling – including area air sampling, personal air sampling and optional sampling, e.g. surface sampling to examine potential contamination in non-production work areas.

This procedure offers a straightforward approach to comparing exposures with BELs. Validation of the procedure in Australia is currently being undertaken by Queensland University of Technology and Workplace Health and Safety Queensland in a Safe Work Australia commissioned project.

Primary engineered nanoparticles are by definition all smaller than approximately 100nm in diameter. In regard to the weight of these particles, an example by Oberdörster et al. (1995) shows that for equal mass concentrations of 10 µg/m^3, 1 $PM_{2.5}$ particle per cm^3 is needed, whereas for a diameter of 20nm, more than 2 million particles per cm^3 are needed. However, the measurement of engineered nanomaterials in workplace settings has found the presence of few primary nanoparticles, but many agglomerates. In a number of situations, mass measurement has been found to be meaningful, e.g. in the evaluation of the use of local exhaust ventilation (LEV) during a nanomaterials reactor cleanout (Old and Methner, 2008). There is also a high correlation between mass and number concentration in the outdoor air, which can be attributed to outdoor sources emitting both larger and smaller (nano-sized) particles. However, measuring emissions of engineered nanomaterials by mass alone will frequently not be sufficient. Measuring particle numbers is also important.

A number of current projects are working on the development of personal sampling devices (EMERGNANO, 2009). Considering the possible health effects of carbon nanotubes, obtaining measurement techniques for this nanomaterial is particularly important. The EMERGNANO report (2009) noted a study by NIOSH which aims to develop a method for quantifying exposure to carbon nanotubes. The results of this study will be important in developing methods to measure exposure to CNTs in the future. Other projects investigating CNTs include a Safe Work Australia funded study by CSIRO focusing on the detection and

[4] Though not for carbon nanotubes, where it is of limited meaning

measurement of CNTs in workplaces. This project also considers limitations in the measurement of CNTs.

In relation to fibre-like nanomaterials, any developed methods will be required to measure nanoparticles in fibres/ml if the BEL is to be based on the asbestos WEL, until there is additional evidence of human health effects to justify a different WEL and/or unit. In addition, optical microscopy cannot be used as it cannot resolve individual CNTs, but only large bundles (Donaldson et al, 2006).

5.5 Regulations/recommendations in other countries

As described previously, the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA), in its online document *Criteria for assessment of the effectiveness of protective measures*, proposes a number of benchmark limits (increases over the background exposure) for monitoring the effectiveness of protective measures in plants (IFA 2009).

Elsewhere, Section 2 of the RMIT (2009) report describes the risk management guidance documents published internationally to provide guidance for the safe use of nanomaterials in the workplace. From the USA, noted documents are:

- NIOSH's "Approaches to Safe Nanotechnology" guidance document, which was recently updated, incorporating additional information NIOSH (2009)
- the US Department of Energy Nanoscale Science Research Centers (DENSRC, 2007) "Approach to Nanomaterial EH&S" guidance document
- the American Standard Testing Method E2535-07 that describes actions required in order to minimize human exposure to ENPs (ASTM 2007).

None of these documents recommend quantitative benchmark exposure levels for safe work with nanomaterials.

In 2008 the ISO published the Technical Report: ISO/TR 12885 – *"Nanotechnologies – Health and safety practices in occupational settings relevant to nanotechnologies"* (ISO 2008b). The scope of this technical report involved a description of safety practices in occupational settings relevant to nanotechnologies. Although risk assessment in occupational settings is described in this report, the report did not discuss the topic of benchmark exposure levels.

An ISO Technical Specification is currently being developed from the BSI Guide. While most elements in the Guide may be adopted, with modification where appropriate, it is understood that quantitative BELs are unlikely to be recommended.

Internationally, the generally accepted approach for safe use of nanomaterials is based on the adoption of a precautionary approach. This is because of uncertainties in the nature of the hazard for the different types of nanomaterials and the current limitation in methods to adequately measure exposure.

5.6 BSI Guide and potential carcinogens

The BSI Guide provides guidance for the handling of potential carcinogens in Figure 3, under the group of CMARs. In Australia, jurisdictions' carcinogen legislation is currently based on the *National model regulations for the control of workplace hazardous substances*

[NOHSC:1005(1994)]"[5] (NOHSC 1994). As an example, in Victoria the control of the use of Schedule 1 and Schedule 2 carcinogens comes under part 4.2 of the Occupational Health and Safety Regulations 2007 (Victoria, 2007). Not all States adopted the carcinogen provisions into regulation. However when the National Model Work Health and Safety Act and Regulations are introduced in 2012, where toxicological and epidemiological data shows any ENPs are carcinogens, they would be handled similarly under the respective state regulations and can be considered for inclusion on the Schedule lists.

5.7 BELs in the Australian context

Discussions with CSIRO and a review of its current Health, Safety, and Environmental Guidelines for Nanotechnologies (April 2009) provided insight to the relevance of the BSI Guide from the perspective of a primarily research organisation in Australia. The CSIRO has adopted the same four nanoparticle hazard-based groups and BELs as the BSI Guide, and developed its own in-house risk assessment tool.

The CSIRO is essentially a laboratory-based research organisation. About half the nanomaterial work in Australia is in research organisations, and their perspective on the management of risk within their workforce is often supported by a tradition of good technical support. For some of the private sector, which produce or use nanomaterials in a non-research environment, work health and safety support may be more limited, especially in small to medium sized enterprises (SMEs)(NICNAS, 2007).

Discussions with some nanotechnology industry representatives indicated that the existence of the BSI Guide was known, and industry would prefer quantitative risk assessment in most cases. The local industry may be in favour of BELs, provided they are supported by a solid body of toxicological knowledge. BELs can be attractive to industry because they could allow companies to have a sense of certainty about the expectations of the local regulatory bodies.

If quantitative exposure levels are adopted, how should they be considered in an Australian context? There are two options for consideration:

(a) as BELs – i.e. guidance on levels for organisations to aim for

(b) as National Exposure Standards.

One approach might be to adopt them as BELs initially, and consider converting to National Exposure Standards as further hazard, risk and measurement data become available.

In Summary:

The quantitative BELs for the nanomaterial hazard groups as described in the BSI Guide have been reviewed. The recommendations are as follows:

- the BEL for insoluble fibrous nanomaterials should be modified to 0.1 fibre/ml as there is no evidence that these nanomaterials are more toxic than asbestos on a fibre-by-fibre basis, and also a higher number of fibres will be counted by electron microscopy. This BEL may also be applied to poorly soluble fibrous nanomaterials
- there is currently limited scientific evidence to support a quantitative BEL for CMARs of 0.1xWEL. It is a recommendation based on prudence and a rule of thumb, and following a precautionary approach until knowledge is enhanced

[5] The policy proposal for Workplace Chemicals Model Regulations, which combines requirements for hazardous substances and dangerous goods into one document, is noted.

- in regard to insoluble nanomaterials, there is toxicological evidence to support a quantitative BEL of 0.066xWEL for nanomaterials similar to TiO_2, but there is a lack of quantitative evidence for most nanomaterials. Combining the use of mass-based BELs and the particle number concentration BEL of 20,000particles/ml may be the optimum approach. The particle size range over which a particle number concentration BEL should be measured needs to be defined
- Although there is currently insufficient evidence to support a quantitative BEL of 0.5xWEL for soluble nanomaterials, this may be prudent due to the possibility that the size, shape and surface chemistry of soluble nanoparticles may lead to increased dose rates, or doses to parts of the body not usually exposed to such materials. However, a number of soluble nanomaterials do not have bulk forms for which exposure limits are set.

6 Control Banding

6.1 Review of use of Control Banding for chemicals generally

Control banding (CB) is a qualitative risk management process developed originally by the pharmaceuticals industry, and used by the British Health and Safety Executive (HSE) in the *COSHH Essentials* model (HSE, 1999; Oldershaw, 2001). CB can be defined as: A strategy or process in which a single control technology (such as general ventilation or containment) is applied to a defined range or band of exposure to a chemical (such as 1-10 mg/m^3) (Schulte et al, 2008), that falls within a given hazard group (such as harmful by inhalation or irritating to respiratory system).

The key to CB is that it eliminates any complex risk assessments in the decision making process. With the CB approach, it is not necessary for organisations to undertake the steps of measurement of a worker's exposure and making comparisons with occupational exposure standards. This is done by experts to inform development of the CB guidance. CB includes the estimation of a specific hazard band for which a hazardous substance is assigned, based on risk statements (often from a Material Safety Data Sheet, MSDS) in combination with other factors, such as the substance's volatility.

There is now a large body of literature on CB (Zalk and Nelson, 2008) and its use has gained wide focus in both Europe and the USA, and notably in the UK with its application in COSHH Essentials. An issue with COSHH Essentials (Kromhout, 2002a; Kromhout, 2002b) is that it does not address some factors that can cause variability in exposure levels. Kromhout considers the large variability in workplace exposures an important issue and notes that quantitative workplace exposure measurements are required for the most efficient risk assessment. Positive results for the CB approach in COSHH Essentials were reported by Maidment (1998) and Tischer et al. 2003. Jones and Nicas (2006a, 2006b) concluded that recommended exposure bands do not provide consistent or adequate margins of safety. However, findings from an evaluation of *COSHH Essentials for Printers* in six Australian printing businesses, based on workplace exposure measurements, indicated that for this package, application of the control bands consistently reduced exposures to significantly below National Exposure Standards (Morris, 2006).

Embedded in the CB approach is the R-phrase (risk phrase) for a substance linking toxicological data with relative hazard from exposure to a substance via a given route of entry. Gardener and Oldershaw (1991) found that the R-phrases could be referenced and applied as guides in the absence of Threshold Limit Values (TLVs®) or occupational exposure limits (OELs) for inhalation of very toxic substances. This clearly has relevance to control of ENP as many of these particles also do not have clearly defined TLVs or OELs due to the lack of toxicological and epidemiological evidence (Toxikos, 2009).

A recent report on the application of control banding in the USA (Bracker et al, 2009) may provide further insight into the utility of CB implementation in Australia. The report found that with implementation of CB in 10 worksites and then followed by an independent assessment by a Certified Industrial Hygienist (CIH), the CIH agreed with the worksite team's qualitative risk assessments 65% of the time. Of the 35% of disagreements, the worksites over-controlled in 71% of the cases. These results are promising and highlight the benefits that may be obtained from good training in CB on an industry-wide basis. The over-control in this study suggested potentially unnecessary cost with no health gain, while the remaining under-control may place workers at risk.

It is generally agreed that CB is easy to understand for health and safety practitioners in the workplace (Paik et al, 2008). Indeed, since CB was specifically designed for ease of use in small to medium enterprises (SMEs) this would seem a reasonable conclusion (Zalk and Nelson, 2008). It is well established that small businesses perceive lack of time and in-house expertise as a major barrier to the control of workplace exposures. An Australian study examined the enablers and barriers to control other hazardous chemicals in SMEs (Pratt et al, 2006). Since many of the present operators in the Australian nano-industry are SMEs, these businesses may face similar issues.

One of the few examples that incorporates the use of CB for industry in Australia is the Safe Work Australia package: *"Essential Chemical Controls for Australian Printers"* (Safe Work Australia 2009). This package was developed following the positive evaluation of *COSHH Essentials for Printers* in Australian printing businesses.

Issues with Control Banding

- Previous studies have shown that general CB guidance recommendations may need some refinement with certain occupational hazards, such as dispersed use of solvents and some powder handling operations (Tischer, 2002; Tischer et al, 2003).
- Adoption of CB may mean less quantitative measurements are taken.
- Acceptance by inspectorates of risk assessments involving CB. There are a number of ways CB can be used:
  - organisations can undertake a control banding evaluation, or
  - experts can develop guidance based on control banding. Organisations can then use this guidance as part of a conventional risk assessment process, choosing the right control guidance sheets, developed by experts, for their materials/processes/tasks.

Applications of Control Banding

- CB is a qualitative risk assessment and control methodology that has had wide acceptance internationally.
- CB is particularly favourable to the control of chemical hazards where there is limited toxicological information and workplace exposure limits are absent.
- CB can be used effectively in many circumstances to facilitate the control of chemicals in the workplace.

6.2 Control Banding and Nanomaterials

There is currently limited data on actual workplace measurements taken before/after a nanomaterial process commences, and before/after control measures have been employed. A review of the literature found no reports on the effectiveness of CB to control nanomaterials to the benchmark exposure levels recommended in the BSI Guide.

Thus, to assess the efficacy of the control banding approach in the BSI Guide, data has been compiled (Table 4). Information on exposure and emissions measurements from nanotechnology processes where information on engineering controls used is provided, to examine:

- if controls used are aligned with those proposed in the BSI Guide (Figure 3) for the same material/process/activity, and
- if those controls achieve exposures below BELs.

A. Alignment of control methods

It is noted that the controls used align with those recommended in the BSI Guide.

B. Do controls achieve exposures below BELs?

Model assumptions

- In relation to whether the controls achieve BELs, the analysis model assumes the exposures measured are full-shift exposures, i.e. this is looking at worst case scenarios.
- Where there is no exposure standard/limit, or the type of nanomaterials is not reported, a default exposure standard is used. This is the ACGIH's respirable TLV for nuisance dust of 3mg/m^3.

Results

The controls achieve exposures below BELs in 5/10 cases. For the other 5 cases:

- In the report by Old and Methner (2008) on emissions during reactor cleanouts, exposure during cleanout would not occur for the full 8-hour shift, and average (TWA) exposures would be less than the exposures with control reported in Table 4 below. However, results indicate that when handling insoluble nanomaterials where significant process aerosolisation is expected, to reduce exposures to below BELs, a more effective LEV system or process enclosure (as preferred in the BSI Guide) is required.
- For the gas phase manufacturing result (59,100particles/cm^3), with enclosed process, the conclusion might be that enclosure design must be adequate.
- For fibres, use of enclosure achieves an exposure level below 0.1f/ml (asbestos exposure standard) – which is the BEL that this report recommends for fibre-like nanomaterials.

These data indicate that the recommended BELs can be achievable in practice using conventional control approaches, as recommended in control guidance described in the BSI Guide.

In a recent paper by Paik et al (2008), the application of a pilot CB Nanotool for risk level assessment and control of nanoparticle exposures was described. The control bands presented by Paik et al are similar to the previously described ones in the literature (Money, 2003; Zalk and Nelson, 2008) as follows:

Control bands:

- Risk Level 1: General ventilation
- Risk Level 2: Fume hoods or local exhaust ventilation
- Risk Level 3: Containment
- Risk Level 4: Seek specialist advice.

This qualitative risk assessment and management approach focuses resources on exposure controls and describes how the risk needs to be managed.

Application of the CB Nanotool was recently evaluated by Zalk, Paik and Swuste (2009). A total of 27 activities were examined for which controls had been implemented using expert industrial hygienist advice. CB Nanotool was used to determine recommended controls for these activities. Results were:

- CB Nanotool recommendation agreed with existing control in 16 cases
- CB Nanotool recommended a higher level of control in 8 cases
- CB Nanotool recommended a lower level of control in 3 cases.

This was consistent with what the authors of the CB Nanotool were aiming to achieve, i.e. a consistent approach that would generally err on the safe side, in light of the uncertainty associated with the health effects related to NMs.

In Table 5, the controls recommended by the CB Nanotool and industrial hygienist (above) are compared with those recommended in the control banding based guidance in Figure 3 of the BSI Guide, for the same material/process/activity situations. It is not possible to undertake a direct comparison for some activities, and thus a comparison was undertaken for about half the activities.

It was found that the preferred control in the BSI Guide is the same or higher than hygienist or CB Nanotool recommendation for material/process/activity. In a number of cases enclosure is preferred in the Guide to extraction, due to the material being fibre-like or a CMAR.

Validation of the CB approach in Australia is currently the subject of a project being undertaken by Workplace Health & Safety Queensland which is evaluating the use of the CB Nanotool (Paik et al, 2008), and should be completed in mid-2010 (McGarry, 2009).

Table 4. Assessing whether engineering controls can achieve exposure levels less than BELs

Material	Process & Facility	Control used	Control recommended in BSI Guide	Exposure without control	Exposure with control	Exposure Standard (ES)	BEL*	Does control give exposure < BEL? **	Ref	Comments
Carbon Nanotubes (Fibrous)	Blending for composites. Carbon nanotube research facility (laboratory).	Enclosure. Enclosed and ventilated furnace.	Enclosure	172.9-193.6f/ml	0.018-0.05f/ml		0.01f/ml	no	Han (2008)	
Zinc oxide (Insoluble)	Sol-gel spraying onto roll. Nanomaterial production process.	LEV. Horizontal LEV behind roll.	Enclosure (preferred) or extraction	225,000 particles/cm^3	7200-12,000 particles/cm^3		20,000 particles/cm^3	yes	Mohlmann (2009)	
Manganese oxide (Insoluble)	Reactor cleanout. Reactor opened on the top. Production area in research & process development facility.	LEV. Portable LEV unit. Horizontal LEV at edge of opening.	Enclosure (preferred) or extraction	3.6mg/m^3	0.15mg/m^3	0.2mg/m^3	0.013mg/m^3	no	Old & Methner (2008)	Re: ES ACGIH TLV for Mn (respirable).
Cobalt oxide (Insoluble)	Reactor cleanout. Reactor opened on the top. Production area in research & process development facility.	LEV. Portable LEV unit. Horizontal LEV at edge of opening.	Enclosure (preferred) or extraction	0.71mg/m^3	0.041mg/m^3	0.05 mg/m^3	0.0033mg/m^3	no	Old & Methner (2008)	Re: ES Australian National ES & ACGIH TLV (respirable).
Silver oxide (Insoluble)	Reactor cleanout. Reactor opened on the top. Production area in research & process development facility.	LEV. Portable LEV unit. Horizontal LEV at edge of opening.	Enclosure (preferred) or extraction	6.7mg/m^3	1.7mg/m^3	0.1mg/m^3	0.0066mg/m^3	no	Old & Methner (2008)	Re: ES Australian National ES, UK WEL & ACGIH TLV.

Material	Process & Facility	Control used	Control recommended in BSI Guide	Exposure without control	Exposure with control	Exposure Standard (ES)	BEL*	Does control give exposure < BEL? **	Ref	Comments
Silver oxide (soluble)	Reactor cleanout. Reactor opened on the top. Production area in research & process development facility.	LEV. Portable LEV unit. Horizontal LEV at edge of opening.	Enclosure (preferred) or extraction	6.7mg/m^3	1.7mg/m^3	0.01mg/m^3	0.005mg/m^3	no	Old & Methner (2008)	Re: ES For soluble silver oxide. Australian National ES, UK WEL & ACGIH TLV.
Nanomaterial (type not reported – assumed insoluble)	Gas phase manufacturing. Reactor system. Industrial pilot plant.	Enclosure. Enclosed reactor.	Enclosure (preferred) or extraction		0.188mg/m^3 Steady state with process operating.	3mg/m^3	0.2mg/m^3	Yes	Demou (2008)	Re: ES Default. ACGIH for Nuisance dust (respirable).
Nanomaterial (type not reported – assumed insoluble)	Gas phase manufacturing. Reactor system. Industrial pilot plant.	Enclosure. Enclosed reactor.	Enclosure (preferred) or extraction		59,100 particles/cm^3 Steady state with process operating.		20,000 particles/cm^3	No	Demou (2008)	Average level over 10-hour shift is approximately 33,000 particles/cm^3
Nanomaterial (insoluble & soluble, many types)	Nanoparticle production by flame spray pyrolysis. Research laboratories. Production rates 0.017-0.46g/min.	Fume hood with extraction. ***	Enclosure (preferred) or extraction		0.037mg/m^3 PM1 (max) differentiated from background.	3mg/m^3	0.2mg/m^3	Yes	Demou (2009)	Re: ES Default for insoluble. ACGIH for Nuisance dust (respirable).

Material	Process & Facility	Control used	Control recommended in BSI Guide	Exposure without control	Exposure with control	Exposure Standard (ES)	BEL*	Does control give exposure < BEL? **	Ref	Comments
Nanomaterial (insoluble & soluble, many types)	Nanoparticle production by flame spray pyrolysis. Research laboratories. Production rates 0.017-0.46g/min.	Fume hood with extraction. ***	Enclosure (preferred) or extraction		10,000-20,000 particles/cm^3 Steady state with process operating.		20,000 particles/cm^3	Yes	Demou (2009)	Maximum increase over background of 103,900 particles/cm^3
Nanoalumina	Pouring/transferring of nanomaterial. Laboratory. Handling up to 100g of nanoalumina particles.	Fume hood with extraction. Type of hoods: conventional, bypass & constant velocity. Parameters examined: sash location & face velocity.	Enclosure (preferred) or extraction		1575-13,260 particles/cm^3		20,000 particles/cm^3	Yes	Tsai (2009)	Breathing zone measurement

Notes: * For insoluble nanomaterials, the mass-based BEL=0.066*Exposure Standard/Limit.

** This assumes that the process operates for a full shift.

*** Researchers in the laboratories wore protective clothing & masks during work. Also, enclosed reactors were used for known toxic substances.

Table 5. A comparison of controls recommended by occupational hygienists, the *Control Banding Nanotool* and the control banding based guidance in Figure 3 of the BSI Guide.

No	Type of NM*	Process	Hygienist Rec**	CB Nanotool Rec	BSI Guide Rec			Comments
					Preferred	***Optional***	***Small Quantities***	
1	Fibre	Synthesis of metal oxide nanowires	Enclosure	Extraction	Enclosure			Process aerosolisation - fibre
2	Insoluble	Synthesis of Ag & CuO nanoparticles	Extraction	Extraction	Extraction		Admin/PPE	Assuming liquid based synthesis
3	Insoluble	Furnace Operations & Maintenance	Enclosure	Enclosure	Enclosure	Extraction		Process aerosolisation
3	CMAR	Furnace Operations & Maintenance	Enclosure	Enclosure	Enclosure			Nickel - CMAR. Process aerosolisation
4	Insoluble	Deposition of liquid suspended nanoparticles onto surfaces	General Ventilation	General Ventilation	Extraction		Admin/PPE	Liquid based process
5	Various	Sample preparation	Extraction	General Ventilation				
6	Fibre	Water poured into container of liquid-suspended CNTs	Extraction	Extraction	Enclosure	Extraction	Admin/PPE	Liquid based fibre process
7	Insoluble	Au nanoparticles used to test CNT filter	General Ventilation	General Ventilation				
8	Insoluble	Mixing polystyrene spheres with buffer	General Ventilation	General Ventilation	Extraction		Admin/PPE	Liquid based mixing
8	Insoluble	Etching nanostructures onto semiconductors	General Ventilation	General Ventilation				
9	CMAR	Addition of CdSe quantum dots onto porous glass	Extraction	Extraction	Enclosure	Extraction	Admin/PPE	CdSe, liquid phase
9	Insoluble	Addition of PbS quantum dots onto porous glass	Extraction	Extraction	Extraction		Admin/PPE	PbS, liquid phase
10	Insoluble	Growth of Pd nanocatalyst	Extraction	Extraction	Extraction		Admin/PPE	Assuming liquid based synthesis & growth
11	Insoluble	Sample preparation & characterisation	General Ventilation	General Ventilation				
12	Insoluble	Sample preparation & characterisation	Extraction	General Ventilation				
12	CMAR	Sample preparation & characterisation	Extraction	General Ventilation				
13&14	Soluble/Insoluble	Synthesis of aerogel	General Ventilation	General Ventilation	Extraction		Admin/PPE	Liquid-based synthesis
15	Various	Synthesis & optical characterisation	General Ventilation	Extraction				
16	CMAR	Sample preparation & characterisation of CdSe nanodots	Extraction	Extraction				
17	Insoluble	Sample preparation & characterisation of C diamonoids	Extraction	Extraction				
18	Insoluble	Sample prep & characterisation of Ag/Au using laser microscopy	General Ventilation	Extraction				
19	Various	Preparation of nanofoam sample for microscopy	General Ventilation	Extraction				
20	Fibre	Preparation of CNTs for microscopy	General Ventilation	Extraction				
21	Insoluble	Machining (e.g turning/drilling) of aerogels & nanofoams	Extraction	Extraction	Enclosure	Extraction		Process aerosolisation
22	Various	Site-wide waste sampling activities	General Ventilation	Extraction				
23	Various	Waste management	General Ventilation	Extraction				
24	Various	Analysis of nanomaterials waste samples in the laboratory	General Ventilation	Extraction				
25	Various	Radioactive and hazardous waste management activities	General Ventilation	Extraction				
26&27	Fibre	Purification & functionalisation of CNTs	Extraction	Extraction	Enclosure			If dry process
26&27	Fibre	Purification & functionalisation of CNTs	Extraction	Extraction	Enclosure	Extraction	Admin/PPE	If liquid process

* NM - Nanomaterial

** Rec - Recommended controls

With a CB approach for nanomaterials, elimination is unlikely (Paik et al, 2008). This is not included in any of the control bands, but all the other parts to the hierarchy of controls may be applied. Substitution/modification, enclosures and engineering controls are the most stringent forms of control.

A recent paper (Conti et al, 2008) described the findings of ICON's international survey of nanomaterial firms and laboratories, regarding their environmental health and safety (EHS) programs. Overall, it concluded that the majority of nanomaterial firms and laboratories are attentive to nanospecific EHS and product stewardship issues. However, a majority of organisations expressed a need for more toxicological information and EHS guidance. Three Australian organisations provided responses to the survey.

Helland et al (2008) reported on a survey of companies in Switzerland and Germany that had nanomaterial-based products on the market. The survey was undertaken in December 2005 and February 2006, and 20 companies from each country responded. Of the 40 companies, 26 were small with less than 100 employees. Notably, 26 companies reported that they did not undertake a risk assessment where nanoparticulate materials are involved. This result supports the need to have available practical risk assessment methodologies for companies, and supports the consideration of control banding.

Information on the current situation in Australia in relation to risk assessment for nanomaterials is currently not available.

In summary

In relation to CB for nanomaterials:

- CB is particularly favourable to the control of chemical hazards where there is limited toxicological information and workplace exposure limits are absent, as is currently the case with engineered nanomaterials
- based on limited evidence, the CB Nanotool can address the satisfactory control of nanomaterials in the workplace. This is currently being validated in Australia by Workplace Health and Safety Queensland
- use of the control banding guidance in the BSI Guide can enable organisations to reduce exposures below the BELs. Exposures below the BELs are achievable using conventional engineering controls.

7 Discussion and conclusions

About benchmark exposure levels

Probably the most controversial element of the BSI Guide has been the assigning of the quantitative benchmark exposure levels (BELs). This report has reviewed these BELs.

The BELs provided in the BSI guide have not been derived from a body of knowledge on human epidemiology. They have been recommended with a precautionary approach in mind, based on the limited toxicological knowledge available.

Some nanotechnology industry representatives suggested they would welcome BELs which have a solid basis, as these would provide a quantitative basis for the precautionary approach to control for nanomaterials where hazard information is limited. However, a survey of the industry is required to determine if this is the majority view.

While there are issues associated with the hazard type groups suggested in the BSI Guide, at the present time they appear to be practical groupings of nanomaterials. There is a clear need for some form of grouping, and the one in the BSI Guide provides substantive differentiation between nanomaterials. An alternative split-up based on two groups, those engineered nanomaterials which do not exist in the bulk form, such as nanotubes and quantum dots, and those that do exist in the bulk form, such as metal oxides, would not differentiate between some very different types of nanomaterials.

In relation to each of the BELs examined, the report finds:

- the BEL for insoluble fibrous nanomaterials should be modified to 0.1 fibre/ml as there is no evidence that these nanomaterials are more toxic than asbestos on a fibre-by-fibre basis, and also a higher number of fibres will be counted by electron microscopy. This BEL may also be applied to poorly soluble fibrous nanomaterials
- there is currently limited scientific evidence to support a quantitative BEL for CMARs of 0.1xWEL. It is a recommendation based on prudence and a rule of thumb, and following a precautionary approach until knowledge is enhanced
- in regard to insoluble nanomaterials, there is toxicological evidence to support a quantitative BEL of 0.066xWEL for nanomaterials similar to TiO_2, but there is a lack of quantitative evidence for most nanomaterials. Combining the use of mass-based BELs and the particle number concentration BEL of 20 000 particles/ml may be the optimum approach. The particle size range over which a particle number concentration BEL should be measured needs to be defined
- although there is currently insufficient evidence to support a quantitative BEL of 0.5xWEL for soluble nanomaterials, this may be prudent due to the possibility that the size, shape and surface chemistry of soluble nanoparticles may lead to increased dose rates, or doses to parts of the body not usually exposed to such materials. However, a number of soluble nanomaterials do not have bulk forms for which exposure limits are set.

If quantitative exposure limits/levels are adopted, then one approach might be to adopt them as BELs (guidance) initially, and consider converting to National Exposure Standards as further hazard, risk and measurement data become available.

About control banding for nanomaterials

Control Banding (CB) for the Australian nanomaterial industry is likely to be the most suitable risk control approach for managing nanoparticle exposure in many situations, even though it is yet to become an accepted form of control for Australian workplaces. Control banding is particularly favourable to the control of chemical hazards where there is limited toxicological information and workplace exposure limits are absent as is currently the case with engineered nanomaterials.

However in general, Australian workplaces do not have wide experience of using the control banding approach for other hazards. This situation is likely to remain so until there is impetus nationally to accept the control banding approach in support of State, Territory and Commonwealth regulations. Control banding should be used together with the conventional approach of assessment and control undertaken in the current jurisdictional regulations, including those existing for human carcinogens.

Two control banding models look promising:

- the Control Banding Nanotool, which has been specifically designed for control of nanomaterials
- use of the control banding guidance in the BSI Guide can enable organisations to reduce exposures below the BELs. Exposures below the BELs are achievable using conventional engineering controls.

Thus, noting also the Australian evidence available (albeit limited) for use of control banding with chemicals (Morris, 2006), it should not be onerous for the Australian nanotechnology industry to utilise control banding in their workplaces if it were to be recommended in an Australian Guide.

The use of both Benchmark Exposure Levels and control banding are consistent with a precautionary approach to handling nanomaterials, as recommended by Safe Work Australia where limited information about hazards and risks is available.

8 Key issues

1. Currently, there are no Australian guides for safe handling and control of specific ENPs that can be incorporated into the current legislation framework used within Australia. CSIRO is developing guidance for safe handling and disposal of carbon nanotubes for Safe Work Australia.

2. While there are issues associated with the hazard groups in the BSI Guide, they currently appear to be practical groupings of nanomaterials.

3. Australia should look to utilise the quantitative BELs recommended in the BSI Guide, with the BEL changed to 0.1f/ml for fibrous nanomaterials. Further development of BELs can be undertaken over time, based on the increasing knowledge base of the toxicology of individual or groups of nanomaterials. This may be relatively slow for some of the ENPs.

4. The use of control banding for control of exposures in Australian nanotechnology workplaces looks promising, particularly where there is limited hazard information available.
    a. The Control Banding Nanotool should be considered, dependent upon current evaluation study results.
    b. Application of the control banding-based guidance in the BSI Guide can reduce exposures effectively.
    c. Further work may be undertaken to understand the practical experiences associated with implementation of control banding with different types of nanomaterials processes as this information becomes available, and a cost effectiveness study on control banding for nanotechnologies may be undertaken.
    d. Control banding should be used in conjunction with current approach to risk assessment where measurements are possible and used in the control for hazardous substances.

5. There is a need to develop further capability of measuring nanomaterial exposures, which will also enable assessment of control against Benchmark Exposure Levels. The OECD WPMN guidance for emissions measurement of nanomaterials appears to be a practical way to measure nanomaterial exposures in workplace settings. This is currently being validated by Queensland University of Technology and Workplace Health and Safety Queensland in a project commissioned by Safe Work Australia. Following completion of the validation, focus should be placed on dissemination of the methodology to hygienists in Australia. This methodology may be used to assess performance against Benchmark Exposure Levels.

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