

Building a Safety Program to Protect the Nanotechnology Workforce:

A Guide for Small to Medium-Sized Enterprises



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health



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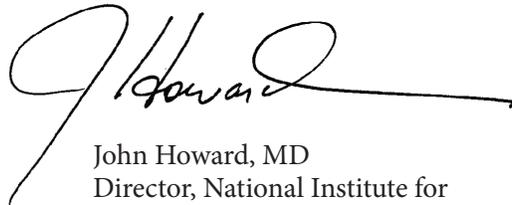
FOREWORD

The National Institute for Occupational Safety and Health (NIOSH) is pleased to present *Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises*. Responsible development of nanotechnologies includes considering and managing the potential, unintended consequences to human health and the environment that might accompany development and use of the technology. This guide will demonstrate that the key to ensuring the safety of your business, particularly when resources are limited, is to prevent occupational exposures and incidents before they happen.

Addressing safety and health issues in the workplace serves these important purposes:

- Promotes and preserves employee well-being
- Saves the employer money
- Supports a competitive advantage
- Adds value to the business
- Engenders public trust.

A strong, proactive safety program built and supported by the entire organization can also build confidence among your employees, investors, business associates, and insurance providers.



John Howard, MD
Director, National Institute for
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ABBREVIATIONS

ABIH	American Board of Industrial Hygiene
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
ASSE	American Society of Safety Engineers
CFR	Code of Federal Regulations
CIB	Current Intelligence Bulletin
CIH	Certified Industrial Hygienist
CSP	Certified Safety Professional
CNF	Carbon nanofiber
CNT	Carbon nanotube
CPSC	Consumer Product Safety Commission
EHS	Environment, health, and safety
EPA	U.S. Environmental Protection Agency
GAO	U.S. Government Accountability Office
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HEPA	High efficiency particulate air
HSE	Health and Safety Executive
ISO	International Organization for Standardization
NIOSH	National Institute for Occupational Safety and Health
NNIN	National Nanotechnology Infrastructure Network
NTRC	Nanotechnology Research Center
OSHA	Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act of 1970
PEL	Permissible exposure limit
PPE	Personal protective equipment
PtD	Prevention through Design
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
REL	Recommended exposure limit
SDS	Safety data sheet
SHIB	Safety and Health Information Bulletin
SNUR	Significant new use rule

TiO ₂	Titanium dioxide
TLV	Threshold limit value
TSCA	Toxic Substances Control Act
VPP	Voluntary Protection Program



1 INTRODUCTION

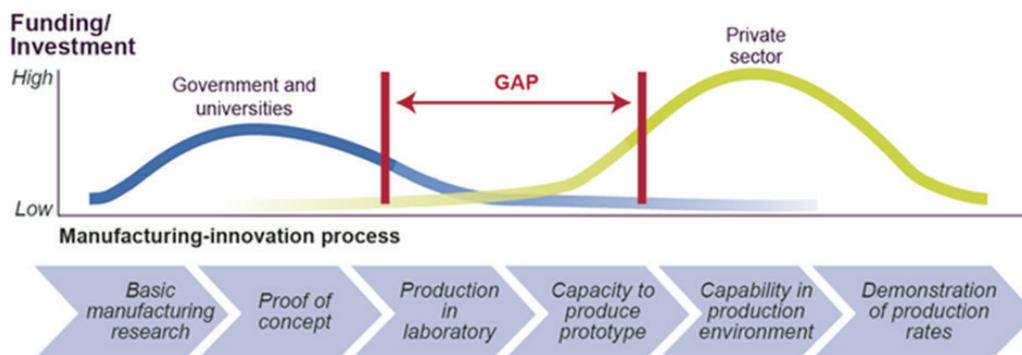
This guide will provide you—the entrepreneurial business owner—with the tools necessary to develop and implement a written health and safety program to protect your most important business asset: your employees and colleagues. You’ll learn to recognize and control potential hazards and risks from your nanomaterial process that may adversely impact the health, safety, and well-being of your employees and the productivity of your business.

2 THE VALUE OF SAFETY AND HEALTH

Congratulations! While meeting the business challenges you face every day—such as generating revenue, compensating mission-critical employees, and paying insurance, taxes, and rent—you are giving priority to safety and health by using this guide. That’s smart. Compared with small companies that survive only 1 to 2 years, those that stay in business for at least 5 years had less than half the rate of occupational injuries in their first year [Holizki et al. 2006]. Research focusing on top-level managers suggests that their attitudes and actions play a significant role in their organizations’ occupational safety performance [Rundmo and Hale 2003]. Managing the development and implementation of an effective safety and health program uses the same skills needed to launch your business. A strong safety culture in the workplace builds confidence among your employees, investors, business associates, and insurance providers.

Nanomaterial start-ups are instrumental in taking ideas from nanotechnology research and proof of concept to production scale. However, the gap between the proof of concept and production in the private sector is sometimes known as the Valley of Death, where good ideas languish from lack of funding (Figure 1). In a start-up environment, any business is just one incident away from losing the ability to operate (survive). Establishing an effective safety and health program will minimize the potential for health and safety incidents. Ensuring employee safety and health within your business, particularly when resources are limited, will assist your

Funding/Investment Gap in the Manufacturing-Innovation Process



Source: GAO adapted from Executive Office of the President.

Figure 1. The investment gap between basic research and production in the private sector [GAO 2014].

business in overcoming barriers to climbing the mountain of success, staying competitive, and allowing for future growth.

Aligning safety goals with your business goals has many advantages:

- Reduced site hazards and thus fewer injuries and health risks
- Reduced workers' compensation insurance costs
- Increased productivity
- Fewer delays due to accidents
- Reduced absenteeism
- Improved morale by addressing real and perceived hazards and associated risks
- Reduced employee turnover [AIHA 2008].

A good place to start creating a basic strategy for workplace safety and health is with the Small Business Handbook from the Occupational Safety and Health Administration (OSHA), available online at www.osha.gov/Publications/smallbusiness/small-business.pdf [OSHA 2005a]. This handbook includes a self-inspection checklist. Two other good resources, which will help you develop the nanotechnology-specific elements of your program, are NanoRisk Framework, developed by DuPont and Environmental Defense Fund (<http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/>), and Nanotechnology Environmental Health and Safety: A Guide for Small Business (www.nanohub.org/groups/gng/nano_basics) [Hull 2010].

Ideally, company management will provide leadership and assume responsibility for implementing, maintaining, and monitoring safety performance. Management and employees should both be involved in a health and safety committee that creates a written company health and safety program, holds regular meetings, investigates incidents (including any near-miss or workplace accidents), and looks for ways to continually improve the health and safety of the workplace.

As a small business owner, you know the importance of focusing on your core expertise and seeking professional input in other areas critical to your success. Therefore, consider using professional resources for developing a health and safety program. An industrial hygienist or safety professional with experience in evaluating materials and processes and can anticipate where you might have exposure potential. An industrial hygienist will also have access to the equipment needed for sampling and evaluating emissions and exposures and can recommend controls. In addition, safety professionals likely can do those things more competently and affordably than you can, particularly while you're focused on developing and growing your business. See www.abih.org/about-abih/cih-caih for a helpful overview of Certified Industrial Hygienist (CIH) qualifications and functions, published by the American Board of Industrial Hygiene (ABIH). Need assistance locating a CIH near you? Follow this link: <http://www.abih.org/about-abih/public-roster>. A helpful guide to hiring the right occupational health and safety professionals, including Certified Safety Professionals (CSPs) is available from the American Society for Safety Engineers, at www.asse.org/assets/1/7/Employer_Handbook_version_5_61.pdf. Hiring a safety professional may be an expense you hadn't planned on, but doing so will likely save you money, time, and headaches down the road.

Also consider joining a business consortium such as the Nanobusiness Commercialization Consortium (www.nanobca.org/) to pool resources and learn about what other companies are doing to protect their business interests.

3 RISK MINIMIZATION

Research from the past 20 years shows that (1) small particles, on an equal mass basis, can be more hazardous than larger ones; (2) some incidental nanoparticles (e.g., welding and diesel fumes) can be carcinogenic when inhaled; (3) small aerosol pollutants have been linked to respiratory and cardiovascular health effects; and (4) certain “legacy produced” nanomaterials, such as ultrafine titanium dioxide, carbon black, and fumed silica, are respiratory hazards [Antonini 2003; Brown et al. 2001; Dockery et al. 1993; Driscoll 1996; Duffin et al. 2002; Gardiner et al. 2001; IOM 2000; Merget et al. 2002; Oberdorster et al. 1994, 2005, 2007; Oberdorster and Yu 1990; Pope et al. 2002; Reuzel et al. 1991; Seaton et al. 2010; Zhang et al. 2000, 2003].

These findings mean that a health and safety program for a business with processes involving the creation or use of nanomaterials may require more and different information than is required by or available from traditional health and safety programs. In addition, information on health hazards for nanomaterials may be harder to access. For example, NIOSH investigators showed that information on health hazards may not be adequately presented in Safety Data Sheets (SDSs); 67% of the nanomaterial SDSs reviewed provided insufficient data for communicating the potential hazards [Eastlake et al. 2012].

Risk includes the probability of quantifiable damage, injury, liability, loss, or any other negative occurrence that is caused by a vulnerability, and it may be avoided through preemptive action. Risk is a measure of the hazard multiplied by the exposure; hence, controlling the exposure will minimize the risk (Figure 2). An effective risk management program should identify the potential safety and health hazards, characterize the opportunities for human or environmental exposures (including exposure by both intended use and accidental release), and include a plan to control the potential exposures. Because there are known hazards associated with some of the raw materials and processes used to create engineered nanomaterials, managing hazardous systems and the receiving, use, and disposal of all of the chemicals and materials involved in your production should be part of your risk management program.



Figure 2. Risk is the product of hazard times exposure.

4 RISK MANAGEMENT

Employers should inform their workers about the dangers of chemical hazards in their workplaces and train their employees on proper safeguards. This includes providing information on the hazards and identities of chemicals they may be exposed to on the job and describing protective measures to prevent adverse effects. Chemical producers and importers must also evaluate their products for chemical hazards and provide hazard information to customers.

Effective risk management requires 3 elements: hazard identification, exposure assessment, and exposure control. A simple way to start is to ask yourself some basic questions:

1. Do any of the chemicals, materials, or processes have any hazardous properties?
2. Are any of my employees exposed, and how would I know?
3. If I have exposures, how do I control or eliminate them?

Hazard Identification: Aside from any nano-specific concerns, what is known about the toxicological properties of the elemental components from which a particular nanomaterial is produced? What is known about the safety properties? Could these particular materials pose an explosion hazard? Are peer-reviewed study reports available for this material that suggest toxicological effects in animal models? What information do you have about all of your process chemicals and materials? This type of information may be found on the product SDS, in the ToxNet database sponsored by the U.S. Library of Medicine (<http://toxnet.nlm.nih.gov/>), or in the NIOSH Pocket Guide to Chemical Hazards (<http://www.cdc.gov/niosh/npg/>). Note that much of the chemical information may pertain to the bulk non-nano chemical and some SDSs are lacking in quality, but these are still a good starting point for obtaining information.

Exposure Assessment: Exposure can occur through inhalation, skin contact, ingestion, or combinations thereof. Does the potential for exposure to the nanomaterial (or other chemical or physical hazards) exist? Have all of the uses in the workplace been evaluated, from receiving to waste disposal to maintenance of equipment? Do you see visible debris outside of your equipment? Is the exhaust filter replaced regularly? Emissions could occur during manual handling, such as transfer of product or cleaning of processing equipment. Employees performing tasks often know more about the handling of materials during specific processes. Ask your employees about possible exposures, as they may be the ones with the most familiarity of possible exposure points. Make sure to think about all of your employees, including the operators, maintenance, and janitorial staff.

Exposure Control: Do you know where you have a high potential for worker exposure, and have you verified that through measurements? What procedures are in place or should be developed to minimize or eliminate worker exposure(s)? Can steps used to control similar problems in other industries be adapted for your process? What are the options for reducing or eliminating exposures until controls are in place?

Answers to these questions will help you formulate a basic health and safety program. Your program should include

- A strong management commitment to workplace health and safety and to building and sustaining an effective health and safety program;

- A written company health and safety policy covering all types of chemical and physical hazards in your workplace that keeps your employees safe and complies with the law;
- Engagement of employees in the workplace health and safety program;
- A clear delineation of roles and responsibilities for everyone in your company involved in the nanomaterial lifecycle, from receiving to disposal; and
- Effective measures for documentation, communication, and training.

Figure 3 illustrates components of an overall health and safety program that includes a nanomaterial risk management program designed to minimize worker exposure to engineered nanoparticles [Schulte et al. 2008a]. This figure demonstrates how risk management for nanomaterials can be incorporated into the health and safety program.

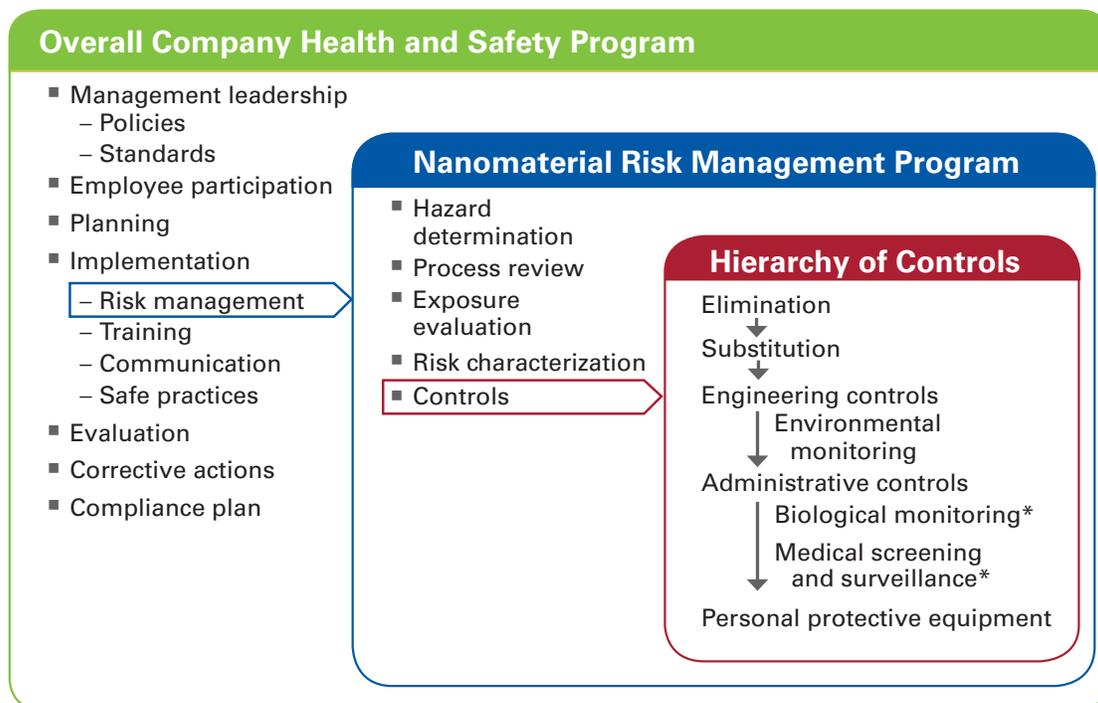


Figure 3. Components of an overall health and safety program.

*See Section 8 for information on biological monitoring and medical screening.

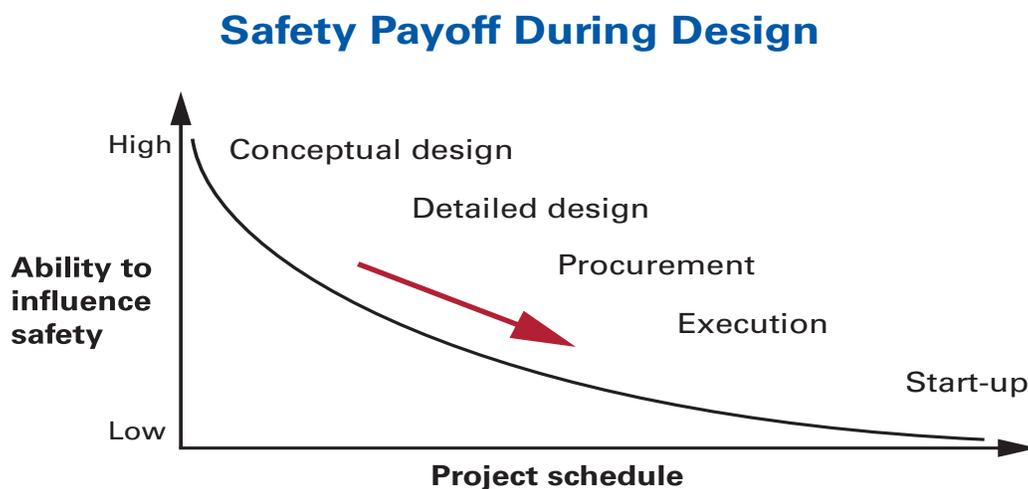
For three nanomaterials—titanium dioxide (TiO₂), carbon nanotubes (CNTs), and carbon nanofibers (CNFs)—NIOSH has completed a risk assessment and provided risk management guidelines in the form of recommended exposure limits (RELs), which are intended to be protective over a working lifetime [NIOSH 2011, 2013]. RELs have not yet been developed for the large (and growing) number of other engineered nanomaterials now being produced and used, as their hazards are not fully known. Given the unlikelihood of every engineered nanomaterial being thoroughly studied, the most effective way to keep workers safe is to decrease the potential for exposure.

5 PREVENTION THROUGH DESIGN

The national initiative on Prevention through Design (PtD) was launched by NIOSH in 2007 with the goal of designing out occupational hazards to protect workers. PtD involves all of the efforts to anticipate and design out hazards to workers in facilities, work methods and operations, processes, equipment, tools, products, materials, new technologies, and the organization of work [Schulte et al. 2008b; NIOSH 2010]. PtD utilizes the traditional hierarchy of controls by focusing on hazard elimination and substitution, followed by risk minimization through the application of engineering controls and warning systems applied during design, redesign, and retrofitting. The best time to think of preventing workplace exposures and incidents that lead to injuries and illnesses is early in the technology, process, or product development. PtD principles, including the design of nanomaterials and strategies to eliminate exposures and minimize risks that may be related to the manufacturing processes and equipment, can be applied at all stages of the lifecycle of an engineered nanomaterial.

The advantages of integrating PtD early in the design of your facility include

- Greater ability to incorporate safety and health principles into facility design
- Cost savings of designing-in safety and health features rather than retrofitting them
- Less impact on the project schedule, by including elements from the beginning rather than adding them later (Figure 4).



[Adapted from Szymberski 1997]

Figure 4. The ability to influence safety is highest during earliest stages of project design [Szymberski 1997].

The most effective approach to creating and maintaining a safe and healthy working environment is to couple PtD concepts with ongoing vigilance and frequent re-examinations of workplace processes. The small business environment, in particular, can be fast-paced and dynamic. Indeed, this ability to rapidly change course in short order is one of the key advantages

that small businesses frequently need and have over larger organizations. In certain instances, small business leaders may feel compelled to alter work practices rapidly in order to pursue a particular opportunity or to satisfy a critical customer need. For example, a new nanomaterial synthesis strategy may be required to achieve a desired yield or material formulation attributes. The repercussions of such changes could have a significant impact on business operations if an incident or exposure occurs. An effective PtD strategy implemented early in the process reduces the potential repercussions by incorporating good management of change.

6 HIERARCHY OF CONTROLS

Health and safety professionals have learned, historically, that there is a hierarchy that can be followed to identify different options for controlling worker exposures. Practitioners have learned over the years which controls are effective and which are most feasible for a given situation. One representation of the hierarchy of controls is shown in Figure 5. The idea behind this hierarchy is that the control methods at the top of the list are more effective and protective than those below them.

PtD Incorporates Hierarchy of Controls



Figure 5. Hierarchy of Controls [adapted from ANSI/ASSE Z590.3 2011; AIHA 2008].

As companies adopt hazard control measures higher in the hierarchy, the business value is increased [AIHA 2008]. These improvements in business value are related to

- Faster time to market
- Improved operational efficiency

- Higher product quality and
- Increased market share

The American National Standards Institute/American Society of Safety Engineers (ANSI/ASSE) Z590.3, Prevention through design guidelines for addressing occupational hazards and risks in design and redesign processes, provides guidance on including PtD concepts within an occupational safety and management system. It includes guidance for a life-cycle assessment and design model that balances environmental and occupational safety and health goals over the life span of a facility, process, or product [ANSI/ASSE 2011].

6.1 Elimination and Substitution

Processes and material applications still in early development stages are good candidates for elimination or substitution because capital costs for change may be lower or more manageable. If the process is still at the design or development stage, elimination and substitution may be relatively inexpensive and simple. Making changes to an established process to eliminate hazards almost always carries a higher capital cost. Engineering and material changes made to existing processes also have the potential to create high indirect costs from quality effects or supply chain interruption. For an existing process, major changes in equipment and procedures may be required to eliminate a hazard. Substituting process chemicals or nanomaterial applications may not involve much change of equipment, but finding a safer material to substitute, with the desired functionality of the original, can be a challenge—albeit not impossible.

For nanomaterials, it is recognized that properties such as size, shape, functionalization, surface charge, solubility, agglomeration, and aggregation state can have profound effects on a particle's toxicological properties and interactions with biological systems [Castranova 2011; Albanese et al. 2012]. In certain instances, it may be possible to reduce the relative hazard of a particular production process while maintaining the desired properties and functionality of the final nanomaterial product. Although it may not be practical or even possible to retain certain properties and functions with less hazardous substitutes in all cases, this approach can be highly effective at reducing risks to workers, consumers, and the environment in some situations. For example, use of less toxic solvents can provide a relatively simple way to reduce nanomaterial production hazards and should be considered for substitution whenever possible. Helpful information for those seeking less hazardous alternatives for their nanomaterial production processes may be found in the white paper “Green Nanotechnology Challenges and Opportunities,” published by the American Chemical Society Green Chemistry Institute (http://greennano.org/sites/greennano1.uoregon.edu/files/GCI_WP_GN10.pdf).

The U.S. Environmental Protection Agency (EPA) uses alternatives assessments to look for safer chemicals. The environmental alternatives assessments are conducted as risk management actions, when warranted, under the Toxic Substances Control Act (TSCA) Work Plan for Chemicals (<http://www2.epa.gov/saferchoice/design-environment-alternatives-assessments>).

It can be challenging to know exactly how and when the substitution of materials or the modification of processes will actually improve safety. Engaging professional help can minimize the likelihood of unintended consequences of simply replacing a recognized hazard or activity with something that might, in fact, be more hazardous or lead to greater risk.

6.2 Engineering Controls

Engineering controls come into play when less hazardous substitutes to a nanomaterial process are not readily identified or easily implemented. Engineering solutions control a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls are typically independent of worker interactions or are integrated easily into tasks and provide a high level of protection.

Engineering controls isolate the process or equipment or contain the hazard. Information on the following variables will assist in determining which exposure controls are appropriate for your processes: the quantity of nanomaterials being handled or produced, their physical form and dispersibility (dustiness), and the task duration. As each one of these variables increases, the chance of exposure becomes greater, as does the need for more efficient exposure control measures (Figure 6). Operations involving easily dispersed dry nanomaterials, such as

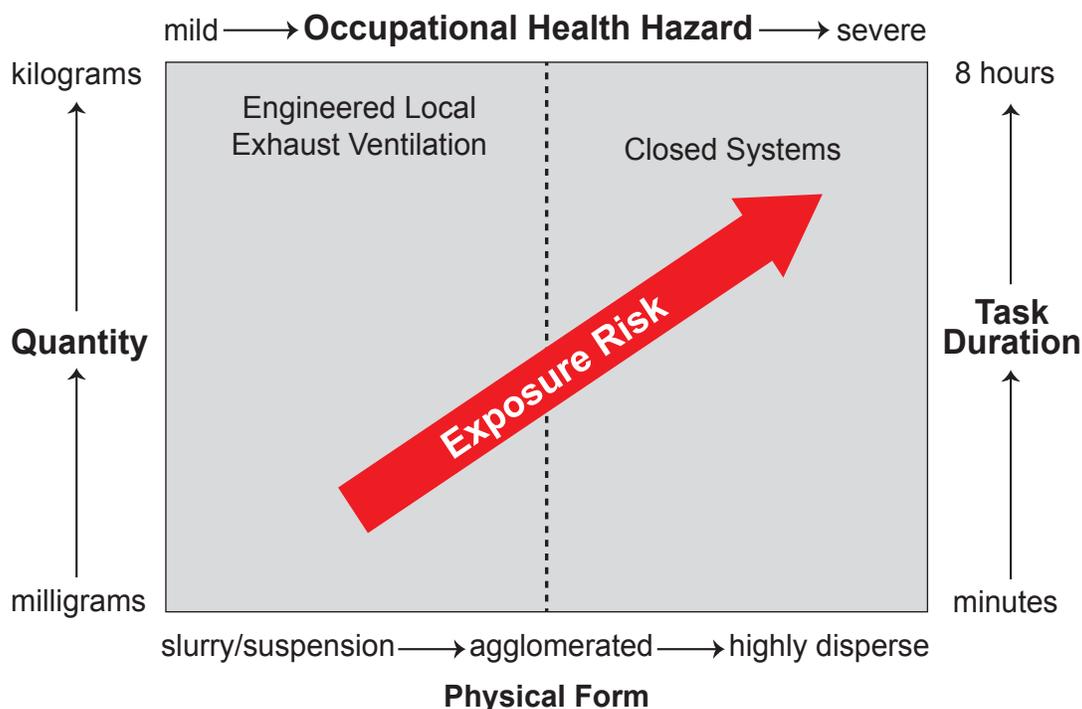


Figure 6. Factors influencing control selection [NIOSH 2009a].

powders, deserve more attention and more stringent controls (such as enclosure) than those involving nanomaterials that are suspended in a liquid matrix or embedded in a solid. Liquid nanoparticle suspensions typically offer less of an inhalation risk during routine operations, but the likelihood of exposure can increase significantly if they are aerosolized through sonication or in unexpected situations such as a spill [Johnson et al. 2010]. Nanomaterials incorporated into bulk solids may pose some risk if the solid matrix is cut, sawed, drilled, sanded, or handled in any way that creates a dust or releases the nanomaterial. One potentially unexpected exposure point is in the handling of waste containers. Wetted wipes can dry out and release nanomaterials that may become airborne when waste bins are handled, thus necessitating procedures such as disposal into a sealed bag.

Examples of specific engineering controls may be found in the NIOSH guidance documents Current Strategies for Engineering Controls in Nanomaterial Production and Downstream Handling Processes (www.cdc.gov/niosh/docs/2014-102) and General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories (www.cdc.gov/niosh/docs/2012-147/). Controls suggested in those documents (Figures 7 and 8) include

- Flexible containment (plastic sleeves, continuous-feed bag liners)
- Low flow containment hood (exhausted through a HEPA filter)
- Plexiglass gloveboxes (exhausted through a HEPA filter)
- Glove box isolators and other types of isolation enclosures



Figure 7. A large-scale ventilated reactor enclosure used to contain production furnaces to mitigate particle emissions in the workplace. Photo by Flow Sciences, Inc.

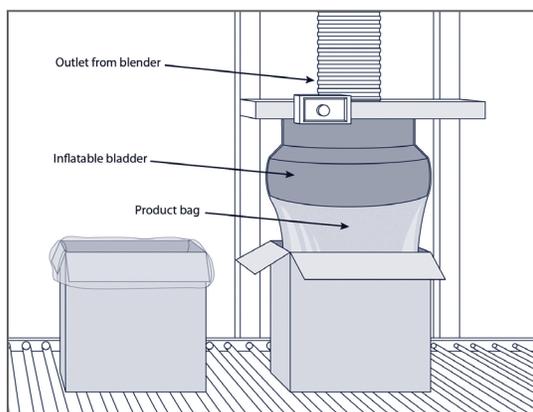


Figure 8. An inflatable seal used to contain nanopowder/dusts as they discharge from a process such as spray drying [NIOSH 2014].

The use of walk off sticky mats at exits can help to reduce potential tracking of nanoparticles outside of the facility. Ideally engineering controls should eliminate the amount of dust collecting on the floor and a well-controlled work environment should have minimal dust collected from the shoes unlike the example in Figure 9.

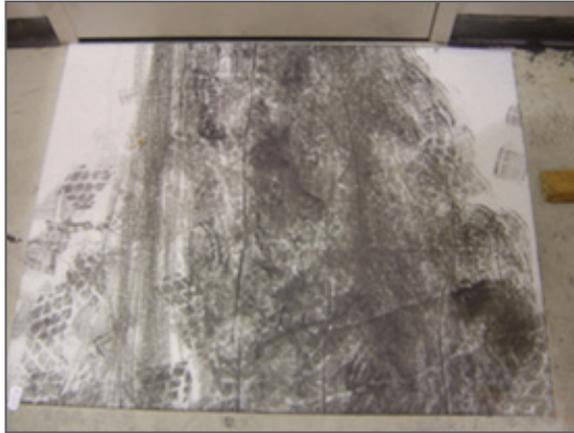


Figure 9. A “sticky mat,” demonstrating the collection of dirt and debris from shoes in a nanomaterial production facility. Photo by Mark Methner, NIOSH.

Although some new controls may be prohibitively expensive for smaller organizations to purchase outright, there are strategies to stretch a limited budget:

- Consider working with partners in academia or larger organizations who can provide access to facilities with suitable high-level controls.
- Consider providers of used laboratory equipment who can offer effective controls at more affordable pricing. (Disclaimer: There are inherent risks to purchasing used equipment, and buyers should take all necessary precautions to ensure that any controls purchased operate within manufacturer specifications and in accordance with applicable certifications prior to use. You should also verify that the equipment was thoroughly decontaminated.)
- Work with regional economic development groups to convey the importance of engineering controls as critical enabling tools for nanotechnology commercialization by small businesses by emphasizing the benefits of protecting workers, the environment, and the community.
- Include discussion of EHS in your business plan as well as financing for high-level controls that your business will need.

6.3 Administrative Controls

Work practices and administrative controls are most effective when they are made part of a greater safety and health culture within an organization. Administrative controls including good housekeeping practices (such as wet-wiping cleanup and use of HEPA-filtered vacuums) can reduce the airborne concentration of workplace contaminants and thus can reduce a worker’s potential exposure. Administrative controls also include training employees, limiting the time the workers handle the material, specifying good housekeeping and other good work practices, and implementing proper labeling and storage of materials. As with any activity involving the handling of hazardous materials, workers should wash their hands after completing a handling task. In addition, workers should wash their hands before eating, drinking, smoking, or leaving the workplace, and consumption of food and drink should be prohibited in the areas where nanomaterials or any hazardous materials or chemicals are handled.

Training your employees on any known or suspected hazards and risks associated with the engineered nanomaterials (and any other chemicals) they work with is one of the most important things you can do. At a minimum, training should

- give them a good level of awareness about the potential hazards from exposure, and locations where exposures could occur
- inform them of knowledge gaps where hazard information is lacking or unknown
- describe appropriate nanomaterials handling and storage techniques
- explain proper use of personal protective equipment
- review the importance of cleaning contaminated surfaces or clothing
- discuss maintenance of engineering controls (such as filter change-out and disposal)
- explain proper disposal of nanomaterials or nanomaterial-contaminated objects [NIOSH 2009a].

Workers should be educated about job tasks that may place them at risk of exposure to nanomaterials (such as material harvesting, material transfer, equipment maintenance, and waste disposal) and the use of engineering controls and work practices to minimize exposure. The ability of employees to translate training into work practices that reduce hazards and risks and that promote reasonably safe working conditions should be evaluated regularly by supervisors working in partnership with qualified health and safety professionals. Measures of employee understanding, actions, and feedback can then be used to determine the frequency of training, the need for retraining, or the need to revise training methods.

The GoodNanoGuide offers a broad range of case studies, worker protections, and training materials that can be adapted to suit your specific safety program (see https://nanohub.org/groups/gng/training_materials).

6.4 Personal Protective Equipment

Personal protective equipment (PPE) is frequently used when hazards are not particularly well controlled or in situations where controls are not feasible, such as maintenance or response to spills. These methods for protecting workers have also proven less effective than other measures, as they require consistent effort on the part of the workers. PPE programs may be less expensive to establish than the initial cost of engineering controls but, over the long term, can be more costly to sustain and may be the source of unexpected exposure and risk.

Unless your processes have been evaluated and appropriate containment/control devices have been installed, and you have evidence that any residual exposures are under control, operators should wear PPE as a precautionary measure (Figure 10). Wearing PPE is strongly suggested for performing maintenance or opening a sealed enclosure. To minimize dermal and respiratory exposure, NIOSH suggests the following PPE:

- Long pants without cuffs and a long-sleeved shirt.
- Laboratory coats or coveralls. Consider lab coats with cuffs and Tyvek-type wrist covers, to protect the exposed skin between the lab coat and glove. Note that laboratory coats made of cotton woven material are not recommended for worker protection against nanoparticle exposure, because of the high particle contamination and release ability [Tsai 2015].

- Nitrile or other chemically impervious gloves as appropriate for handling nanomaterial powders and liquids. Note that latex gloves do not provide protection from most chemical solvents and may present an allergy hazard.
- Closed-toe shoes made of a low-permeability material (such as leather). Disposable over-the-shoe booties may be used.
- Safety glasses, safety goggles and/or face shields, based on an assessment of the hazard risk from liquid splashes. Note that a face shield alone is not sufficient protection against unbound dry materials.
- Respirators.

Respirators, selected according to the NIOSH Respirator Selection Logic (<http://www.cdc.gov/niosh/docs/2005-100/>) [NIOSH 2005], should be used when workers could inhale nanomaterials due to lack of effective engineering controls or during activities with higher nanomaterial-exposure potential (such as maintenance or emergencies). All respirator use should follow the OSHA respiratory protection standard 29 Code of Federal Regulations (CFR) 1910.134. The standard specifies that workers wearing respirators have to be in a respiratory protection program that includes fit-testing and medical clearance to wear a respirator [OSHA 1992]. Studies have indicated that N95 and P100 filter cartridges are effective at capturing nanoparticles [Shaffer and Rengasamy 2009], but the potential for face seal leakage (that is, leakage of particles through gaps between the respirator and the face) could be significantly greater than that through the filter itself. This is particularly more likely with half-mask respirators, including disposable filtering facepiece respirators. Note that medical procedure or surgical masks are not appropriate for protection against nanomaterials. Also note that the EPA has issued Significant New Use Rule for some types of carbon nanotubes, requiring the use of full face respirators with N100 cartridges if exposure is not effectively controlled (<http://www.gpo.gov/fdsys/pkg/FR-2011-05-06/html/2011-11127.htm>).



Figure 10. Nanomaterial worker wearing personal protective equipment in a work area with local engineering controls. Photo by Mark Methner, NIOSH.

To prevent contamination of the clean areas (offices, breakrooms, etc.) of the facility, use a change room to put on and remove PPE at the entrance to the manufacturing areas.

7 VERIFICATION OF CONTROLS

Once you have established the controls, you need to verify that they are working correctly. You can develop simple yet effective strategies to test the effectiveness of your control systems. The procedures you use will be dictated by the type of engineering controls used or the nature of the task or process being controlled. When testing how well your exposure control measures are working, it's best to take measurements of the nanomaterial of interest in the same units the exposure standard is expressed in. Right now, exposure standards exist for only three nanomaterials [NIOSH 2011, 2013]:

- ultrafine titanium dioxide (TiO_2): REL = $300 \mu\text{g}/\text{m}^3$
- carbon nanotubes (CNTs) and carbon nanofibers (CNFs): REL = $1.0 \mu\text{g}/\text{m}^3$ as elemental carbon (background-corrected)

The RELs for these materials are expressed as mass per volume, on a respirable fraction. Thus, these nanomaterials should be sampled on a mass-per-volume basis for comparison. However, for other nanomaterials, the effectiveness of your controls will need to be verified with a combination of quantitative indicators and evaluation of particle number concentrations:

- Testing and certification procedures specified by ANSI Z9.5 and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) 110 for laboratory containment such as inflow (face) velocity profiling, smoke testing, cross-draft airflow testing, tracer gas containment testing, and variable air volume testing [ANSI 2012a, ASHRAE 1995]
- Qualitative indicators of proper installation and functionality of the control systems, such as whether gaskets, shrouds, and ventilation hoses are in their required locations and free of visible defects
- Quantitative indicators of proper installation and functionality of the control systems, such as whether hood face velocities are within proper ranges
- Semiquantitative measures of potential worker exposures, such as determinations of airborne dust or particle concentrations near the exposure control device (near the local exhaust ventilation or at the opening of the fume hood, for instance)
- Quantitative measures of worker exposures, such as personal sampling for the nanomaterial of interest

Exposure assessment and control verification can be done with industrial hygiene sampling methods. These methods include personal sampling, where samplers are located in the breathing zone of the worker, and area/background sampling, where they are placed at static locations. The assessment should use both filter-based samples and particle counters [NIOSH 2009a; Methner et al. 2009]. Particle counters tell you the real-time quantity of nanomaterials (as well as other, incidental background particles). Filter-based samples identify the nanomaterial. Two common methods applied to filters are electron microscopy, especially for visualizing objects of less than about 200 nm, and elemental analysis (Figure 11). Elemental analysis involves the collection of an air sample on a substrate (such as a filter), which is then analyzed

for the element of interest by means of chemical techniques. Elemental analysis will identify the presence and quantity of a specific element contained in your nanomaterial, but it cannot tell you anything about the size of the particle that contained the element unless you include the use of a size-selective sampler (such as a cyclone to capture the respirable fraction). Ideally, a complete exposure assessment to verify control requires all three sampling methods: particle counters, elemental analysis, and electron microscopy. The combination of these techniques should help address these basic questions:

1. Did a release occur in my nanomaterial process?
2. Did employee exposure occur?
3. Was my nanomaterial involved in the exposure?
4. Was the process contained?

Undertaking the tasks of exposure assessment and control verification without the assistance of an experienced industrial hygienist may be challenging but not impossible for the determined entrepreneur. If this is you, you may find it helpful to reach out to academic partners for assistance. Many major research universities in the United States offer their electron microscopy and elemental analysis facilities to external users through fee-for-service contracts. Additionally, the U.S. National Nanotechnology Infrastructure Network (NNIN) provides a network of user facilities across the country whose mission is, in part, to provide nanomaterial characterization assistance to users in academia, business, and government (see <http://www.nnin.org/>). Many commercial vendors rent out particle counters and size analyzers. Renting these instruments can dramatically reduce the up-front costs for small businesses.

Correlate Simple and Complex Measurements

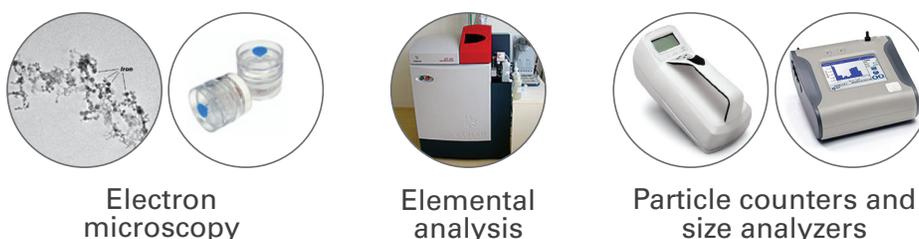


Figure 11. Equipment for assessing possible exposures includes filter samples for both electron microscopy and elemental analysis, as well as real-time particle counters and sizers.

8 MEDICAL SCREENING AND MEDICAL SURVEILLANCE

Medical screening in the workplace focuses on the early detection of adverse health effects for individual workers. The purpose of screening and early detection is to provide an opportunity for intervention before unintended health effects or disease processes occur. Screening may involve obtaining and reviewing an occupational history, medical examination, and medical

testing. Medical surveillance is different from screening in that it involves the ongoing health evaluation of a group of workers. Medical surveillance data are collected for the purpose of preventing disease and evaluating the effectiveness of intervention programs.

Medical screening should not replace primary prevention efforts to minimize worker exposures to nanomaterials. Additionally, occupational medical screening should be integrated with the employee's ongoing, comprehensive medical care, because comorbidities such as asthma, heart disease, and diabetes may play a significant role in the individual outcomes of exposure to workplace chemicals, including nanomaterials.

If any employees use a respirator, you will need to review the medical surveillance requirements under the OSHA respiratory protection standard [OSHA 1992]. Employees must be medically cleared on an annual basis to wear a respirator if their employer provides respirators.

A basic medical surveillance program should contain the following elements [Trout and Schulte 2010; NIOSH 2009b]:

- A baseline medical evaluation performed by a qualified health professional and other examinations or medical tests deemed necessary by the health professional
- Periodic evaluations including symptom surveys, physical exams, or specific medical tests based on data gathered in the initial evaluation
- Post-incident evaluations
- Worker training
- Periodic analysis of the medical screening data to identify trends or patterns.

Note that there is a growing body of evidence from laboratory animal studies that some nanomaterials cause adverse health outcomes. However, there are no specific screening tests or health evaluations that can identify health effects in people that are caused solely by exposure to engineered nanomaterials.

9 EMERGENCY PREPAREDNESS

Your business should be prepared to respond to any type of emergency. Emergencies can vary in scale, duration, and risk and can range from calling an ambulance for a sick or injured worker, to knowing where to shelter in place during a tornado or earthquake, or responding to chemical spills. It is important to maintain a first-aid kit, post emergency phone numbers, and know where the nearest medical facilities are located. Establish emergency evacuation routes and procedures, and practice escape and sheltering plans regularly.

Have a plan for accidental spills. A good nanomaterial spill kit will include these items:

- Barricade tape
- Nitrile or other chemically impervious gloves
- Elastomeric full-facepiece respirator with P100 or N100 filters (fitted appropriately to responder)

- Adsorbent materials (such as spill mats)
- Disposable wipes (Kimwipes® or shop rags)
- Sealable plastic bags
- Walk-off mat (such as a sticky mat)
- HEPA-filtered vacuum (never use compressed air to blow dust, never dry-sweep, and never use a vacuum without a HEPA filter)
- Spray bottle with deionized water or other appropriate liquid (such as surfactants or alcohols) to wet dry powders.

Have a spill kit on hand, before you need it. Several commercial companies sell spill kits.

10 FIRE AND EXPLOSION

Per OSHA's Safety and Health Information Bulletin (SHIB) entitled Combustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions (www.osha.gov/dts/shib/shib073105.html), any "material that will burn in air" in a solid form can be explosive when in a finely divided form [OSHA 2005b]. The SHIB also reports that dust particles with a diameter smaller than 420 microns (those passing through a U.S. No. 40 standard sieve) are considered combustible. However, larger particles can still pose an explosion hazard. For instance, as larger particles are moved, they can abrade each other, creating smaller particles. In addition, particles can stick together (agglomerate), causing them to become explosible when dispersed [OSHA 2005b]. For an explosion to occur, all five elements of the explosion pentagon (dispersion, confinement, fuel, oxygen, and ignition) are required (Figure 12).

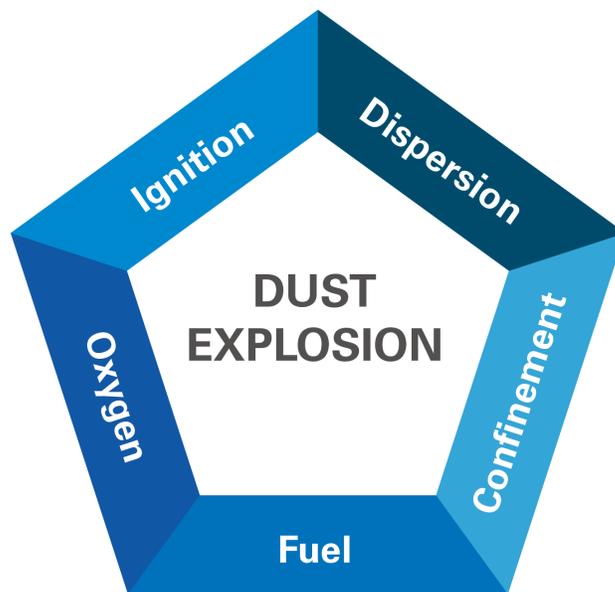


Figure 12. All five elements of the explosive triangle are required for a dust to explode.

Combustible dusts often originate from organic or metal solid materials that are ground into very small particles, fibers, fines, chips, chunks, flakes (or a small mixture of these), which present a fire or deflagration (sudden and rapid combustion) hazard when suspended in air or some other oxidizing medium over a range of concentrations. If the burning is confined by an enclosure such as a building, room, vessel, or processing equipment, then the resulting pressure rise may cause an explosion. Secondary explosions can occur if settled dust is released during initial explosions, so it is important to regularly inspect and clean areas where materials could become concentrated in your workplace (such as in drop ceilings and behind production equipment).

Explosions are classified as St 1 (Explosion), St 2 (Energetic explosion), or St 3 (Violent explosion). Published data on a few types of carbonaceous nanomaterials indicate that they would fall into the St 1 category, with explosion properties similar to those of wood dust or coal dust [Turkevich et al. 2015]. Studies have shown that nanosized aluminum can have an explosion classification of St 2 or St 3, depending on the size of the aluminum particles [Bouillard et al. 2009; Wu et al. 2010]. Nanosized titanium is borderline St 1/St 2 [Dastidar et al 2013]. The explosion characteristics of nanometals are highly dependent on the manufacturer and the humidity [Dastidar et al. 2013; HSE 2010].

The reduction of the explosion risk depends on controlling three of the components necessary for an explosion, oxygen, the combustion material and the ignition sources (flames, heat, friction, static, etc.) [Ostiguy et al. 2010]. Prevent dust emissions and accumulations, eliminate the ignition sources and ensure adequate fire protection.

Not all nanomaterials have the same potential for a fire or explosion hazard. Some nanomaterials are specifically designed to be explosive propellants, and others are designed to be fire retardants. If you want to know the probability and potential severity of your nanomaterial exploding, have it tested by one of the companies that advertise dust combustibility testing (you can locate one by searching online). Detailed testing procedures can be found in the Health and Safety Executive (HSE) report on Fire and Explosion Properties of Nanopowders (<http://www.hse.gov.uk/research/rrpdf/rr782.pdf>) [HSE 2010]. This report also contains data for several nanomaterials under varying relative humidities.

11 PRODUCT STEWARDSHIP

You are to be commended for thinking about how you can take action to reduce risks and costs to workers, consumers, disposers, and the environment. You share the responsibility for proper use of your nanomaterial during its manufacture and uses throughout its lifecycle. This is good product stewardship.

Product stewardship means your company is taking responsibility for the environmental, safety, and health impact of your product at key points in its design, manufacture, use, recycling, and disposal. This stewardship is especially important when you develop a new material, because the initiative and the costs of dealing with such matters will be yours almost exclusively. Customers, workers, disposal services, and other end-users of the material may each have different requirements when it comes to accepting your material. The Hazard Communication Standard provides a comprehensive structure to the types of information you must disclose.

All data or information you provide must be vetted by your own properly controlled testing or that of a trusted source.

The Hazard Communication Standard requires chemical manufacturers, distributors, or importers provide Safety Data Sheets (SDSs) (formerly known as Material Safety Data Sheets, or MSDSs) to communicate the hazards of hazardous chemical products. As of June 1, 2015, the HCS requires new SDSs to be in a uniform format and include the section numbers, the headings, and associated information under the headings below [OSHA 2012]:

Section 1. Identification includes product identifier; manufacturer or distributor name, address, phone number; emergency phone number; recommended use; restrictions on use.

Section 2. Hazard(s) identification includes all hazards posed by the chemical and required label elements.

Section 3. Composition/information on ingredients includes information on chemical ingredients and trade secret claims.

Section 4. First-aid measures includes important symptoms/effects (acute or delayed) and required treatment.

Section 5. Fire-fighting measures lists suitable extinguishing techniques and equipment, in addition to chemical hazards from fire.

Section 6. Accidental release measures lists emergency procedures, protective equipment, and proper methods of containment and cleanup.

Section 7. Handling and storage lists precautions for safe handling and storage, including incompatibilities.

Section 8. Exposure controls/personal protection lists OSHA's Permissible Exposure Limits (PELs); Threshold Limit Values (TLVs); engineering controls; and personal protective equipment (PPE).

Section 9. Physical and chemical properties lists these characteristics of the chemical.

Section 10. Stability and reactivity lists chemical stability and possibility of hazardous reactions.

Section 11. Toxicological information includes routes of exposure; related symptoms and acute and chronic effects; and numerical measures of toxicity.

Section 12. Ecological information

Section 13. Disposal considerations

Section 14. Transport information

Section 15. Regulatory information

Section 16. Other information includes the date of preparation or last revision.

The manufacturer is responsible for communicating possible hazards through SDSs and product labels, and if you are purchasing nanomaterials you can make effective use of that information. However, to accurately portray the hazards of the nanomaterial or nano-enabled product that you are producing, you will be responsible for the creation of the SDS and the product labels, so you may need to have toxicological and other testing completed. There are companies available to assist you with creation of the SDS and labeling requirements, and these types of companies can be found by an internet search. The International Standards Organization (ISO)/TR 13329:2012 standard, Nanomaterials—Preparation of Material Safety Data Sheet (SDS), provides guidance on the development of content for, and consistency in, the communication of information on safety, health, and environmental matters in SDS for substances classified as manufactured nanomaterials and for chemical products containing manufactured nanomaterials.

12 FEDERAL REGULATORY COMPLIANCE

There are many regulations that you, as a manufacturer or user of engineered nanomaterials, should be aware of and that apply to many aspects of your business. Note that the regulations in this section do not comprise an exhaustive list and that some may only pertain if your business meets certain conditions. For example, the OSHA Injury and Illness log pertains only if you employ more than 10 employees, and provisions of the U.S. EPA TSCA are applicable only if your business meets certain production conditions. Because every small business is different and the quantities produced and the number of employees are subject to change, you should be aware of all of the applicable local, state, and federal regulations. These regulations should be reviewed annually as your business grows. Regulations apply to all of the chemicals in your process, not just the nanomaterials. Beyond regulatory compliance, your nanotechnology business may also be exposed to certain occupational, environmental, and consumer liability concerns—many of which are not necessarily unique to nanomaterials and nano-enabled products. A detailed discussion of these concerns is beyond the scope of this document, but others have provided thorough treatment of this subject [Monica and Calster 2010].

12.1 OSHA Requirements

Under the Occupational Safety and Health Act of 1970 (OSH Act), employers are responsible for providing a safe and healthful workplace. The OSHA mission is to ensure safe and healthful workplaces by setting and enforcing standards and by providing training, outreach, education, and assistance. Employers must comply with all applicable OSHA standards. All employers and businesses, no matter the size, must also comply with the General Duty Clause of the OSH Act, which requires employers to keep their workplace free of serious recognized hazards. A small business guide detailing all of the regulations that may apply to your small business workplace may be found at the OSHA website: www.osha.gov/dcsp/smallbusiness/index.html. Be sure to check out the General Industry Compliance Assistance Quick Start web page: www.osha.gov/dcsp/compliance_assistance/quickstarts/general_industry/index_gi.html.

The following are examples of OSHA standards that may be applicable in situations where employees are exposed to nanomaterials:

- Section 5(a)(1) of the OSH Act of 1970 (29 U.S.C. 654), often referred to as the General Duty Clause, requires employers to “furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.”
- 1904, Recording and reporting occupational injuries and illness. While this requirement only applies if you have more than 10 employees (and are not classified as a partially exempt industry), complying even with 10 or fewer employees demonstrates a good standard of practice and commitment to health and safety.
- 1910.132, Personal protective equipment, general requirements
- 1910.133, Eye and face protection
- 1910.134, Respiratory protection
- 1910.138, Hand protection
- 1910.1200, Hazard communication (creation of Safety Data Sheets and communication with your employees)
- 1910.1450, Occupational exposure to hazardous chemicals in laboratories
- Certain substance-specific standards (for example, 1910.1027, Cadmium)

12.2 EPA Requirements

The EPA regulates nanomaterials under the Toxic Substances Control Act (TSCA): <http://www.epa.gov/laws-regulations/summary-toxic-substances-control-act>. Various sections of TSCA provide authority for EPA to do the following:

- Require, under Section 4, testing of chemicals by manufacturers, importers, and processors where risks or exposures of concern are found.
- Require, under Section 5, notification of “new chemical substances” before their manufacture. In some cases, existing chemicals manufactured at the nanoscale have been determined to be new chemical substances.
- Issue Significant New Use Rules (SNURs), under Section 5, when it identifies a “significant new use” that could result in exposures to, or releases of, a substance of concern.
- EPA has permitted limited manufacture of new chemical nanoscale materials through the use of consent orders or SNURs under TSCA.

If any bacterial claims are being made about the nanomaterial, then it would be regulated under the U.S. EPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): www.epa.gov/agriculture. Other existing EPA statutes such as the Clean Air Act or Clean Water Act may also apply to your nanomaterial manufacturing or use.

12.3 CPSC Requirements

The Consumer Product Safety Commission (CPSC) protects consumers primarily from products that pose fire, electrical, chemical, or mechanical hazards. Federal law requires manufacturers and importers to test many consumer products for compliance with consumer product

safety requirements. On the basis of test results, the manufacturer or importer must certify the consumer product as compliant with the applicable consumer product safety requirements in a written or electronic certificate. Certificates are required to accompany the applicable product or shipment of products covered by the certificate, and a copy must be provided to retailers, distributors, and (upon request) the government. If a substance is considered hazardous, then the Federal Hazardous Substances Act requires cautionary labeling (see <http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/FHSA-Requirements/>).

12.4 REACH Requirements

If you are shipping materials to Europe, you will need to comply with the European Chemical Agency Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH): <http://echa.europa.eu/web/guest/regulations/reach/>. Companies have the responsibility of collecting information on the properties and uses of substances that they manufacture or import at or above quantities of 1 ton per year. They also must assess the hazards and potential risks presented by the substance. Although there are no explicit requirements for nanomaterials under REACH, they meet the regulations' substance definition, and therefore the provisions apply.

12.5 NIOSH

NIOSH (the publisher of this booklet) is a nonregulatory agency that conducts research and makes recommendations to prevent worker injury and illness. NIOSH has published recommended exposure limits for titanium dioxide, carbon nanotubes and carbon nanofibers [NIOSH 2011, 2013].

12.6 Other Requirements

Authorities in your state or local area may have issued additional regulations specific to production and management of waste or discharges (in air and water) of chemicals used in your process.

13 BUILDING AND SUSTAINING A SUCCESSFUL PROGRAM

As your business grows with success and changes, your health and safety program can keep pace. A relationship with a health and safety professional can help you stay abreast of changing requirements and practice advancements. As illustrated in Figure 13, you can apply the concept of “Plan, Do, Check, Act” to keep your program relevant and your health and safety program strong. This concept is based on ANSI Z10 Safety Management Systems and encourages integration with other management systems to facilitate organizational effectiveness [ANSI/AIHA/ASSE 2012b]. Although the scope of ANSI Z10 covers occupational health and safety, it can also be used to support other initiatives such as social responsibility and sustainability. Sustainable growth encourages organizations to continually improve all facets of their business. The adoption of Z10 fits well with organizations desiring long-term sustainable growth in a socially responsible manner by reducing injury and illness and improving overall employee well-being.

The purpose of the standard is to provide organizations with an effective tool for continual improvement of their occupational health and safety performance.

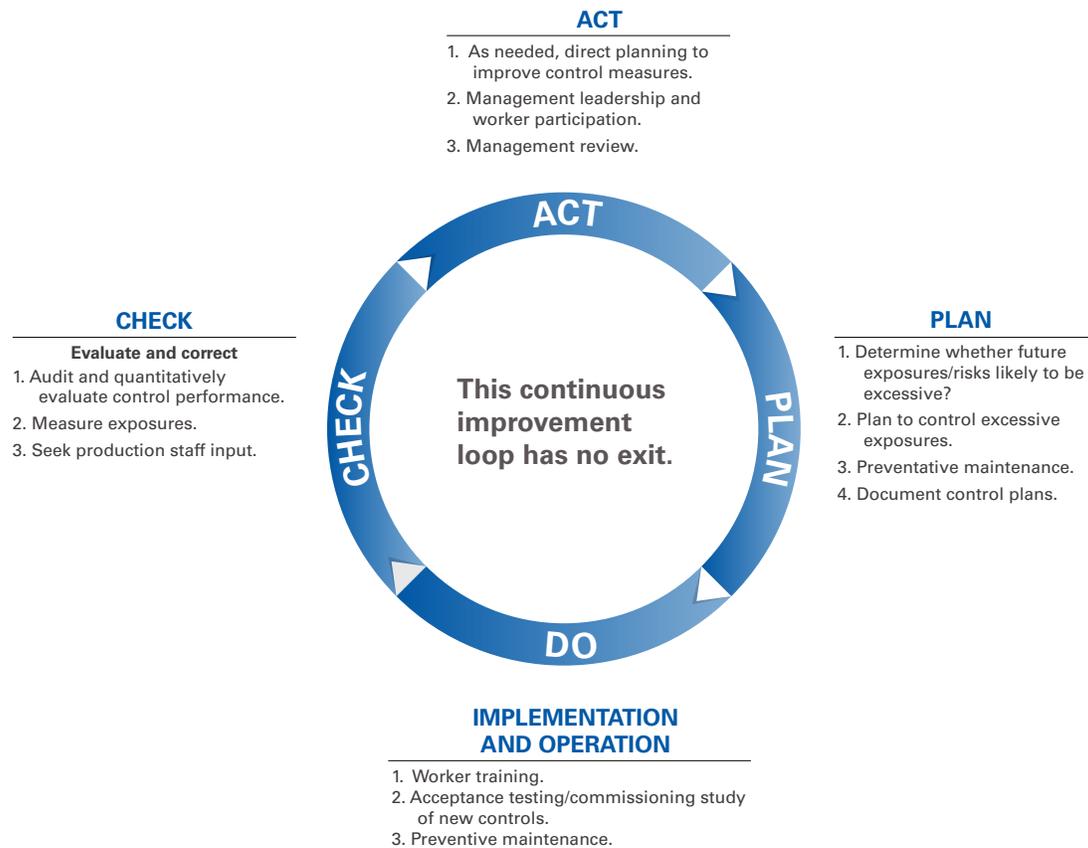


Figure 13. A proven business approach to keeping all aspects of your enterprise strong and effective (adapted from ANSI/AIHA/ASSE [2012b]).

The new ISO 45001 Occupational Safety and Health Management standard (due to be published in 2016) stresses that an organization must look beyond its immediate health and safety issues and take into account the wider societal scope such as contractors, suppliers, and even neighbors in the surrounding area. ISO 45001 requires health and safety to be part of the overall management system and no longer just an extra issue, requiring a strong buy-in from management and leadership.

Under OSHA's Voluntary Protection Programs (VPP), many employers have improved their workplace safety and health management systems and implemented activities or procedures that have produced outstanding results and contributed to improved safety and health for workers: https://www.osha.gov/dcsp/vpp/all_about_vpp.html. The VPP has a 20+ year history, and the average VPP worksite has a Days Away, Restricted, or Transferred case rate that is 52% below the average for its industry. VPP participation can also lead to lower employee turnover and increased productivity and cost savings.

14 CONCLUSIONS

Ensuring the workplace health and safety of your business and your employees is paramount to the success and future growth of your business. This responsibility for businesses that use or handle engineered nanomaterials has been made even more challenging by research showing that some nanomaterials cause respiratory and cardiovascular risks in laboratory animals. Your employees may be at risk of exposure by inhalation, skin absorption, or ingestion. Several factors can affect their potential for exposure, including

- The route, concentration, duration, and frequency of any exposure
- The ability of the nanomaterial to be easily dispersed (such as a dust or aerosol)
- The control measures in place to reduce or limit exposures.

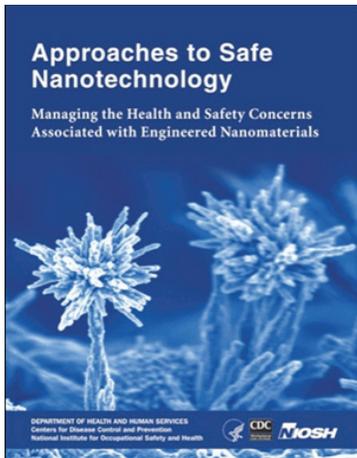
The best way to control potential exposures and to protect your workers includes creating and following a risk management plan that incorporates the hierarchy of controls: elimination, substitution, engineering controls, administrative controls, and personal protective equipment.

A true pathway to success is to build a safety program that responds to the rapidly changing environment of the nanomaterial market. A good safety program builds a bridge between the needs that are basic to any business: (1) generate revenue, (2) keep people safe, and (3) obey the law.

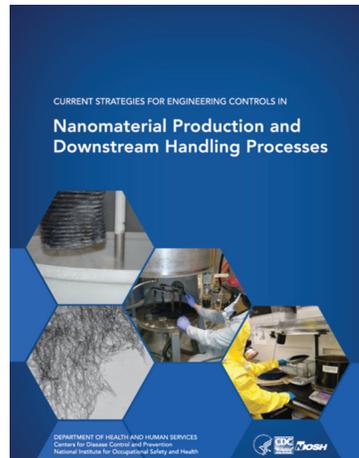
These elements are the keys to a successful health and safety program:

- Leadership by top management
- Inclusion of employees
- Establishment of a Safety Committee
- Creation of a written risk-management plan that includes
 - Identification of potential hazards
 - Identification of exposure potential
 - Establishment of controls following the hierarchy of controls
 - Verification of controls
 - Preparation for emergencies
 - Regulatory compliance
- Continued evaluation of the safety program
 - Plan, Do, Check, Act

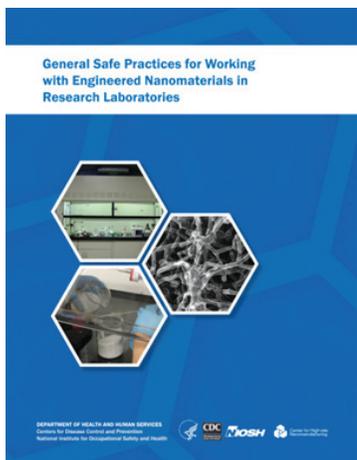
15 HELPFUL RESOURCES



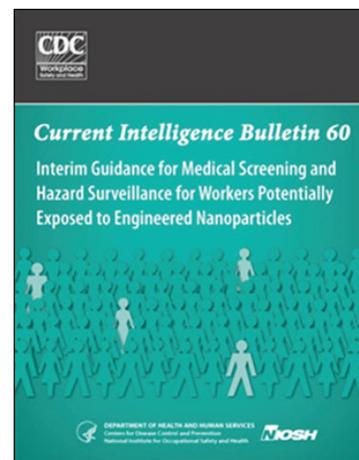
<http://www.cdc.gov/niosh/docs/2009-125/>: Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials. NIOSH Publication No. 2009-125.



www.cdc.gov/niosh/docs/2014-102/: Current Strategies for Engineering Controls in Nanomaterial Production and Downstream Handling Processes. NIOSH Publication No. 2014-102.



<http://www.cdc.gov/niosh/docs/2012-147/>: General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories. NIOSH Publication No. 2012-147.



<http://www.cdc.gov/niosh/docs/2009-116/pdfs/2009-116.pdf>: Current Intelligence Bulletin 60: Interim Guidance for the Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles. NIOSH Publication No. 2009-116.

www.cdc.gov/niosh/docs/2005-100/: Respirator Selection Logic. NIOSH Publication No. 2005-100.

<http://www.cdc.gov/niosh/topics/nanotech/>: NIOSH Nanotechnology web page.

<http://www.cdc.gov/niosh/npg/>: NIOSH Pocket Guide to Chemical Hazards. NIOSH Publication No. 2005-149.

<http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf>: Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide. NIOSH Publication No. 2011-160.

<http://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf>: Current Intelligence Bulletin 65: Occupational Exposure to Carbon Nanotubes and Nanofibers. NIOSH Publication No. 2013-145.

<http://www.cdc.gov/niosh/topics/smbus/guide/default.html>: NIOSH Small Business Resource Guide web page.

<http://www.abih.org/about-abih/cih-caih>: A Helpful Overview of Certified Industrial Hygienist (CIH) Qualifications and Functions, published by the American Board of Industrial Hygiene (ABIH).

<http://www.abih.org/about-abih/public-roster>: A search function to help you locate a CIH near you, maintained by the ABIH.

http://www.asse.org/assets/1/7/Employer_Handbook_version_5_61.pdf: A Helpful Guide to Hiring the Right Occupational Health and Safety Professional, published by the American Society for Safety Engineers.

www.greennano.org: Green Nanotechnology Challenges and Opportunities, part of the Safer Nanomaterials and Nanomanufacturing Initiative.

<http://www.nano.gov/bizfaqs>: Frequently Asked Questions for Business, maintained by National Nanotechnology Initiative (NNI), a U.S. Government research and development (R&D) program.

https://nanohub.org/groups/gng/nano_basics: Nanotechnology Environmental Health and Safety: A Guide for Small Business.

https://nanohub.org/groups/gng/training_materials: GoodNanoGuide offers a broad range of training materials that can be adapted to suit your specific safety strategy.

<http://www.nnin.org/>: A network of user facilities across the country that provide nanomaterial characterization assistance to users in academia, business, and government, maintained by the U.S. National Nanotechnology Infrastructure Network.

www.osha.gov/dcsp/compliance_assistance/quickstarts/general_industry/index_gi.html: General industry compliance assistance Quick Start Web page.

www.osha.gov/dcsp/smallbusiness/index.html: Details all of the regulations that may apply to your small business.

www.osha.gov/Publications/smallbusiness/small-business.html: Small Business Guide providing many self-inspection checklists that cover everything from abrasive grinding to walkways, plus clarification about when you need to maintain an OSHA Form 300 (Log of Work-Related Injuries and Illnesses).

www.osha.gov/dts/shib/shib073105.html: Safety and Health Information Bulletin (SHIB): Combustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions.

16 REFERENCES

- AIHA [2008]. Demonstrating the business value of industrial hygiene. American Industrial Hygiene Association, http://www.orc-dc.com/files/2008/2260/Final_AIHA_VOP_Report.pdf.
- Albanese A, Tang P, Chan W [2012]. The effect of nanoparticle size, shape, and surface chemistry on biological systems. *Annu Rev Biomed Eng* 14:1–16.
- Antonini JM [2003]. Health effects of welding. *Crit Rev Toxicol* 33(1):61–103.
- ANSI/ASSE [2011]. PtD Standard Z590.3.2011, Prevention through Design: guidelines for addressing occupational risks in design and redesign processes. Des Plaines, IL: American National Standards Institute/American Society of Safety Engineers.
- ANSI/ASSE [2012a]. Z9.5. Laboratory ventilation. Des Plaines, IL: American National Standards Institute/American Society of Safety Engineers.
- ANSI/AIHA/ASSE [2012b]. Z10. Safety management systems. Des Plaines, IL: American National Standards Institute/American Society of Safety Engineers.
- ASHRAE [1995]. ASHRAE 110: Method of testing performance of laboratory fume hoods. Atlanta, GA: American Society of Heating, Refrigerating, and Air-Conditioning Engineers.
- Brown DM, Wilson MR, MacNee W, Stone V, Donaldson K [2001]. Size-dependent proinflammatory effects of ultrafine polystyrene particles: a role for surface area and oxidative stress in the enhanced activity of ultrafines. *Toxicol Appl Pharmacol* 175(3):191–199.
- Bouillard J, Vignes A, Dufaud O, Perrin L, Thomas D [2009]. Explosion risks from nanomaterials. *J Physics Conf Series* 170 (2009):012–032.
- Castranova V [2011]. Overview of current toxicological knowledge of engineered nanoparticles. *Journal of Occupational and Environmental Medicine* 53:S14–S17.
- Dastidar AG, Boilard S, Amyotte PR, Turkevich LA [2013]. Explosibility of nano-sized metal powders. In: Proceedings of the 9th Global Congress on Process Safety, San Antonio, TX, April 30. New York: American Institute of Chemical Engineers.
- Dockery DW, Pope CA, Xu X, Spengler JD, Ware JH, Fay ME, Ferris BG Jr, Speizer FE [1993]. An association between air pollution and mortality in six U.S. cities. *N Engl J Med* 329(24):1753–1759.
- Driscoll KE [1996]. Role of inflammation in the development of rat lung tumors in response to chronic particle exposure. *Inhal Toxicol* 8:139–154.
- Duffin R, Tran C, Clouter A, Brown D, MacNee W, Stone V, Donaldson K [2002]. The importance of surface area and specific reactivity in the acute pulmonary inflammatory response to particles. *Ann Occup Hyg* 46(1):242–245.
- Eastlake A, Hodson L, Geraci C, Crawford C [2012]. A critical evaluation of material safety data sheets (MSDSs) for engineered nanomaterials. *J Chem Health Saf* 19(5):1–8.
- GAO [2014]. Nanomanufacturing: emergence and implications for U.S. competitiveness, the environment, and human health. Washington, DC: U.S. Government Accountability Office.
- Gardiner K, van Tongeren M, Harrington M [2001]. Respiratory health effects from exposure to carbon black: results of the phase 2 and 3 cross sectional studies in the European carbon black manufacturing industry. *Occup Environ Med* 58:496–503.
- HSE [2010]. Fire and explosion properties of nanopowders. Norwich, UK: Health and Safety Executive.
- Holizki T, Nelson L, McDonald R [2006]. Injury rate as an indicator of business success. *Ind Health* 44:166–168.
- Hull M [2010]. Occupational safety and health considerations for small businesses manufacturing nanomaterials. Blacksburg, VA: Nanosafe, Inc.
- IOM [2000]. Development of a biomathematical lung model to describe the exposure-dose relationship for inhaled dust among UK coal miners. In: Tran CL, ed. IOM Research Report TM/00/02. Edinburgh: B.D., Institute of Occupational Medicine.
- ISO [2012]. ISO/TR 13329-2012. Nanomaterials: preparation of material safety data sheets. Geneva: International Organization for Standardization.
- Johnson D, Methner M, Kennedy A, Steevens J [2010]. Potential for occupational exposure to engineered carbon-based nanomaterials in environmental laboratory studies. *Environ Health Perspect* 118(1):49–54.

- Merget R, Bauer T, Kupper HU, Philippou S, Bauer HD, Breitstadt R, Bruening T [2002]. Health hazards due to inhalation of amorphous silica. *Arch Toxicol* 75:625–634.
- Methner M, Hodson L, Geraci C [2009]. Nanoparticle emission assessment technique (NEAT) for the identification and measurement of potential inhalation exposure to engineered nanomaterials—part A. *J Occup Environ Hygiene* 7(3):127–132.
- Monica J, Calster V [2010]. Nanotechnology: a legal framework. In: Hull M, Bowman D, eds. *Nanotechnology environmental health and safety, risk, regulation and management*. New York: Elsevier USA, ISBN 978-0-1855-1586-9.
- NIOSH [2005]. NIOSH respirator selection logic. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2005-100.
- NIOSH [2009a]. Approaches to safe nanotechnology: managing the health and safety concerns associated with engineered nanomaterials. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2009-125.
- NIOSH [2009b]. Current intelligence bulletin 60: interim guidance for the medical screening and hazard surveillance for workers potentially exposed to engineered nanoparticles. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2009-116.
- NIOSH [2010]. Prevention through design: plan for the national initiative. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2011-121.
- NIOSH [2011]. Current intelligence bulletin 63: occupational exposure to titanium dioxide. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2011-160.
- NIOSH [2012]. General safe practices for working with engineered nanomaterials in research laboratories. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2012-147.
- NIOSH [2013]. Current intelligence bulletin 65: occupational exposure to carbon nanotubes and nanofibers. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2013-145.
- NIOSH [2014]. Current strategies for engineering controls in nanomaterial production and downstream handling processes. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2014-102.
- Oberdorster G, Yu CP [1990]. The carcinogenic potential of inhaled diesel exhaust: a particle effect. *J Aerosol Sci* 21(S1):S397–S401.
- Oberdorster G, Ferin J, Soderholm S, Gelein R, Cox C, Baggs R, Morrow PE [1994]. Increased pulmonary toxicity of inhaled ultrafine particles: due to lung overload alone? *Ann Occup Hyg* 38:295–302.
- Oberdorster G, Maynard A, Donaldson K, Castranova V, Fitzpatrick J, Ausman K, et al. [2005]. Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy. *Particle Fibre Toxicol* 2:8.
- Oberdorster G, Stone V, Donaldson K [2007]. Toxicology of nanoparticles: a historical perspective. *Nanotoxicology* 1(1):2–25.
- OSHA [1992]. Respiratory Protection Standard 29 CFR 1910.134. U.S. Department of Labor, Occupational Safety and Health Administration, Code of Federal Regulations.
- OSHA [2005a]. Small business handbook. Small business safety and health management series. U.S. Department of Labor, Occupational Safety and Health Administration, 2209-02R 2005.
- OSHA [2005b]. Safety and health information bulletin (SHIB): Combustible dust in industry: preventing and mitigating the effects of fire and explosions. U.S. Department of Labor, Occupational Safety and Health Administration, SHIB 07-31-2005.

- OSHA [2012]. Hazard communication. 29 CFR Parts 1910, 1915, and 1926. Fed Reg 77(58), Monday, March 26.
- Ostiguy C, Roberge B, Woods C, Soucyet B [2010]. Engineered Nanoparticles: Current Knowledge about OHS Risks and Prevention Measures, in Chemical Substances and Biological Agents: Studies and Research Projects. Institut de recherche Robert-Sauvé en santé et en sécurité du Travail (IRRSST): Montreal. Report R-656.
- Pope A, Burnett R, Thun M, Calle E, Krewski D, Ito K, Thurston G [2002]. Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. *JAMA* 287(9):1132–1141, doi:10.1001/jama.287.9.1132.
- Reuzel PGJ, Bruijntjes JP, Feron VJ, Woutersen RA [1991]. Subchronic inhalation toxicity of amorphous silicas and quartz dust in rats. *Food Chem Toxicol* 29(5):341–354.
- Rundmo T, Hale A [2003]. Managers' attitudes toward safety and accident prevention. *Saf Sci* 41:557–574.
- Schulte P, Geraci C, Zumwalde R, Hoover M, Kuempel E [2008a]. Occupational risk management of engineered nanoparticles. *J Occup Environ Hyg* 5:239–249.
- Schulte P, Rinehart R, Okun A, Geraci C, Heidel D [2008b]. National prevention through design (PtD) initiative. *J Safety Res* 39:115–121.
- Seaton A, Tran L, Aitken R, Donaldson K [2010]. Nanoparticles, human health hazard and regulation. *J R Soc Interface* 7(Suppl 1):S119–S129.
- Shaffer R, Rengasamy S [2009]. Respiratory protection against airborne nanoparticles: a review. *J Nanoparticle Res* 11(7):1661–1672.
- Turkevich L, Dastidar A, Hachmeister Z, Lim M [2015]. Potential explosion hazard of carbonaceous nanoparticles: explosion parameters of selected materials. *J Hazard Mater* 295:97–103.
- Tsai C [2015]. Contamination and release of nanomaterials associated with the use of personal protective clothing. *Ann Occup Hyg* 59(4):491–503.
- Szymberski R [1997]. Construction project safety planning. *TAPPI J* 80(11):69–74.
- Trout D, Schulte P [2010]. Medical surveillance, exposure registries, and epidemiologic research for workers exposed to nanomaterials. *Toxicology* 269(2–3):128–135.
- Wu HC, Ou HJ, Hsiao HC, Shih TS [2010]. Explosion characteristics of aluminum nanopowders. *Aerosol and Air Quality Research* 10:38–42.
- Zhang QW, Kusaka Y, Donaldson K [2000]. Comparative pulmonary responses caused by exposure to standard cobalt and ultrafine cobalt. *J Occup Health* 42(4):179–184.
- Zhang QW, Kusaka Y, Zhu XQ, Sato K, Mo YQ, Kluz T, et al. [2003]. Comparative toxicity of standard nickel and ultrafine nickel in lung after intratracheal instillation. *J Occup Health* 45(1):23–30.

APPENDIX A

Suggested Steps to a Health and Safety Program

1. Create a company policy that puts a focus on employee health and safety.
2. Create a safety committee with management and staff members.
3. Identify all of the potential health and safety risks in the facility.
 - a. Follow each chemical from receipt to departure.
 - b. Identify hazardous processes (high heat, electricity, dangerous gases, filter change-out, reactor cleaning, etc.)
4. Identify and install controls (following the hierarchy of controls).
5. Verify that controls are working as designed.
6. Create a written health and safety plan.
 - a. Document required procedures to be followed.
 - b. Include all of the regulatory-required information (such as hazard communication, respiratory protection, and documentation of injuries).
 - c. Include information on emergency response for medical emergencies and chemical spills.
 - d. Document procedures for waste (including solid waste as well as air and water discharges).
7. Train employees on the written health and safety plan.
8. Continue reevaluation of the workplace on a routine basis (every 6 or 12 months).

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