CHAPTER

11 Managing Nanotechnology Risks in Small Business—A National Institute for Occupational Safety and Health Perspective

Laura L. Hodson, Charles L. Geraci
Nanotechnology Research Center, NIOSH, Cincinnati, OH, United States

11.1 INTRODUCTION

Responsible development of nanotechnology needs to start in the workplace. Employees are the first in any society to be exposed to any new technology and its materials, and a primary area of concern is the potential adverse impact of engineered nanomaterials on workers' health. Understanding the potential risks and how to manage those risks should be part of every business plan. As demonstrated throughout other chapters in this book, much is known about the potential toxicological issues of nanomaterials but there is still a lot we do not know. What is certain is that companies that have proactive health and safety programs and promote responsible development are more likely to achieve business success. The National Institute for Occupational Safety and Health (NIOSH) is the U S federal agency with the mission to develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice. The NIOSH authors hope that this chapter in concert with all of the other chapters in this book will provide nanomaterial research and development workers, manufacturers, and users with the tools necessary to keep workers safe, develop public trust, and in turn accelerate commercialization of nanomaterials and provide for a safe and responsible move into advanced manufacturing.

Compared with small companies that survive only 1–2 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). Workers in small businesses endure a disproportionate share of the burden of occupational injuries, illnesses, and fatalities (Mendeloff et al., 2006; Morse et al., 2004; Sinclair et al., 2013). 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).

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Managing the development and implementation of an effective safety and health program uses the same skills needed to launch a business. A strong safety culture in the workplace builds confidence among employees, investors, business associates, and insurance providers and promotes a positive image of the company and its products.

Small business start-up companies are instrumental in taking ideas from nanotechnology research and proof of concept through scale up to production. 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 (Fig. 11.1). 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 will assist businesses in overcoming barriers to climbing the mountain of success, staying competitive, and allowing for future growth.

Ideally, company management will provide leadership and assume responsibility for implementing, maintaining, and monitoring safety performance. Including safety in the start-up business plan ensures that safety and the cost of preventative measures (e.g., engineering controls) are considered from the very beginning. As the business grows, management and employees should both be involved in a collaborative effort, such as a health and safety committee that develops a safety strategy and policy and creates a written company health and safety program, creates open communication, including 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.

Aligning safety goals with business goals has many advantages:

- Reduced site hazards and thus fewer injuries and health risks
- Reduced workers' compensation insurance costs

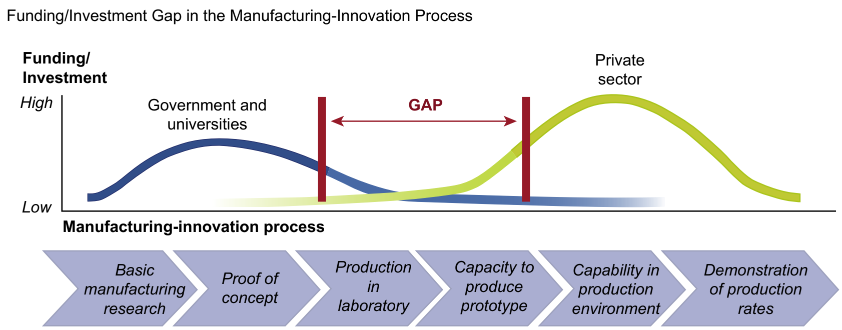

FIGURE 11.1

The investment gap between basic research and production in the private sector (GAO, 2014).

GAO adapted from Executive Office of the President.

- Increased productivity
- Fewer delays due to accidents
- Reduced absenteeism
- Improved morale by addressing real and perceived hazards and associated risks
- Increased competitive advantage by reducing potential delays and accelerating speed to market.

Good health and safety programs can improve productivity and efficiency and should not be considered as an additional burden but rather as a key component of a business culture.

11.2 RISK MINIMIZATION

Research from the past 20 years shows that (1) submicron particles, on an equal mass basis, can be more hazardous than larger particles; (2) some incidental nanoparticles (e.g., welding and diesel fumes) can be carcinogenic when inhaled; (3) small ambient particle aerosol pollutants have been linked to respiratory and cardiovascular health effects; and (4) certain nanomaterials that have been produced in the past, known as “legacy produced” nanomaterials, including 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; Oberdörster et al., 1994, 2005, 2007; Oberdörster and Yu, 1990; Pope et al., 2002; Reuzel et al., 1991; Seaton et al., 2010; Zhang et al., 2000, 2003).

Risk includes the probability of quantifiable damage, injury, liability, loss, or any other negative occurrence, and it may be reduced through preemptive action. Risk is a product of the consequence of a health or physical hazard and the probability of exposure to that hazard; reducing either or both components will minimize the risk. The potential for exposure is dependent on the quantities of material, physical state of the material (dustiness), the types of processes involved, and frequency of the exposure. Risk minimization is best achieved through an effective risk-management program.

Small business owners know the importance of focusing on core expertise and seeking professional input in other areas critical to success. While a small company may have strong business development skills, they may not have the knowledge to develop a health and safety program on their own. To close this gap, NIOSH recommends that companies consider making use of available professional resources and a safety professional such as a certified industrial hygienist (CIH) or certified safety professional to help. These types of safety professionals have the experience needed to evaluate materials and processes and anticipate exposure potential. A CIH will also have access to equipment needed to conduct sampling and evaluate emissions and exposures and make recommendations for controls. Also, safety professionals can likely do those things more competently and affordably than a nonexperienced business person could, particularly while the business focus is on developing and growing the business. See www.abih.org/about-abih/cih-caih for a helpful overview of CIH qualifications and functions, published by the American Board of Industrial Hygiene. Need assistance locating a CIH? Follow this link www.abih.org/about-abih/public-roster. There is also a link to a helpful guide to hiring the right occupational health and safety professional, published by the American Society for Safety Engineers www.asse.org/assets/1/7/Employer_Handbook_version_5_61.pdf. While hiring a safety professional on either a short-term or permanent basis may be an expense a small business had not planned on, doing so is likely to save the company money, time, and potential headaches down the road.

Small business enterprises should also consider joining a business consortium such as the Nanobusiness Commercialization Association www.nanobca.org/ to pool resources and learn about what other companies are doing to protect their business interests. Occupational Safety and Health Administration (OSHA) also has free resources for small businesses available at www.osha.gov/dcsp/smallbusiness/index.html.

11.3 RISK MANAGEMENT

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

1. Do any of the chemicals, materials, or processes have any hazardous properties?
2. Are any employees potentially exposed?
3. How can exposures be controlled or eliminated?

Hazard Identification: Aside from any nanospecific concerns, what is known and not 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 the material that suggests toxicological effects in animal models? What information is available for all of the process chemicals and materials? This type of information may be found on the product Safety Data Sheet (SDS), in the ToxNet database sponsored by the US 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 material, and unfortunately some SDSs are lacking in quality. NIOSH investigators showed that information on health hazards may not be adequately presented in SDSs; as 67% of the nanomaterial SDSs reviewed provided insufficient data for communicating the potential hazards (Eastlake et al., 2012). These SDSs were lacking in toxicological information, did not note that the occupational exposure limit for the bulk size material may not be protective for the nanoscale material, or listed vague information such as “There are no reports of adverse health effects on this material from our customers and operators in the plant" (Eastlake et al., 2012).

Exposure Assessment: Exposure associated with the material of interest being in a nanosize form 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 precursor materials to waste disposal and including such processes as maintenance of equipment? Is there visible debris outside of 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, so the employees, including operators and maintenance staff, should be asked about possible exposure points.

Task and Process Analysis: The way a material is handled and used can contribute to the degree that exposure can occur. A good approach is to develop a material flow diagram that shows the nanomaterial from the time it enters the facility to the point it leaves as an intermediate or final product. Describe how the material is handled and the types of tools and processes used. What kind of energy is involved or applied? How is the material added to a process?

Exposure Control: Once the locations/processes/tasks that have a high potential for worker exposure have been identified, controls and procedures should be developed to minimize or eliminate worker exposure(s). Utilizing the hierarchy of controls (see Section 11.5), determine if steps used to control similar problems in other industries can be adapted for the nanomaterial process. Identify the options for reducing or eliminating exposures until controls are in place.

Risk-Management Program: The information gained from the four elements should inform the risk management of the overall health and safety program, which 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 and accompanying plan covering all types of chemical and physical hazards in the workplace that accomplishes keeping employees safe and complying with the law;
- Engagement of employees in the workplace health and safety program;
- Incident investigation and follow-up;
- A clear delineation of roles and responsibilities for everyone in the company involved in the nanomaterial life cycle from receiving to disposal; and
- Effective measures for documentation, communication, and training.

Fig. 11.2 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 for can be incorporated into the health and safety program.

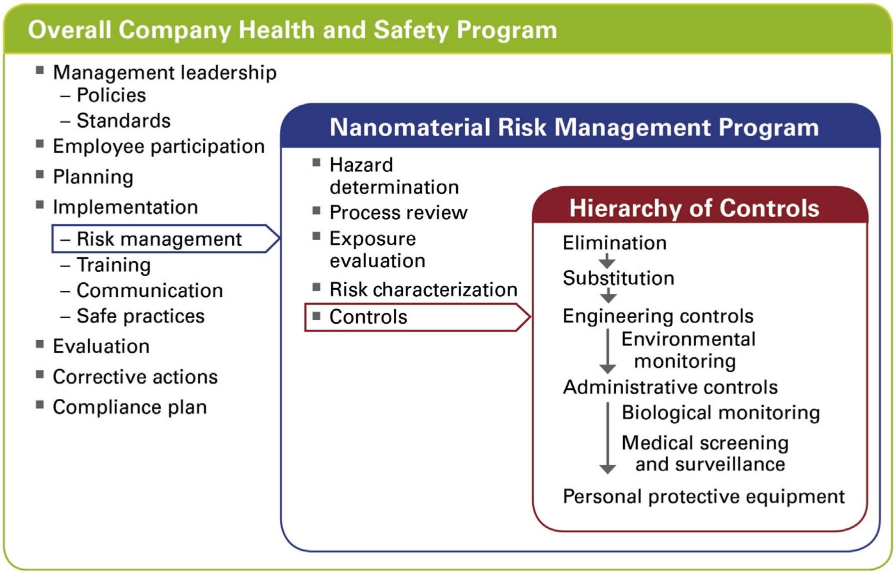

FIGURE 11.2

Components of an overall health and safety program (Schulte et al., 2008a).

11.4 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 (see Section 11.5) 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 life cycle of an engineered nanomaterial.

The advantages of integrating PtD early in the design of a 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 (Fig. 11.3).

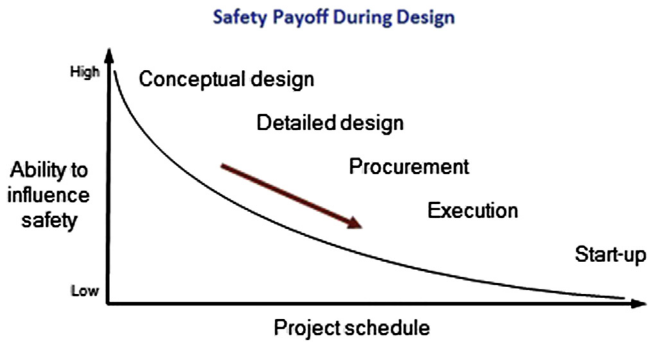

FIGURE 11.3

The ability to influence safety is highest during earliest stages of project design.

Adapted from Szymberski, R., 1997. Construction project safety planning. TAPPI Journal 80 (11), 69e74.

The most effective approach to creating and maintaining a safe and healthy working environment is to couple PtD concepts with ongoing vigilance and frequent reexaminations of workplace processes. An effective PtD strategy implemented early in the process reduces the potential repercussions by incorporating good management of change. John Weaver presents a case study of a safety through design concepts specific to the Birck Nanotechnology Center in another chapter in this book.

11.5 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. Fig. 11.4 is the representation of the hierarchy of controls. 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.

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 (ANSI)/American Society of Safety Engineers Z590.3, *Prevention through design guidelines for addressing occupational hazards and risks in design and redesign processes*, provides guidance on

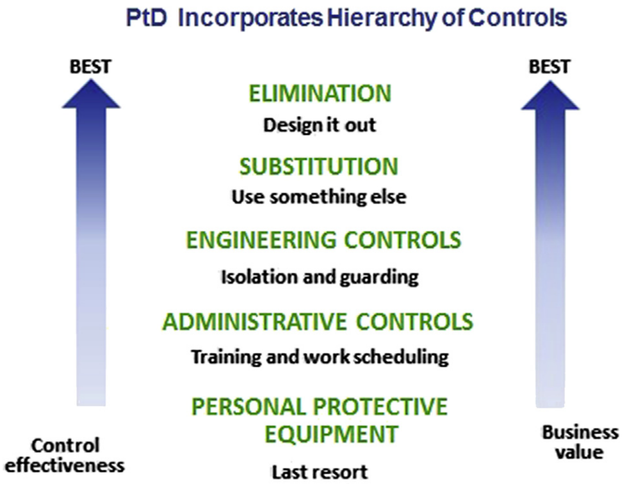

FIGURE 11.4

Hierarchy of controls. PtD, Prevention through Design

Adapted from ANSI/ASSE, 2011. PtD Standard Z590.3.2011, Prevention through Design: Guidelines for Addressing Occupational Risks in Design and Redesign Processes. American National Standards Institute/American Society of Safety Engineers, Des Plains, IL and AIHA, 2008. Demonstrating the Business Value of Industrial Hygiene. American Industrial Hygiene Association. www.orc-dc.com/files/2008/2260/Final_AIHA_VOP_Report.pdf.

including PtD concepts and the hierarchy of controls 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).

11.5.1 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. Yet, for an existing process, major changes in equipment and procedures may be required to eliminate a hazard. Substituting process chemicals or nanomaterial applications should 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 US 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 Work Plan for Chemicals (http://www2.epa.gov/saferchoice/design-environment-alternatives-assessments).

11.5.2 ENGINEERING CONTROLS

Engineering controls come into play when less hazardous substitutes to the 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 the 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 (Fig. 11.5). Operations involving easily dispersed dry nanomaterials, such as 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

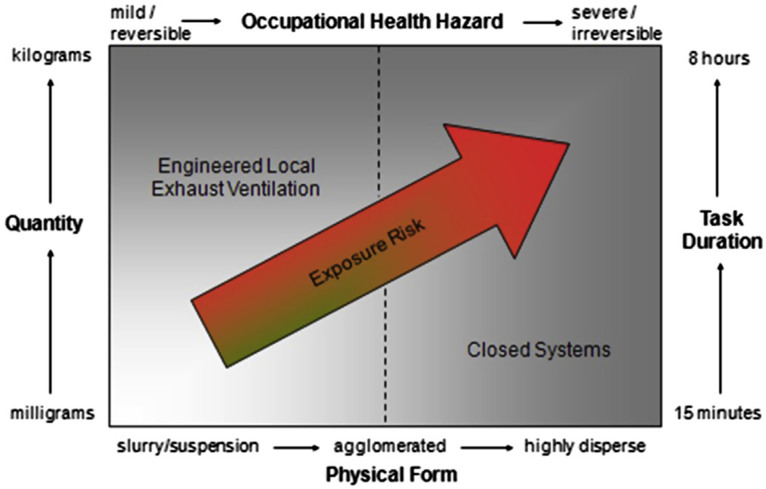

FIGURE 11.5

Factors influencing control selection (NIOSH, 2009a).

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 (Figs. 11.6 and 11.7) include

- Flexible containment (plastic sleeves, continuous-feed bag liners)
- Low flow containment hood (exhausted through a high efficiency particulate air [HEPA] filter)
- Plexiglas gloveboxes (exhausted through an HEPA filter)
- Glove box isolators and other types of isolation enclosures

While some new controls may be prohibitively expensive for smaller organizations to purchase out-right, 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

FIGURE 11.6

A large-scale ventilated reactor enclosure used to contain production furnaces to mitigate particle emissions in the workplace (NIOSH, 2014a).

Used with permission from Flow Sciences, Inc.

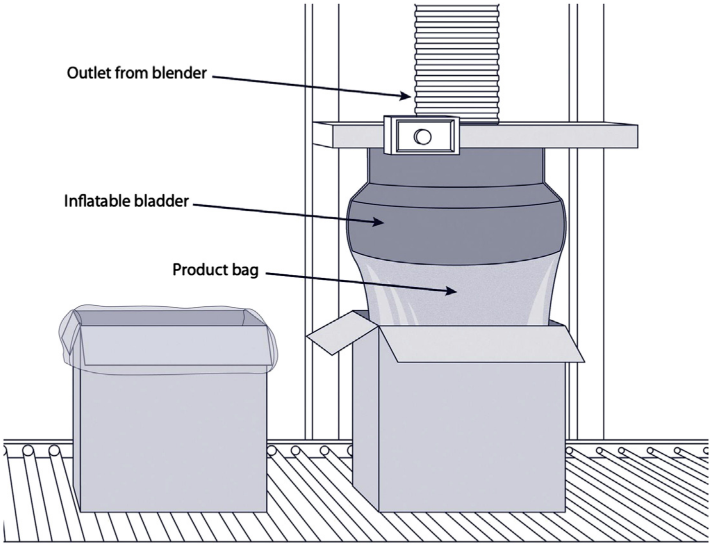

FIGURE 11.7

An inflatable seal used to contain nanopowder/dusts as they discharge from a process such as spray drying (NIOSH, 2014a).

accordance with applicable certifications prior to use. Verify that any used 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 business by emphasizing the benefits of protecting workers, the environment, and the community.
- Include discussion of EHS in the business plan and financing for high-level controls that may be needed.

11.5.3 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 in any activity involving the handling of hazardous materials, 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 employees on any known or suspected hazards and risks associated with the engineered nanomaterials (and any other chemicals) they work with is a very important step in risk management and is also a regulatory requirement under the OSHA Hazard Communication Standard (HCS) (OSHA, 2012). At a minimum, training should

- give employees a good level of awareness about the potential exposure hazards
- inform employees of knowledge gaps where hazard information is lacking or unknown
- describe the nanomaterials handling and storage techniques
- explain proper use of personal protective equipment (PPE)
- review the importance of cleaning contaminated surfaces or clothing
- discuss maintenance of engineering controls (such as filter change-out and disposal), and
- explain proper disposal of nanomaterials or nanomaterial-contaminated objects (NIOSH, 2009a)
- describe procedures to follow in the event of an emergency such as a spill.

Employees 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, hosted on nanohub.org, offers a broad range of case studies, worker protections, and training materials that can be adapted to specific safety programs (see https://nanohub.org/groups/gng/training_materials).

11.5.4 PERSONAL PROTECTIVE EQUIPMENT

PPE is frequently used to reduce exposure to hazardous materials when the exposures are not particularly well controlled or as an interim measure until controls are installed, or when controls are not feasible, such as maintenance or response to spills. The use of engineering controls is always preferred over PPE, but it has long been recognized among small businesses that PPE might be the more economical approach. The reality is that 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.

Operators should wear PPE as a precautionary measure, unless the processes have been evaluated and appropriate containment/control devices have been installed, and there is evidence that exposures are under control. 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 or organics and may present an allergy hazard.
- Closed-toe shoes made of a low-permeability material (such as leather). Disposable over-the-shoe booties should be considered.
- 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, as an important element of overall PPE, should be selected according to the NIOSH Respirator Selection Logic (http://www.cdc.gov/niosh/docs/2005-100/) (NIOSH, 2005) and 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 1910.134. The standard specifies that workers wearing respirators have to be in a respiratory protection program that includes annual training, 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 faceseal 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 Rules for some types of carbon nanotubes (CNTs), 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).

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

11.6 VERIFICATION OF CONTROLS

Once controls have been put into place, it is necessary to verify that they are working correctly. There are some simple yet effective strategies to test the effectiveness of control systems. The procedures will be dictated by the type of engineering controls used or the nature of the task or process being controlled. The effectiveness of controls can be verified with a combination of quantitative indicators including

- 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
- 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.

11.6.1 QUANTITATIVE MEASURES OF WORKER EXPOSURE

Worker exposure assessment and control verification can be done by applying readily available industrial hygiene sampling methods. These methods include personal sampling, where samplers are located in the personal breathing zone (PBZ) of the worker (e.g., the filter samples are placed as close to the nose and mouth as possible and are usually attached to a shirt collar), and area sampling, where they are placed at static locations. The assessment should use both filter-based samples and direct-reading (also known as real time) particle counters (NIOSH, 2009a; Eastlake et al., 2016).

For three nanoparticles—titanium dioxide (TiO_2), CNTs, and CNFs—NIOSH has completed a risk assessment and provided risk-management guidelines, including detailed sampling and analysis guidance and recommended exposure limits (RELs), which are believed to be protective over a working lifetime (NIOSH, 2011, 2013). These RELs are expressed as the respirable fraction of mass per unit volume of air, over a full work shift:

- ultrafine titanium dioxide (TiO_2): REL = 300 micrograms per cubic meter ($\mu g/m^3$)
- CNTs and CNFs: REL = 1.0 $\mu g/m^3$ as elemental carbon.

RELs have not yet been developed for every one of the large (and growing) number of engineered nanomaterials now being produced and used, as their hazards are not fully known. Exposure potential for engineered nanomaterials without RELs can be determined by following the NIOSH Nanomaterial Exposure Assessment Technique (NEAT 2.0) (Eastlake et al., 2016). NEAT 2.0 includes filter-based sampling (i.e., elemental mass analysis and particle morphology) in the worker's PBZ (collected for both full shift and shorter duration task specific) and area samples to develop job exposure matrices (Fig. 11.8). NEAT 2.0 includes a comprehensive assessment of emissions at processes and job tasks, using the direct-reading instruments (i.e., particle counters) in data-logging mode to better understand peak emission periods (Fig. 11.9). Evaluation of worker practices, ventilation efficacy, and other engineering exposure control systems and risk-management strategies serve to allow for a comprehensive exposure assessment.

As noted earlier in this chapter, with the exception of TiO_2, CNTs, and CNFs, no recommended sampling and analytical methods have been developed that are specific for elemental analysis of nanomaterials. Therefore, the existing analytical methods published in the NIOSH Manual of Analytical Methods or from the

FIGURE 11.8

Outfitting a worker with samples in the Personal Breathing Zone.

Photo credit C. Sparks, NIOSH.

FIGURE 11.9

A set of area direct-reading particle counters and filter-based samples.

Photo credit L. Hodson, NIOSH.

OSHA can be used, but these methods may require slight modification, including maximizing the flow rate, within the prescribed range of the method, to improve the likelihood of collecting sufficient mass for elemental analysis (NIOSH, 2014b; OSHA, 2014). Elemental analysis involves the collection of an air sample on a filter that 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 a nanomaterial, but it cannot quantify the size of the particle that contained the element unless a size-selective sampler (such as a cyclone) is used to capture the respirable fraction. As occupational exposure criteria do not exist for most nanomaterials, the elemental mass analyses could be compared with corresponding occupational exposure criteria for the parent compound with the understanding that this REL may not be protective because nanomaterials have been shown to have more significant toxicological concerns than the larger material forms from which they are derived (NIOSH, 2009a; Grassian et al., 2007; Lam et al., 2004; Oberdörster, 1996; Shvedova et al., 2008a,b, 2005; Warheit et al., 2004). Guidance in applying the parent compound REL to a nanomaterial is provided by the British Standards Institution and suggests exposure limits that range from 0.067 to 0.5 times the REL depending on if the material is fibrous, carcinogenic, insoluble, or soluble (BSI, 2007).

The NEAT 2.0 approach uses two filter samples, the first being used for elemental analysis as described in the previous paragraph. Morphologic data from electron microscopy of the second of the filters in each sampling set are used to understand the contribution of the nanomaterial of interest to the elemental mass load and can provide an "order of magnitude" evaluation of the extent of its contribution. Electron microscopy will provide a qualitative assessment of the particle size, degree of agglomeration, and if the nanomaterial is free or contained within a matrix. Hazard identification and characterization can then be performed based on a holistic assessment of the integrated filter samples. Field-portable direct-reading instruments (photometric size analyzers capable of providing total particle count, size distribution, and mass) can be used to characterize the process emissions by determining the number or mass concentration and approximate size range of airborne particles. The instruments' data-logging capabilities allow continuous recording of normal fluctuations in particle counts, attributable to the process or task in which nanomaterials of interest are being handled or processed. By documenting the workers' activities, data-logged results can then be used to identify workplace tasks or practices that contribute to any increase or spikes in the nanomaterial concentrations or counts. Data-logged results can enable identification of events that result in an increase in ambient or incidental particles. Use the data with caution as direct-reading instruments will identify the real-time quantity of all nanomaterials including any incidental background particles such as may occur from motor exhaust, pump exhaust, heating vessels, etc. (Table 11.1)

Ideally, a complete exposure assessment will use all three sampling and analysis methods: elemental analysis, electron microscopy, and particle counters. The combination of these techniques should help address these basic questions:

1. Did a release occur from the nanomaterial process?
2. Did employee exposure occur?
3. Was the nanomaterial involved in the exposure, and was it present in high or low concentrations relative to other materials?
4. Was the process contained?

Table 11.1 Components of the Nanomaterial Exposure Assessment Technique (NEAT 2.0)

Sample Type	Analysis	Locations	Sample Times	Results
Filter 1 Mixed cellulose ester (for elements) Quartz fiber (for carbonaceous materials)	Elemental analysis based on National Institute for Occupational Safety and Health Manual of Analytical Methods or Occupational Safety and Health Administration methods	Personal breathing zone (PBZ), source and background	Task and full shift	Identifies the element of interest but yields no information on size.
Filter 2 Polycarbonate or teflon	Electron microscopy analysis	PBZ, source and background	Task and full shift	Semiquantitative identification of size. Determines if particle is free form, agglomerated, or embedded in a matrix.
Direct-reading instruments Condensation particle counter or optical particle counter	Particles per cubic centimeter	Source and background	Data-logging full shift	When used in conjunction with documented observations can identify potential sources of exposure. Caution must be applied to the results because they count all nanoparticles (including incidental) not just the element of interest.

11.7 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, 2005). The SHIB also reports that dust particles with a diameter smaller than 420 microns (those passing through a US 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, 2005). For an explosion to occur, all five elements of the explosion pentagon (dispersion, confinement, fuel, oxygen, and ignition) are required (Fig. 11.10).

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 the 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

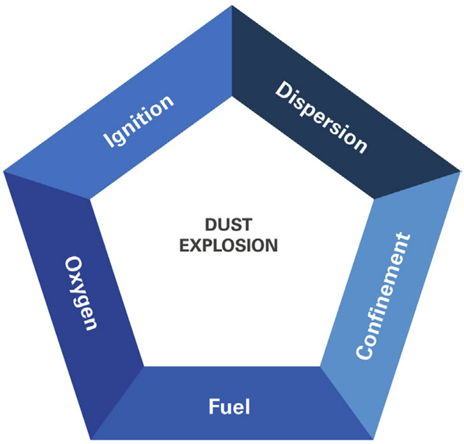

FIGURE 11.10

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

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 nanosized metal powders 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, whereas other nanomaterials are designed to be fire retardants. The probability and potential severity of a specific nanomaterial explosibility can be determined by having it tested by any of the companies that advertise dust combustibility testing. Detailed testing procedures can be found in the Health and Safety Executive report on Fire and Explosion Properties of Nanomaterials (http://www.hse.gov.uk/research/rrpdf/rr782.pdf) (HSE, 2010). This report also contains data for several nanomaterials under varying relative humidity conditions.

11.8 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 (such as engineering controls or the use of PPE) 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. It is important to share all employee exposure sampling data with the employee who can in turn share the results with their occupational physician.

If any employees use a respirator, employers will have to follow 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
- Postincident 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.

11.9 EMERGENCY PREPAREDNESS

Businesses 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, postemergency phone numbers, and know where the nearest medical facilities are located. Businesses should invite the local fire department/first responders to visit the facilities to learn about chemicals and processes in use prior to an emergency. Local fire departments may also request that floorplans and chemical inventories be posted for their use (often these are in a weather proof box just inside the company property line). It is important to establish emergency evacuation routes and procedures, and practice escape and sheltering plans regularly. Visit https://www.ready.gov/ for additional emergency preparedness tips.

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
- Adsorbent materials (such as spill mats)
- Disposable wipes (Kimwipes or shop rags)
- Spray bottle with deionized water or other appropriate liquid (such as surfactants or alcohols) to wet dry powders.
- Sealable plastic bags

- Walk-off mat (such as a Tacki-Mat)
- HEPA-filtered vacuum (never use compressed air to blow dust, never dry-sweep, and never use a vacuum without an HEPA filter)

11.10 PRODUCT STEWARDSHIP

Product stewardship means taking responsibility for the environmental, safety, and health impact of products at key points during the life cycle of the material, including design, manufacture, use, recycling, and disposal. This stewardship is especially important when developing a new material because the initiative and the costs of dealing with such matters will fall on the developer. Customers, workers, disposal services, and other end users of the material may each have different requirements when it comes to accepting the material.

The health communication standard (HCS) requires chemical manufacturers, distributors, or importers to provide SDSs to communicate the hazards of hazardous chemical products. As of June 1, 2015, the HCS requires new SDSs to be in a uniform format with 16 specified sections (OSHA, 2012) including

1. Identification
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information (nonmandatory)
13. Disposal considerations (nonmandatory)
14. Transport information (nonmandatory)
15. Regulatory information (nonmandatory)
16. Other information, including date of preparation or last revision

The International Standards Organization (ISO)/TR 13329:2012 standard, Nanomaterials—Preparation of Material SDS, also 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.

Additional and equal important product stewardship activities should include product safety testing, proper labeling, noting any possible transportation issues (e.g., dangerous goods), responding to customer inquiries, compliance with product safety regulations, consideration, and guidance for recycling and disposal.

11.11 NANOMATERIAL USES IN ADVANCED MANUFACTURING

Advances in material science, created by nanotechnology, are combining with the rapid development of new manufacturing technologies, promoted in the United States by the Advanced Manufacturing Initiative, to give us a vision of 21st Century Manufacturing. The Advanced Manufacturing Initiative focuses on the development and adoption of cutting-edge materials and manufacturing technologies for making new, globally competitive products, and has become a priority initiative in the United States.

The number of new, active materials used in manufacturing continues to rise dramatically. Some of these new materials are defined as engineered nanomaterials, but a growing number are being referred to as advanced materials. Advanced materials refer to all new materials and modifications to existing materials that are specifically engineered to exhibit novel or enhanced properties that result in superior performance in one or more characteristics, relative to conventional materials, which are critical for the application under consideration. Size, geometry, surface area, and surface functionality contribute to the enhanced properties of an advanced material and are similar in characteristics of an engineered nanomaterial. As a result of their unique characteristics and heightened reactivity and efficiency, these advanced materials may have a new or different hazard and risk profile. Many of the advanced manufacturing technologies, such as additive manufacturing, 3D printing, direct-write technology, powder bed fusion, biomanufacturing, and synthetic biology will change the way manufacturing is done in the United States. For example, Fused Deposition Modeling, or FDM technology, is used for 3D prototyping and manufacturing with desktop and industrial size 3D printers and is increasingly being used by both small and large businesses. While most of the printers use a thermoplastic filament, some use a metal wire (with a thermoplastic coating), which may contain nanomaterials. Powder bed fusion uses metal powders, which may include the nanosized component. It is important for the businesses owner to keep pace with the changes in processes, the continued introduction of new and more active materials, and the changing face of the workplace and the workforce.

11.12 BUILDING AND SUSTAINING A SUCCESSFUL HEALTH AND SAFETY PROGRAM

As a business grows with success and changes, the health and safety program can keep pace. As illustrated in Fig. 11.11, the concept of “Plan, Do, Check, Act” can keep the health and safety program relevant and 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,

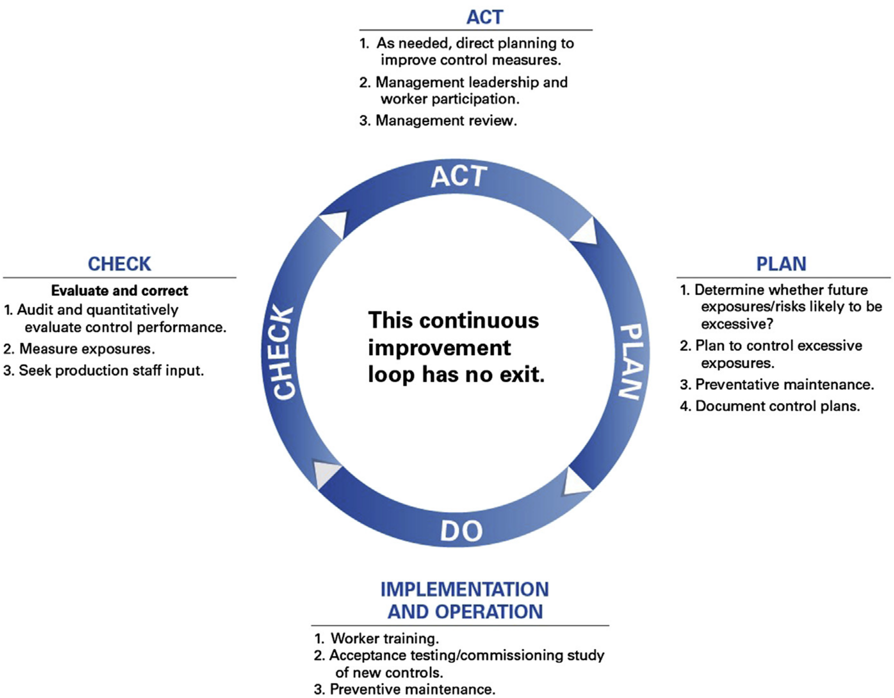

FIGURE 11.11

A proven business approach to keeping all aspects of your enterprise strong and effective.

Adapted from ANSI/AIHA/ASSE, 2012. Z10. Safety Management Systems. American National Standards Institute/American Society of Safety Engineers, Des Plains, IL.

2012). 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.

The ISO 45001:2018 Occupational Safety and Health Management standard 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 (VPPs), 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.

11.13 CONCLUSIONS

Ensuring the workplace health and safety of employees is paramount to the success and future growth of nanomaterial businesses, as well as businesses based on other emerging and converging technologies. 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. 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 workers includes creating and following a risk-management plan that incorporates the hierarchy of controls: elimination, substitution, engineering controls, administrative controls, and PPE.

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

ACKNOWLEDGMENTS

Most of the information contained in this chapter was previously published under an NIOSH document "Building a safety program to protect the nanotechnology workforce: a guide for small to medium-sized enterprises" by L. Hodson and M. Hull (NIOSH, 2016). That information was refreshed and revised for this book to include guidance for companies of any size and is also pertinent to companies moving into advanced manufacturing. Readers seeking to learn more about the NIOSH Nanotechnology Research Program and other guidance documents are encouraged to visit the NIOSH topic page at https://www.cdc.gov/niosh/topics/nanotech/.

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