Key Elements of a Responsible Development Plan for Nanomanufacturing

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ABSTRACT

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. A primary area of concern is the potential adverse impact on workers, since they are the first people in society who are exposed to the potential hazards of nanotechnology.

Keywords: responsible development, risk management, occupational exposure, nanomaterials.

1 INTRODUCTION

Responsible development should include implementing an effective risk management program that addresses the following elements: 1) anticipate, identify, and track potentially hazardous nanomaterials in the workplace; (2) assess workers' exposures to nanomaterials; (3) assess and communicate hazards and risks to workers; 4) manage occupational safety and health risks; and (5) foster the safe development of nanotechnology and realization of its societal and commercial benefits [1]. All these criteria are necessary for responsible development to occur. Since it is early in the commercialization of nanotechnology, there are still many unknowns and concerns about nanomaterials. Therefore, it is prudent to treat them as potentially hazardous until sufficient toxicology, and exposure data are gathered for nanomaterial-specific hazard and risk assessments.

2 CRITERIA FOR RESPONSIBLE DEVELOPMENT

Due diligence and legal mandates by OSHA require employers to be aware of hazards to which their employees could be exposed and all hazards present in facilities that they control (including nanomaterials as well as other chemical or physical hazards). When there is uncertainty about the nature, degree, and extent of hazards of nanomaterials, it is incumbent on employers to know what nanomaterials are in their workplaces, to identify processes where exposures can occur, and to support studies to determine the bioactivity of the nanomaterials.

2.1 Anticipate, identify, and track potentially hazardous nanomaterials in the workplace

Employers must consider the potential hazards of materials they manufacture or procure. The first step should include identifing the nanomaterials in the workplace. Could the nanomaterial of interest be harmful? 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 the material pose an explosion hazard? Are peer-reviewed studies available for this material that suggest toxicological effects in animal models? This type of information may be found on the product Safety Data Sheet, in the ToxNet database sponsored by the US Library of Medicine, http://toxnet.nlm.nih.gov/ , in the NIOSH Pocket Guide to Chemical Hazards http://www.cdc.gov/niosh/npg/ or in peer reviewed literature. Employers who manufacturer or use naomaterials may need to consider conducting toxicologic studies or sending the material out for testing.

A risk management plan should include safety reviews to identify and track chemical use (including nanomaterials) prior to startup, development of Standard Operating Procedures, and worker training. Through these methods, project managers can take a high-level view of the work to be done and ensure that no aspect of worker safety is overlooked.

2.2 Assess workers' exposures to nanomaterials

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 and maintenance of equipment?

Exposure assessment and control verification can be done using traditional industrial hygiene sampling methods. These methods include personal sampling, where samplers are located in the breathing zone of the worker, and area sampling, where they are placed at static locations close to where tasks are being performed. The assessment should use both filter-based samples and particle counters [2]. Particle counters tell you the real-time quantity of nanoparticles present. These instruments are limited in use as they are not specific to engineered nanomaterials and cannot specify nanomaterial type. 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. 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 using 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.

Right now, exposure standards or recommended exposure limits (RELs) exist for only three nanomaterials [3, 4]:

- ultrafine titanium dioxide (TiO_2) REL = 300 μg/m3;
- carbon nanotubes (CNT), and carbon nanofibers (CNF) REL = 1.0 μg/m3 as elemental carbon

The RELs for these materials are expressed as mass per volume, on a respirable fraction. Thus, these nanomaterials should be collected on filters and analyzed for mass on a mass per volume basis for comparison.

2.3 Assess and communicate hazards and risks to workers

Worker training is a key component in risk management and an indicator of responsible development of any technology [5]. Employers must train workers on workplace hazards and job tasks that may expose them to nanomaterials; on routes of exposure and methods used for controlling exposures; and on the use of respiratory protection and good work practices.

The right of workers to know risk information is widely accepted and the duty of employers to communicate risk information derives from it. In some cases, explicit risk information is not available to employers, but there is information on components of risk—hazard and exposure. If employers communicate nanomaterial hazard and exposure information, they are conducting a basic form of risk communication. Risk is a probabilistic concept that depends on both the hazard and the exposure. Characterizing the reliability and the uncertainty in risk estimates will be important in risk communication and management. Hazard and risk communication should be conducted by employers to nanomaterial workers, and also by manufacturers to their downstream users who may then use such information in their communications with workers.

2.4 Manage occupational safety and health risks

Anticipating and "designing out" occupational hazards in facilities, work methods and operations, processes, equipment, tools, products, new technologies, and the organization of work is the most effective way of preventing occupational injuries, illnesses and fatalities [6]. 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 [6, 7]. PtD utilizes the traditional hierarchy of controls by focusing on hazard elimination and substitution followed by risk minimization through the application of controls applied during design, re-design, and retrofit activities (Figure 1).

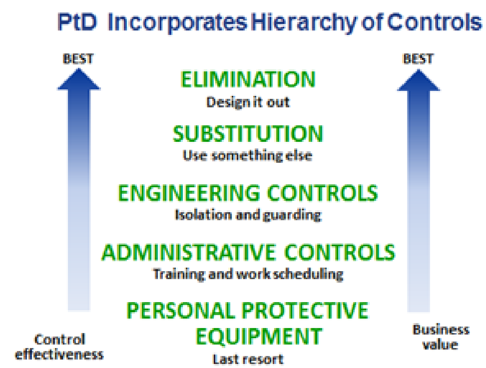

Figure 1. Heirarchy of Controls adapted from American National Standards Institute (ANSI) / American Industrial Hygiene Association (AIHA) Z10-2005 Standard [7].

In addition to reducing the risk of serious injury and illness, significant business costs savings are associated with hazard elimination and the application of engineering controls to minimize risks. As businesses adopt hazard control measures higher in the "hierarchy of controls," i.e., designing-out hazards and minimizing risks, the business value increases. These improvements in business value are related not only to lower worker compensation rates and health care costs to care for injured workers but also to achieving faster time to market, improved operational efficiency, improved employee morale, decreased employee absenteeism and turnover, higher product quality, and increased market share [8].

2.4.1 Elimination and Substitution

Elimination and substitution, while most effective at reducing hazards, also tend to be the most difficult to implement in an existing nanomaterial production or use process. If the process is still at the design or development stage, elimination and substitution of hazards may be inexpensive and simple to implement. For an existing process, major changes in equipment and procedures may be required to eliminate or substitute for a hazard.

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 [9]. 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. While 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.

2.4.2 Engineering Controls

Well-designed engineering controls provide a high level of protection and are typically independent of worker interactions or are integrated easily into tasks. Engineering controls isolate the process, 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, 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 2) [2]. Operations involving easily dispersed dry nanomaterials, such as powders, deserve more attention and more stringent controls (e.g., 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 [10]. 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.

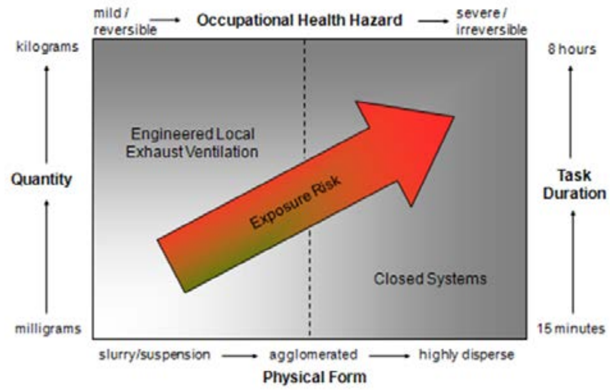

Figure 2. Factors influencing control selection [2].

2.4.3 Adminstrative 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 training, good housekeeping practices (e.g., wet-wiping cleanup, use of HEPA-filtered vacuums), limiting the time the worker is handling the material, limiting access, limiting quantities, and implementing proper labeling and storage of materials.

2.4.4 Personal Protective Equipment

Personal protective equipment (PPE) should be 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.

Unless your processes have been evaluated and appropriate containment/control devices installed, operators should wear PPE as a precautionary measure. 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.
- Nitrile or other chemically impervious gloves.
- Closed-toe shoes made of a low permeability material or disposable over-the-shoe booties.
- Safety glasses and/or face shields, as appropriate, based on the hazard risk from liquid splashes.
- Appropriate respirators, selected according to the NIOSH Respirator Selection Logic should be used when the potential exists that workers may inhale nanomaterials due to lack of effective engineering controls or during activities

with higher nanomaterials exposure potential (e.g., maintenance or emergencies) [11].

2.5 Foster the safe development of nanotechnology and realization of its societal and commercial benefits

Responsible development of nanotechnology can provide innovative products that address critical societal problems in materials, health, transportation, energy, and pollution. The workforce also benefits from nanotechnology research where nanotechnology-enabled products, such as nanotechnology-enabled sensors for detecting hazardous agents, nano-enhanced protection equipment, and nanomaterials, that are safer than traditional chemicals, have been developed to help ensure a safe work place. Additional benefits to the U.S. include supporting local economies through the creation of good high paying jobs.

3 CONCLUSIONS

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. A primary area of concern is the potential adverse impact on workers, since they are the first people in society who are exposed to the potential hazards of nanotechnology. 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 including elimination, substitution, engineering controls, administrative controls, and personal protective equipment.

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