Occupational Health and Safety Management Systems for the Safe Commercialization of Nano-enabled Products

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ABSTRACT

The value of an occupational health and safety management systems (OHSMS) for the safe synthesis of engineered nanoparticles and safe commercialization of nano-enabled products will be discussed. An OHSMS framework integrates continual improvement goals into an organization's management system. Applying this approach to organizations handling engineered nanomaterials assures that worker health and safety is considered at each step in the supply chain and supports the ongoing re-assessment that is required as new information is developed about the hazards of nanomaterials and new applications for this technology are commercialized, resulting in sustainable health and safety performance. This paper provides an overview of the essential management system steps, including hazard identification and assessment, worker exposure assessment, laboratory analysis, interpretation of exposure monitoring results, and exposure control for each step in the supply chain. Recent successes in laboratory methods development and sample analysis will be featured.

Keywords: management systems, engineered nanoparticles, sampling, risk assessment, supply chain

1. OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS OVERVIEW

An Occupational Health and Safety Management System (OHSMS) provides a structured method to assess and improve occupational health and safety (OHS) performance through the effective management of hazards and risks in the workplace. An OHSMS also provides a framework for including OHS considerations into the design, operation, maintenance, and eventual repurposing of facilities and processes. In addition, an OHSMS supports the inclusion of OHS into the development of new products, including engineered nanomaterials (ENM) and nano-enabled products. Based on Dr. W. Edwards Deming's "Plan-Do-Check-Act" (PDCA) [1] cycle for monitoring business performance on a continual basis, OHSMS aligns OHS performance; that is, keeping workers free from occupational injuries, illnesses and exposures, with the achievement of business goals. How better to achieve our business goals than by keeping the workforce safe and healthy?

2. "PLAN"

Applying OHSMS approach to the safe synthesis of ENMs and the safe commercialization of nano-enabled products begins with Deming's "Plan" step. Planning involves the setting of an OSH policy, the allocation of appropriately-skilled resources, the identification of hazards, and the assessment of risk. Establishing OHS policy requires executive leadership and support. An executive position statement addressing all activities-from the research bench, to production, and on to distribution and use-clearly demonstrates management commitment to ensuring worker health and safety and establishes requirements for developing internal procedures for the safe handling of ENMs. Since regulations requiring the control of worker exposures to ENMs do not yet exist, and codes and standards to include appropriate engineering controls into the design of facilities, processes, and equipment for ENMs have not been established, worker health and safety exposure controls may not be considered during product, process, and facility design. Therefore, upper management must support expectations that guidance, from authoritative sources such as the National Institute for Occupational Safety and Health (NIOSH), on how best to protect workers from exposure to ENM is considered, rather than waiting for the development of regulations. In addition, voluntary consensus standards including the

American Society for Testing and Materials (ASTM) 2535-07 Standard [2], American National Standards Institute (ANSI)/American Industrial Hygiene Association (AIHA)/American Society of Safety Engineers (ASSE) Z10-2012 [3] and Occupational Health & Safety Advisory Services (OHSAS) 18001 [4] provide guidance on the development of internal design guides and work practices that will support the integration of worker health and safety considerations at each step of the product, process, and facility design and development processes. And, since management must begin with the end in mind, policies and procedures to consider OHS in decommissioning, repurposing and eventual disposal must be included in any OHSMS plan. The OHSMS must be comprehensive, robust, and integrated, specifying core values, management policies, standards, guidelines, data systems, program manuals, and training. However, the OHSMS must also be flexible so it can be implemented by small, start-up companies as well as large, multi-national organizations.

2.1 Industrial Hygiene Process

The industrial hygiene process, as defined by the American Industrial Hygiene Association [5], provides a structured approach for hazard identification and risk assessment and is foundational to an OHSMS for ENM. Assessing exposure risks to ENM begins with the collection of data about the workplace, workforce, and the nanomaterials and nano-enabled substances. The workplace is characterized by understanding the process equipment containment; the ventilation system exchange rates and filtration; the air, materials, and "people" movement throughout the facility; local exhaust ventilation and dust collection systems; the room finishes where ENMs will be handled; and areas for workers to don and doff personal protective equipment and clothing. All of these workplace elements, together with the worker tasks, will significantly impact worker exposure risks. Information about the workforce includes job titles on all work shifts with potential exposure risks during normal operations and also quality, engineering, maintenance, cleaning, waste handling, and spill response activities. For each job title with potential exposure, the industrial hygienist documents a brief overview of the activities, including the number of hours per shift (or other relevant time period), and begins the process of task analysis. Tasks are characterized through observation of how the worker interfaces with the equipment or conducts the activity. Details about the implementation of exposure controls, such as local exhaust ventilation, work practices to minimize the generation and release of aerosols, and the personal protective equipment worn are collected, including the capability of the controls that are currently in place. The final contributor to the exposure risk is the ENM itself. Even identifying the presence of an ENM or nano-enabled products may be difficult since hazard communication and labeling requirements are still in development. When safety data sheets (SDS) are developed for ENM, the developing organization may use hazard information, including OELs, developed for the bulk or "normal" sized aggregated state of the material. A NIOSH study determined that 67% of the SDSs obtained in 2010-2011 provided insufficient data for communicating the potential hazards of engineered nanomaterials [6]. In addition, health effects data on most nanomaterials are still lacking. In the absence of nanomaterial-specific data, progress is being made on developing a process for grouping these un-studied ENMs with other materials, either ENMs with adequate toxicity information to develop occupational exposure limits (OELs), or "normal" size materials with similar mode of action, toxicity, and physical-chemical properties, to establish acceptable ranges of occupational exposures, commonly referred to as occupational exposure bands (OEBs) [7]. Together with the workplace and workforce characterization, these ENM OELs and OEBs allow the industrial hygienist to identify the job tasks for each job title with potential exposure risks above the OEL or OEB or those that result in uncertain assessment of risk.

2.2 Sampling and Analysis

Measuring occupational exposures to engineered nanoparticles requires using both standard and nonstandard sampling and analytical techniques. A stratified, or tiered, exposure assessment approach is currently recommended and includes commonly applied measurement techniques, such as particle counts and elemental mass, and more sophisticated nanoparticle analysis, including characterization by electron microscopy.

Elemental carbon is also used as a selective marker for quantifying carbon nanofiber (CNF) and carbon nanotube (CNT) worker exposure [8] [9]. Using direct reading instruments, respirable particle mass is a more practical monitoring metric than particle number, since there are other particle sources in the workplace, including worker clothing, papers, cardboard boxes, not to mention particles that are drawn into the workplace through the general ventilation system [10]. NIOSH recently published a modified sampling and analytical method, including airborne mass concentration using NMAM 5040 [11], for carbon nano tubes/carbon nano fibers, to quantify occupational exposures to these materials [12]. Therefore, surveys that include respirable particle mass and other particle metrics may be the best approach for characterizing ENM exposures. The use of NMAM 5040 for elemental carbon may need to be supplemented with other analytical methods such as NMAM 7500 modified for graphite to differentiate background carbonaceous ultrafine particles from carbon nanotubes.

3. "DO"

In the OHSMS approach, the Deming "Do" step refers to actual implementation and on-going operation of the program to control worker exposure risks. The best way to control exposures to ENM is to design them out, a concept known as Prevention through Design" (PtD) [13]. Designing in OHS considerations begins at the conceptual design stage, when goals for managing worker exposure risks become part of the project goals. When designing a new ENM, methods to moderate the toxicity or bioavailability of the particle by modifying physical-chemical properties may be considered. At this design stage, substituting less hazardous ENM should be discussed.

During the preliminary design stage, it is necessary to identify worker activities with each hazard and develop task-based exposure risks assessments. For ENMs, the risk and exposure assessment outcomes of the IH process will inform the design team of areas that require specialized containment and engineering controls. It is also critical to consider public perceptions of hazard when designing ventilation and waste water systems. Alternatives to mitigate risk while achieving OHS goals are developed and proposed to the design team. Worker input into the development of risk mitigation alternatives will be valuable.

During detailed design, specifications are developed for including appropriate exposure controls during equipment and materials procurement. It is important to specify the level of exposure containment and control that is required and carefully select equipment based on the demonstrated capability for controlling worker exposures to the ENM OEL or OEB. Mock ups made of wood or plastic that include actual components provide valuable information about their ability to be used for the process in design when they are provided to the workers as prototypes. An often overlooked step during detailed design is the development of test protocols for factory acceptance testing and commissioning. ENM surrogates, of similar size, shape, and bulk density, may be used to demonstrate the appropriate exposure control during factory acceptance. Sampling for the actual nanoparticle may also be considered for commissioning. During detailed design of ENM facilities, special attention must be paid to the movement of airflow, people, materials, and equipment to ensure that nanoparticle aerosols do not move out of the expected areas.

4. "CHECK"

During project execution and commissioning, OHSMS are guided by Deming's "Check" as safety reviews prior to startup are conducted, SOPs are developed, workers are trained, and health surveillance, if indicated, is implemented. Containment and control verification may be done using approaches such as industrial hygiene exposure monitoring surveys, computational fluid dynamics, or mannequin studies on fume hoods. "Check" also includes assessments in an organization's manufacturing and distribution H&S supply chain. The unique hazards and the rapid development of new information about the toxicity of nanomaterials means that the supply chain will look to the organization for information on how to safety handle ENMs or nano-enabled products. Protecting the health and safety of the supply chain workers will also ensure that preventable OHS issues won't disrupt the business flow. Monitoring supply chain activities, disseminating new information about nanomaterial hazards and appropriate risk-based controls, and measuring OHS performance globally will create business value and ensure the health and safety of all the workers potentially exposed to an organizations ENMs or nano-enabled products.

5. "ACT"

Finally the "Act" step closes the Deming cycle with a review of the OHSMS, seeking out opportunities for continual improvement, an important step for ENMs due to the rapidly expanding number of ENMs and nano-enabled products and the development of toxicity testing results. An effective OHSMS includes an on-going process to measure the effectiveness of the OHS program and make necessary changes. This includes periodic self and independent assessments and includes root cause analysis for incidents and procedure deviations [14].

6. CONCLUSIONS

The safe synthesis of ENM and commercialization of nano-enabled materials requires a structured, yet flexible management systems approach that is integrated with an organization's new product, process, and facility development and delivery processes. An Occupational Health and Safety Management System (OHSMS), based on Deming's Plan-Do-Check-Act approach for continuous improvement, provides this structured method to assess and improve occupational health and safety (OHS) performance through the effective management of hazards and risks in the workplace. Including OHS considerations into the design, operation, maintenance, and eventual repurposing of facilities and processes provides a pro-active system for controlling worker exposures to ENMs.

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