Chapter 12

Adaptive Governance for the Nanotechnology Workplace

Vladimir Murashov* **and John Howard**

National Institute for Occupational Safety and Health,
395 E. Street, SW, Suite 9200, Washington, DC 20201, United States
***E-mail: vem8@cdc.gov.**

Adaptive governance is commonly used in reference to the responsible introduction of emerging technologies such as nanotechnology into the society. A component of adaptive governance for nanotechnology, the proactive risk mitigation for nanotechnology workplaces, is presented in this paper.

Introduction

The notion of adaptive governance emerged about two decades ago from the intersection of two areas of inquiry the application of ecological systems theory to natural resource management and the study of self-governing institutions (*1*).

There are two components to the term: governance and adaptation. Governance refers to "the institutional arrangements which shape actors' decisions and behavior within groups or organizations (such as firms or nations)" (*1*). Governance is in essence a fluid mediating the formal and informal negotiations of decisions between actors with different forms and degrees of influence. Adaptation refers to an unmanaged, but systematic process of change in response to competitive pressures. Thus, adaptive governance refers to the evolution of the rules and norms that promote the realization of underlying human needs and preferences given changes in understanding, objectives, and the social, economic and envrionmental context (*1*). It operates at the high societal level. The component of adaptive governance for nanotechnology which is of interest to the U.S. National Institute for Occupational Safety and Health is the proactive or anticipatory risk mitigation for nanotechnology workplaces.

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Proactive/Anticipatory Risk Mitigation for Nanotechnology Workplaces

Proactive risk mitigation for an emerging technology such as nanotechnology represents a number of challenges, opportunities and solutions (*2*). The main challenge is deciding how to best incorporate higher levels of uncertainty in assessing risks and controls into the standards development process (*3*).

The primary opportunities presented by nanotechnology include 1) the possibility to evaluate and mitigate risks of nanomaterials throughout the life cycle stages of nanomaterials; and 2) the opportunity to design hazards out and to minimize exposures through material and process design. In the life-cycle approach nanomaterial safety is evaluated through stages of nanomaterial life starting from the production of raw nanomaterials to manufacturing of consumer products, to the use of products containing nanomaterials, to the product end of life when it goes to landfills, incinerated or recycled or ends up in the environment through other wastestreams (*4*). Worker exposure to nanomaterials can occur at any of these stages. The life-cycle approach was recognized by the U.S. National Nanotechnology Initiative (NNI) as one of research needs in safety research: "Application of adaptive management tool to evaluate life cycle analysis implementation" (*4*). Thus, the NNI strategy for environmental, health and safety of nanotechnology also highlighted the application of the adaptive approach to nanomaterials safety.

The next opportunity in risk management of nanotechnology is the opportunity to design hazards and exposures out through nanomaterial and process design. In the workplace, safety is managed through the so-called hierarchy of controls (*5*). In this approach the first step is to attempt elimination of hazardous nanomaterials or replacement with less hazardous alternatives. If this first step does not bring the risk to an acceptable level, the next step is to reduce exposure through the use engineering controls. If after these steps, the risk remains high, administrative controls such as training and job assignment rotations, are implemented. Finally, personal protective equipment, such as respirators and gloves, is recommended as the last line of defense.

Due to the great flexibility of nanomaterials in their size, shape, chemical composition resulting in a wide spectrum of possible physico-chemical properties, nanomaterials are particularly well-suited for the application of the proactive risk mitigation at the first step of the hierarchy of controls: hazard elimination or substitution with a less hazardous analog. For example, hazards of nanomaterials could be eliminated or reduced by avoiding hazardous elements such as regulated heavy metals in their chemical composition, improving their biodegradability, utilizing safer formulations by avoiding toxic solvents and improving safety of manufacturing processes.

The primary solutions for proactive risk mitigation of nanomaterials in the workplace include employing 1) prudent measures to mitigate exposures when a paucity of hazard data exists; 2) qualitative anticipatory risk mitigation tools; 3) integration of soft (voluntary) and hard law (mandatory) approaches; 4) broad expert and stakeholder participation through public-private partnerships; and 5) sharing best available mitigation strategies among stakeholders.

Prudent Measures To Mitigate Exposures

Several calls have been made to implement prudent measures to mitigate exposures to potentially hazardous nanomaterials (*6*, *7*). This can be accomplished with conventional engineering controls, such as local exhaust ventilation, for mitigating exposure to airborne materials. It has been shown that conventional controls are effective at reducing the amount of nanomaterials in workplace air when chosen wisely and employed properly (*8*).

Qualitative Anticipatory Risk Mitigation Tools

An example of a qualitative anticipatory risk mitigation tool is control banding for nanomaterials developed by ISO (*9*). In this proactive approach hazard potential of nanomaterials is assessed using available information about toxicity and physico-chemical properties. As a result of this analysis, nanomaterials are assigned into one of five hazard bands. Similarly, exposure potential to nanomaterial in the workplace is assessed using available information about the form of nanomaterial (powder, liquid dispersion, solid dispersion in polymer matrix, etc.) and the type of manufacturing process (mechanical reduction, wet chemistry, gas phase synthesis, etc.). Based on that assessment, each exposure situation is assigned into an exposure potential band. A combination of the hazard band and the exposure potential band would produce a recommended control option out of five possible ranging from using general ventilation to full containment and seeking expert advice.

Qualitative exposure assessment is also a part of a harmonized tiered approach for nanomaterial exposure assessment in the workplace recently published by the Organization for Economic Cooperation and Development (OECD) (*10*). In this approach, the first tier starts with information gathering to evaluate whether any exposure to nanomaterials is possible. If the answer is "yes," the second tier, basic exposure assessment is conducted using readily available and inexpensive devices such as particle counters. If these measurements indicate that the concentration of airborne particles is significantly increased over the background levels and their origin is known, then additional risk management measures are implemented to reduce the exposure. Otherwise the third tier, expert exposure assessment is conducted. It includes the use of sampling equipment and subsequent chemical analysis.

Integration of Soft and Hard Law Approaches

In the proactive risk mitigation there is a paucity of data to develop hard regulations. Therefore, in this regime it is necessary to operate at the bottom of the regulatory pyramid, which relies on information gathering and multi-stakeholder norms and self-regulation (*11*). In this regime international voluntary occupational safety and health standards play an increasing role in shaping national regulatory standards. International standards can be 1) nationalized; 2) used to support enforcement of the employer's general duty to provide work free of recognized hazards; and 3) adopted as voluntary guidance by the government (*12*).

There are a number of international standards developing organizations active in the area of nanomaterial safety. The most active and influential are the International Organization for Standardization (ISO) and the Organization for Economic Cooperation and Development (OECD). The ISO Technical Committee 229 (TC229) Nanotechnologies has four working groups (*13*). WG1 on terminology is presently working on core terms for nanotechnology and nanomaterials, terminology for two-dimentional nanomaterials, nanocellulose and quantum phenomena. WG2 on measurements is developing standards for characterization of nanocellulose and graphene, for using UV-Vis absorption to characterize cadmium chalcogenide, mass-spectroscopy to characterize single nanoparticles, and electron microscopy to measure size of nanoparticles. WG3 on health and safety is developing standards on *in vitro* toxicity testing of nanomaterials, a framework for setting occupational exposure limits for nanomaterials, and characterization of nanomaterials for their risk assessment. WG4 on material specification is developing standards for carbon nanotube dispersions. As of July 22, 2015 this technical committee published a total of 43 standards of which 13 were prepared by WG3 and deal directly with the safety and health issues of nanomaterials (*14*).

OECD Working Party on Manufactured Nanomaterials has four steering groups. Steering group on testing and assessment is in the process of publishing dossiers with data on toxicity testing and physico-chemical characterization for eleven nanomaterials. It is also responsible for updating test guidelines to make them suitable for nanomaterials. Steering group on risk assessment and regulatory programs is looking at interspecies variability factors in toxicity studies and at dissolution as a function of surface chemistry. Steering group on exposure measurement and mitigation is developing a protocol for measuring carbon nanotubes in the air and a report on measuring biodurability of nanomaterials. Finally the fourth steering group is looking at environmentally sustainable use nanomaterials. As of July 22, 2015 this working party published 57 reports (*15*).

Public-Private Partnerships

In order to develop proactive safety standards, public-private partneships are critical. In the workplace partnerships between government research organizations, nanotechnology manufacturers and downstream users, workers, academic researchers and safety and health practitioners are needed to collaboratively develop risk assessment and risk control strategies to eliminate worker risk and help achieve nanotechnology's promise (*16*). Aims of such public-private partnerhisps would be 1) protecting workers by encouraging implementation of prudent exposure mitigation measures; 2) promoting nanotechnology risk assessment and risk mitigation research; 3) collecting and sharing exposure information among nanotechnology workplaces; 4) identifying and studying the use of candidate occupational risk mitigation practices; and 5) developing the evidence base to provide protection for workers (*16*). An example of a public-private partnership for nanotechnology workplace safety is the NIOSH field team effort (*17*). Since mid-2006 when this team was established, it conducted on a volutary basis over 100 visits to 65 different sites.

The team investigated potential exposures in a diversity of sites, nanomaterials and applications using knowledge and experience gained to advance guidance and recommendations for ensuring safety of workers in nanotechnology workplaces. Partnerships with the private sector is a key to the success of the NIOSH field team.

There are other examples of NIOSH partnerhsips with the private sector. In 2014 NIOSH signed a memorandum of understanding with the College of Nanoscale Science and Engineering at SUNY Polytech Institute in Albany, NY to advance research and guidance on occupational safety and health of nanoelectronics (*18*). NIOSH guidance on safe practices for working in research laboratories (*19*) was developed under a memorandum of understanding with the Center for High-Rate Nanomanufacturing at Northeastern university. Formal NIOSH collaborations with the Center for Multifunctional Polymer Nanomaterials and Devices has focused on comprehensive evaluation of manufacturing processes, assessing worker exposures, evaluating exposure control methods and making recommendations for improvement, incorporating safe and sustainable design in facilities and processes, and providing an effective risk management framework suitable for small start-up businesses. NIOSH collaboration with the Center for Biological and Environmental Nanotechnology and International Council on Nanotechnology at Rice University produced GoodNanoGuide web-based guidance and training materials (*20*).

Coordination

With so many players actively involved in ensuring the safety of nanotechnology, close coordination is necessary in order to optimize the use of limited resouces. Coordination can be realized at several levels: 1) coordination of research, e.g. US-EU Communities of Research on nanoEHS; 2) coordination of regulatory programs (*e.g.* Canada-US Regulatory Cooperation Council); 3) coordination of standards development among government-level international organizations (*e.g.* United Nations, OECD), private international standards developing organizations (*e.g.* ISO, ASTM International) and multi-stakeholder *ad hoc* organizations (*e.g.* International Alliance for NanoEHS Harmonization, Global Measurement Harmonization Workgroup, NanoRelease).

Concluding Remarks

In conclusion, proactive risk mitigation of nanotechnology in the workplace follows a well established framework. In this framework risk is first anticipated, then recognized and evaluated. Appropriate levels of controls are applied and their effectiveness is confirmed. This cycle is repeated as necessary to reduce risk to an acceptable level and to capture on-going changes in the workplace. Only through partnerships among industrial hygienists, toxicologists and other researchers, engineers, businesses, and regulators, can this framework be applied proactively to emerging tehcnologies such as nanotechnology. By working together we can be successful in the safe introduction of nanotechnology into our everyday lives.

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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