A Small Business Approach to Nanomaterial Environment, Health, and Safety

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Objective: Integral to the commercialization process for nanotechnology enabled products is the methodology for protecting workers potentially exposed to nanomaterials during product development. Occupational health surveillance is a key aspect of protecting employees and involves both hazard identification and surveillance of known medical data. However, when the health effects and exposure pathways of both new and existing "nano-scale" chemical substances are not yet well understood, conservative hazard controls and baseline data collection can facilitate both immediate and long-term worker protection. **Methods:** Luna Innovations uses a conservative approach based on risk assessment and the OSHA General Duty Clause. **Results:** To date, Luna's approach has been effective for our business model. **Conclusions:** Understanding and managing potential hazards to our nanotechnology workers is key to the success and acceptance of nanotechnology enabled products.

The impact of nanotechnology is universal with both advocates and critics in agreement: nano has potential to become the 21st century's transformative technology. In fact, with a convergence of sciences now occurring in the name of nano, this technology could easily become key to a future in which one does not simply add knowledge; one achieves mastery over matter at the molecular level. Each entity driving nanotechnology commercialization has a specific approach to bring nanotech products to market. Integral to this process is the methodology for protecting workers potentially exposed to nanomaterials during product development. Occupational health surveillance is a key aspect of protecting employees and involves both hazard identification and surveillance of known medical data. However, when the health effects and exposure pathways of both new and existing "nano-scale" chemical substances are not yet well understood, conservative hazard controls and baseline data collection can facilitate both immediate and long-term worker protection.

Luna Innovations Incorporated (Luna) is a Virginia-based small business (as defined by the Small Business Administration) with a diverse coalescence of scientists, engineers, and business professionals developing and manufacturing new-generation products for the health care, telecommunications, energy, aerospace, and defense markets. Luna focuses on researching, developing, and commercializing innovative technologies through our contract research groups. With nearly 200 people in four locations across Virginia, Luna Innovations utilizes a disciplined and integrated business model designed to accelerate the process of bringing to market innovative new products. Luna diligently identifies technologies to fulfill large and unmet market needs taking these technologies from the applied research stage through commercialization.

One of Luna's core technologies is the production and modification of carbonaceous nanomaterials for potential use in applications such as diagnostics, therapeutics, and solar energy. This research is mainly conducted at Luna's nanoWorks Division site in Danville, Virginia. In addition, a variety of nanomaterials are explored through Luna's contracts research division for various applications such as multifunctional composites and coatings, remediation, and antitamper technologies. This work is primarily conducted at Luna's technology development division sites in Blacksburg and Charlottesville, and the nanomaterials in question may be commercially available or synthesized on site in small quantities for internal use or use by select research partners. Given the diversity of nanomaterial use, Luna must consider two types of scenarios when evaluating potential worker exposure to engineered nanoparticles: a research setting where a variety of new or familiar nanomaterials may be involved albeit in extremely limited quantities and perhaps only used a single time for screening purposes; and a production setting where larger quantities of familiar nanomaterials are synthesized regularly and potential for exposure may be present daily or weekly. This presents a challenge for not just Luna but many small research and development businesses. How does a business identify potential significant exposure threats without becoming bogged down in evaluating a vast number of small "research only" nanomaterial events consisting of a particular material being used a single time in a quantity on the milligram scale for a single well controlled reaction or formula?

Luna's Approach to Nanomaterial EHS

Luna has a designated component for environment, health, and safety (EHS) management. In 2007, Luna hired an EHS Manager with 20 years EHS consulting and compliance experience for industry and government to oversee EHS for the company's diverse activities. The EHS Manager is responsible for development and maintenance of the EHS management system for Luna and interacts with each location on a regular basis to implement and continually improve various EHS programs. In addition, facility managers and lab researchers with other primary responsibilities have been designated and trained as EHS representatives to assist in the day-to-day implementation of EHS programs at each location. The EHS Steering Committee, chaired by the EHS Manager, comprising senior managers and technical experts within the company provides management support for commitment to EHS compliance and employee safety for all activities at Luna Innovations. Like other small nanotechnology companies,[1] Luna seeks responsible risk management strategies to protect its employees working with nanomaterials.

Luna's overall approach to protecting workers involved in nanomaterial research and manufacturing follows OSHA's (Occupational Safety and Health Act) General Duty Clause,[2] which assigns the responsibility to the employer to furnish each employee a place of employment free from recognized hazards with the potential to cause physical harm.

Sufficient evidence to support the presence of legally "recognized" hazards of nanomaterial(s) is not yet available for all nanomaterials with which Luna works. Luna's internally produced carbonaceous nanomaterials represent an unknown hazard in our laboratories; therefore, Luna has implemented several controls for minimizing or eliminating exposures. For instance, there is scientific basis for recognizing hazards associated with multiwall carbon nanotubes but there is currently no definitive evidence for fullerenes similar to those the nanoWorks Division in Danville, Virginia, is producing.

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Luna uses a traditional risk management process and a hierarchy of control methods to accomplish this goal in a cradle to grave approach.

Risk Management at Luna Innovations

Basic risk management steps used at Luna include the following:

- Assess potential and known hazards,
- Assess potential or known exposures,
- Assess potential and known risk
  - Potential or known hazard + exposure = potential or known risk,
- Control risks through hazard control selection and implementation, and
- Monitor and review controls regularly through program reviews and collect baseline medical surveillance information for use when exposure risks are better defined.

The risk management methodology begins by assessing potential risks through various hazard and exposure assessment activities. For instance, Luna conducts initial hazard assessments of research facilities and new project-specific EHS analysis at the genesis of the project. Internal checklists have been developed and are used at all locations. This checklist requires the principal investigator (PI) to consider and answer questions on various aspects of the forthcoming work, including the identity of potential hazardous materials (nanomaterials included) and whether aspects of the project may impact the environment through changes in Luna's waste stream (by significantly changing the quantity of an existing waste material, introducing a new material to the current waste stream or identification of materials whose effect on the environment is ill defined and whose method of safe disposal is in question or undefined). The answers provided by the PI are reviewed internally to determine the suitability of the approach to be conducted at Luna's laboratories with existing engineering controls.

Once a program is initiated, or a request for material is received, a new project EHS consideration/hazards analysis worksheet is completed by the Luna PI. A portion of this form asks specifically if nanomaterials will be used, which ones, and whether the Material Safety Data Sheet forms have been entered into the electronic database Luna maintains. The PI also must answer questions related to known hazards, whether dust or vapor potential exists, and whether the recommended engineering controls for the materials are already in place at Luna. Disposition of the waste and residual raw materials is also addressed, as well as potential for air emission and waste water discharge. Through this review, Luna attempts to ensure the PI has considered new and current chemicals from cradle to grave. In addition, the amounts of materials expected to be brought on-site may be addressed at this point. If the amounts are large, meetings may be held to specifically review engineering controls and waste generation. This review may be conducted annually for programs lasting more than 1 year. Otherwise, a closeout meeting is conducted to ensure the waste and remaining raw materials have been accounted for and proper disposal is planned.

The continuous production scenario at Luna's nanoWorks facility is managed in a similar but slightly different fashion. Because numerous new projects and materials are not the major concern here and the initial hazard assessment was conducted before production commenced, hazard assessments and periodic nano-EHS program reviews are conducted and reviewed on an annual basis. During these reviews, typical hazard identification and characterization occurs and potential worker exposure is reassessed. Engineering controls are evaluated to ensure proper operation, and personal protective equipment (PPE) selection is reviewed to ensure that the appropriate selection is available for the operators. Documentation of good work practices is revisited, and improvements and updates to worker training are conducted. Luna also conducts a medical surveillance review and determines whether follow-up testing is warranted for its personnel. Finally, Luna reviews its procedures against recent regulatory developments to ensure environmental, OSHA, and DOT compliance.

Any issues or concerns are logged into a matrix consisting of requirements and actions taken along with appropriate dates in a formal tracking system. In addition to the periodic reviews, both the EHS Steering Committee and individual employees may bring issues to the attention of senior management through this corrective action matrix throughout the year. Luna's EHS program includes regular reviews of chemical hazards and regulatory developments throughout the year to implement recommended or required changes as necessary with respect to the nano-EHS program. In addition, operations are continually surveyed to identify potential exposures to nanomaterials to better select or improve engineering controls or identify needed administrative controls.

Exposure Assessment at Luna Innovations

Exposure assessment has been a critical part of Luna's risk management plan from conception, especially at the nanoWorks facility. For instance, early exposure assessment determined possible exposure to the prototype fullerene product by technicians during nanomaterial generation and processing, and during dust collector maintenance. Luna has voluntarily participated in monitoring studies conducted by Virginia Tech (VT) and Oak Ridge National Laboratories (ORNL) as well as hosted National Institute for Occupational Safety and Health (NIOSH) and OSHA voluntary compliance assistance visits. These external reviews have been conducted to better assess potential exposure routes during production of Trimetaspheres nanomaterials (Luna nanoWorks, Danville, Virginia) and related carbonaceous nanomaterials.

Luna periodically monitors work environments for engineering control performance. A Dust Trak Aerosol Monitor uses a laser photometer to measure particle concentrations at the site in the range of 100 nm to 10 microns. Data collected assists Luna in determining whether current controls are functioning properly or if new control methods should be considered or implemented. In addition, hoods are regularly calibrated and their airflow tested to ensure proper face velocities are present.

Instrumentation R&D with ORNL

Many current industrial processes for production of engineered nanomaterials do not have effective monitoring systems to ensure high-precision nanomaterial production. This lack of instrumentation can lead to inconsistent product quality, which hinders technology development, and can result in significant waste of precious raw materials. Luna is working with DOE's ORNL Nanoapplications Center to research the manufacturing of advanced engineered nanomaterials. The objective is the development of novel on-line monitoring systems of the manufactured nanoparticles in real time. These new instruments are targeted to monitor an array of variables relevant to the quality of nanoparticles, such as size distribution, size dispersion, density, surface charge, and material-specific data such as ionic, elemental, and molecular composition. Efficient fusion of such data can be performed by advanced chemometrics methods to yield high-valued information such as size-resolved chemical composition as a function of time and space in a nanoparticle reactor. The suite of instruments will be applicable to characterize a wide range of nanomanufacturing processes involved, and Luna has served as a test site for the evaluation of new technologies for this type of monitoring, which may be utilized for assessment of nanoparticle characterization outside of the reactor as well.

CONTROL OF POTENTIAL RISKS AT LUNA INNOVATIONS

Potential risk of nanomaterial exposure at Luna is handled through hazard control selection and implementation. Three main types of controls are used—administrative, engineering, and PPE.

Effective administrative controls can go a long way in minimizing potential exposure. The first of the administrative controls actually goes all the way back to the initial risk review: is the facility equipped to handle the nanomaterial in question, and if not, should the project be pursued? In other words, can the work plan be accomplished through the use of another material (one less hazardous or one that Luna is familiar with handling for instance)?

Once Luna has determined the risk of bringing the material on-site or the production of a particular nanomaterial is acceptable and is in Luna's business interests, other administrative controls become important in managing risks such as reducing or eliminating potential nanomaterial exposures. This includes having a robust hazard communication program and chemical hygiene plan that address nanomaterials, conducting hazard assessments to determine PPE requirements, having an appropriate waste management program, and having proper standard operating procedures (SOPs) for both production equipment and research laboratories that handle the nanomaterials.

Engineering controls are another very important aspect of risk management and are intertwined with the laboratory SOPs. Engineering controls are only effective if the SOPs are followed and the equipment is properly maintained and operating correctly. In the research laboratories, Luna relies mainly on chemical hoods and a specially designed integrated dust collection system to contain any airborne nanomaterials in dust or aerosol form. In laboratories where nanomaterials are in use, all process equipment is moved into these hoods so that the materials do not have to be dispensed or transported outside of the hood, thereby minimizing the potential for contamination of surrounding bench tops and equipment. In some cases, special handling techniques to minimize particulate generation are used by researchers in the hoods. At the nanoWorks facility, a Thiel Air Technologies Dust Collection System has been installed with high-efficiency, self-cleaning cartridge filters to minimize airborne particulates within and outside of the production facility. This unique exhaust system has been verified to be able to capture particles down to 1 nm.

Personal protective equipment is the final element of risk management to be considered. Luna employs laboratory coats, impervious gloves, safety glasses, and NIOSH-approved elastomeric half-face respirators with P100 cartridges where appropriate to further minimize the possibility of exposure to the worker. Respirators are approved and used in accordance with OSHA's Respiratory Protection Standard.[3]

Medical Surveillance of Nanomaterial Handlers at Luna Innovations

Interim guidance issued by the NIOSH in 2009 concluded, "Currently there is insufficient scientific and medical evidence to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles."[4] Luna has decided to follow prudent recommendations for its workers at the nanoWorks facility including maintaining strict exposure controls, detailed worker record keeping, and characterization of baseline and periodic health status of workers. For workers at Luna's other sites, it has been determined that the potential for nanomaterial exposure is extremely low because of the amounts and frequencies in use combined with the implemented controls, whereby medical surveillance is currently not necessary. This, of course, would be reevaluated if during risk assessment of new programs it is determined that the potential for exposure or repeated exposure is higher.

For the nanoWorks facility, the EHS and human resources group at Luna maintains medical records and job descriptions for each employee. The job description includes the workers primary job function and tasks associated with it. Medical records include baseline chest radiographs and pulmonary function test results. All laboratory activities on a daily basis are required to be recorded in log books. A respiratory protection program exists as well and within its record keeping are medical questionnaires and medical approvals, pulmonary function test results, and fit testing.

Future Concepts for Data Handling at Luna Innovations

Luna is a small business, where less than 20% of the employees currently have the potential for nanomaterial exposure. Therefore, data collection, storage, and analysis of the related documents are straightforward. For larger entities, an on-line system may be needed to allow a program to sort and store data sets and information securely. One possibility would be for Luna to use a system similar to other internal tracking systems used for logging laboratory activities. A simple daily spreadsheet is being considered to record the employee's identification, the amount and type of nanomaterial in use, and the potential exposure time. At a later date, the EHS department could then determine total potential exposure time between a particular set of dates for an individual.

A more complex system could be envisioned where not only the daily log activities were recorded but also the medical testing, engineering control testing, and training records could be stored along with general EHS information related to safety and the materials themselves. Luna has worked on a prototype Web portal for the Air Force that could support such a system called WINGS-**W**eb **I**nterfaced **N**anotechnology Environmental, Safety, and Occupational Health Guidance System.[5] In its current Beta site form, it serves to provide comprehensive guidance modules related to regulations and industry's best practices, while also serving as a repository for related literature. It also includes tools for risk assessment and for searching trusted sites but is intended to be expandable to include tools and questionnaires related to medical tracking and medical surveillance. By centralizing the entire EHS program into a single portal, the WINGS program has the capability to simplify risk management assessment while storing data in a form that could be exported to another program for plotting trends or creating formalized reports.

CONCLUSIONS

The success and public acceptance of nanotechnology-enabled products will depend upon the nanotechnology community's ability to understand and manage potential hazards to our nanotechnology workers. The immediacy of the need for responsible and sustainable development of engineered nanomaterials cannot be overstated. Therefore, building an EHS knowledge base is essential to ensure the future of nanotechnology and the safety of those working in this emerging field.

In the current absence of formal guidance and well-defined toxicological and health data, Luna has chosen to pursue a conservative approach to nanomaterial safety. This approach is centered on using administrative and engineering controls, as well as PPE, to diligently identify nanomaterial uses and minimize or completely eliminate exposures. This systematic approach has been institutionalized into a flexible platform for the production, characterization, and development of nanotechnology enabled products.

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